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| 13. SUPPLEMENTARY NOTES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |             |                                 |                            |                                                       |                                           |
| 14. ABSTRACT<br>The <b>overarching goal</b> of the BADER Consortium is to advance and strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior. <b>Key Accomplishments to date:</b> The BADER consortium publication count reached 158 published abstracts/presentations and 42 published manuscripts. We continue to engage with and monitor three BADER-funded protocols. Grant applications related to BADER funding were submitted and awarded. To date, the submissions have resulted in 17 awards, 14 of which total \$15.5 million in external funding. The Consortium has nearly eight million dollars in research proposals among various agencies pending review and awarding. An application was submitted to the Joint Warfighter Medical Research Program Funding Opportunity Number: W81XWH-18-JWMP. If awarded, the Consortium will secure up to \$6,000,000 to continue activities. Integral to the above mentioned JWMP application is a renewed, highly interactive and productive partnership with the Extremity Trauma and Amputation Center of Excellence (EACE) in particular, its Research and Surveillance Division (RSD). One immediate partnership activity is the adoption of the RSD steering committee as a new structure for the BADER Consortium and consisting of a central leadership team comprising EACE/RSD lead scientists and BADER leaders with appropriate Administrative Core support. An award from JWMP will propel this committee into the role of oversight and policy hub for joint EACE/RSD and BADER continuation activities. |             |                                 |                            |                                                       |                                           |
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**Contents**

Introduction..... - 2 -

Project Year 7 Research accomplishments..... - 3 -

    Overall: ..... - 3 -

    Administrative Core:..... - 4 -

    Clinical Research Core (CRC):..... - 10 -

    Scientific Technical Cores: ..... - 13 -

Progress Reports on Clinical Studies ..... - 15 -

Key Research Accomplishments Per Project Year ..... - 42 -

Reportable Outcomes..... - 50 -

Conclusion ..... - 69 -

    Administrative Overview: ..... - 70 -

APPENDICES..... - 73 -

    APPENDIX A: Affiliations ..... - 74 -

    APPENDIX B: BADER Consortium Affiliates..... - 75 -

    APPENDIX C: Quad Charts for active BADER-funded research projects..... - 80 -

    APPENDIX D: Select Manuscripts and Presentations ..... - 84 -

## Introduction

### The BADER Consortium

The **overarching goal** of the BADER Consortium is to Bridge Advanced Developments for Exceptional Rehabilitation. The BADER Consortium is a multi-institutional Consortium that works in concert and partnership with military Medical Treatment Facilities (MTFs), Veteran's Affairs Centers, Academic and Industry leaders to conduct innovative, high-impact, clinically relevant research to further strengthen evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each wounded warrior.

The success of the Consortium relies on strong partnerships with military Medical Treatment Facilities, the VA and non-government entities in each of the following strategic areas to:

1. Strengthen and support orthopaedic rehabilitation research capabilities:
  - infrastructures and cultures
  - partnerships
2. Conduct a variety of innovative, high impact, and clinically relevant research studies
3. Establish a self-sustaining research enterprise
  - Broaden the scope of impact and support for the BADER Consortium

This report describes how the BADER Consortium has made progress based on the approved Statement of Work for the period September 30, 2017 – September 29, 2018.

## Project Year 7 Research accomplishments

### Overall

- The BADER consortium publication count reached 158 published abstracts/presentations and 42 published manuscripts. Additionally, one (1) manuscript is in review, two (2) have been submitted and six (4) are in preparation.
- Continue to engage with and monitor three BADER-funded protocols. Updated quad charts for all active BADER funded studies are included in Appendix C.
- During this period of performance, grant applications related to BADER funding were submitted and awarded. To date, the submissions have resulted in 17 awards, 14 of which total \$15.5 million in external funding. The BADER Consortium has nearly eight million dollars in research proposals among various agencies pending review and awarding.
- One of the submitted applications proposes to continue the BADER Consortium. The application was submitted to the Joint Warfighter Medical Research Program Funding Opportunity Number: W81XWH-18-JWMRP. If awarded, BADER Consortium will secure up to \$6,000,000 to continue implementing its powerful Research Competitiveness Enhancement Model to exclusively support EACE/RSD efforts to further establish impactful research partnerships, an efficient technology translational pipeline, and EACE/RSD investigator goals of obtaining research independence by obtaining PI status on externally-funded grants.
- Integral to the above mentioned JWMRP application is a renewed, highly interactive and productive partnership with the Extremity Trauma and Amputation Center of Excellence (EACE) in particular, its Research and Surveillance Division (RSD).
- One immediate partnership activity proposed by the Director of the EACE is the adoption of the RSD steering committee as a new structure for the BADER Consortium and consisting of a central leadership team comprising EACE/RSD lead scientists and BADER leaders with appropriate Administrative Core support. An award from JWRMP will propel this steering committee into the role of oversight and policy hub for joint EACE/RSD and BADER continuation activities.

## Administrative Core

### **Task 1: Financial Support and Oversight:**

- 1a. Provide oversight of the overall Consortium budget including auditing for allowable expenses, managing re-budget requests and preparing all required financial reports
  - 1b. Ensuring all Military Treatment Facilities (MTFs) receive infrastructure support as required including procurement of materials, personnel, equipment
  - 1c. Manage costs supporting the Cores and Clinical Study Sites
  - 1d. Perform quarterly financial audits for compliance
  - 1e. Maintain files for internal or external audit purposes
- Quarterly review of the BADER Consortium finances resulted in zero audit findings.
  - Provided financial oversight of the Consortium.
  - Maintained complete and accurate files for internal and external auditing purposes.

### **Problem areas related to this task:**

- Delays in invoicing by subcontractors puts overall award spending behind resulting in excess cash on hand for one BADER funded research project. Subcontractors are reminded to bill in a timely manner.
- Closure of one BADER funded research project (PI, Pruziner) has resulted in a positive balance projection for the Consortium. The BADER Coordinating Center is in communication with the CDMRP Grants Officer Representative and with the Extremity Trauma and Amputation Center of Excellence and its three sites located at MTFs to ascertain optional uses, that align with existing statement of work activities, for reallocating the funds in support of MTF research capacity-building activities.

### **Task 2: Human Resources Support and Oversight**

- 2a. Manage Human Resources function including recruitment, on-boarding, facility/system access, annual performance appraisals, and handling benefits questions
- 2b. Provide support as needed for labor relations actions
- 2c. Manage payroll function for UD employees (at UD and MTF sites)
- 2d. Work with Steering Committee to develop appropriate job descriptions
- 2e. Manage recruitment activities of personnel

**Table 1: Status of BADER funded positions.**

| Position                        | Location               | Current Status      |
|---------------------------------|------------------------|---------------------|
| Director/PI, BADER Consortium   | University of Delaware | Filled, part-time   |
| Director, Administrative Core   | University of Delaware | Vacant, not filling |
| Manager, Clinical Research Core | University of Delaware | Filled, part-time   |
| Administrative Assistant        | University of Delaware | Filled, part-time   |
| Consortium Protocol Manager     | University of Delaware | Vacant, not filling |
| Research Associate              | WRNMMC                 | Vacant, not filling |
| Laboratory Engineer             | NMCSD                  | Vacant, not filling |
| Research Associate              | NMCP                   | Vacant, not filling |
| Physical Therapy Assistant      | BAMC/CFI               | Vacant, not filling |
| Protocol and Data Coordinator   | WRNMMC                 | Vacant, not filling |
| Protocol and Data Coordinator   | NMCSD                  | Vacant, not filling |
| Protocol and Data Coordinator   | NMCP                   | Vacant, not filling |
| Protocol and Data Coordinator   | BAMC/CFI               | Vacant, not filling |
| Research Associate              | NMCP                   | Vacant, not filling |
| Research Physical Therapist     | NMCSD                  | Vacant, not filling |
| Limited Term Researcher         | NMCSD                  | Vacant, not filling |

**Problem areas related to this task:**

- To the best of our knowledge, it appears that the MTF have felt the pinch of not having BADER Consortium Clinical Research Core staff on site. The nature of these hires provided MTF the opportunity to flex staff across projects opposed to staff hired under contracts and assigned to a single or a set number of research projects.
- Current MTF, BADER-funded projects, appear to be challenged without this critical research support infrastructure.

**Task 3: Reporting Coordination and Management:**

- 3a. Request, coordinate and submit all required technical reports
- 3b. Preparation of all required financial reports
- 3c. Develop templates for reports to ensure consistency

- Submitted required technical reports.
- Submitted required financial reports.

**Problem areas related to this task:**

- The vacated Director, Administrative Core position has resulted in a re-allocation of the important activities across remaining Coordinating Center staff. While not an optimal situation, this important task is being accomplished.

**Task 4: General Administrative Support:**

- 4a. Coordinate meetings, calendars, travel, etc.
- 4b. Facilitate communications across Consortium
- 4c. Prepare administrative documents
- 4d. Coordinate all official BADER correspondence

- This period realized an unusually and close impactful partnership with the Extremity Trauma and Amputation Center of Excellence (EACE).
- Using non-BADER funds, the Administrative Core staff coordinated with EACE leadership to prepare and submit application to the Joint Warfighter Medical Research Program Funding Opportunity Number: W81XWH-18-JWMRP. If awarded, BADER Consortium will secure up to \$6,000,000 to conduct BADER sustainability and transition activities. Under the proposed continuation, BADER-II proposes to execute eight (8) neuromusculoskeletal injury rehabilitation research related pilot projects modeled after the NIH Small Grant Program (R03) funding award and with EACE investigators as primary PIs. Specific aims of this BADER II proposal are:
  1. Partner with EACE/RSD leadership to steer the strategic review and prioritization of current and proposed EACE/RSD research project concepts. We propose to join forces with RSD to refine and formalize their process for prioritizing a collection of compelling, shovel ready, research projects that align with EACE mission-critical research initiatives, CDMRP priority areas, and rehabilitation technology-translation readiness needs. This will result in a comprehensive set of research projects ranked in order of priority.
  2. Support the advancement of forming RSD research project concepts by implementing BADER's Research Support and Capacity-Building Components. BADER's highly effective team will work to refine and propel, in accordance with priority, each research project concept and associated investigators towards proposals for BADER pilot project funding.
  3. Execute eight, two-year, BADER-funded pilot projects from a subset of the prioritized RSD investigator-led research projects. We propose to award and support a total of eight, two-year, pilot projects to RSD investigators as prioritized by the RSD Steering Committee's (RSD-SC's) emerging research project vetting and alignment process. The primary goals of each pilot project will be to: Effectively establish and demonstrate the capacity and capability to conduct the proposed research project; Collect and disseminate sufficient pilot data that establishes or furthers the PI's research initiative; and Develop and submit an award-winning grant application to CDMRP or equivalent agency.
  4. Transition BADER's Research Support and Capacity-Building Components to EACE/RSD leadership to effectively sustain their research program capabilities. BADER's team will help RSD investigators achieve research independence, that is, obtain additional grant funding. Resources derived from awarded grants will ideally support the transition of key BADER components to RSD and the ARCs - effectively sustaining BADER's highly effective Research Competitiveness Enhancement Model within the EACE/RSD.

- Recent communications with EACE focus on exhausting the current BADER award funds in support of MTF/EACE research programs and prepare for the immediate launch of BADER extension activities in the event that our BADER-EACE joint JWMRP proposal is awarded.
- Drs. Stanhope and Milbourne travelled to Ft. Detrick on April 4, 2018 to provide a status update to Drs. Redington and Roach and have frequent remote correspondence and communication.
- Communications with BADER-funded project PIs to closely monitor study progress over the remaining six months of research projects period of performance.

**Problem areas related to this task:**

- Continuing to support the MTFs at the highest possible level without them feeling abandoned as BADER activities begin to shut down.
- Policy changes have made it difficult to travel government employees to scientific meetings.

**Task 5: Policies and Procedures:**

- 5a. Develop, implement and ensure compliance of all SOPs for The BADER Consortium
- 5b. Ensure compliance with all existing policies and procedures
- 5c. Create a policy and procedure manual to be distributed to all BADER stakeholders

- This task is complete.

**Problem areas related to this task:**

- With the pending completion of the BADER Consortium activities, further updating of the BADER SOP manual has ceased.

**Task 6: Proposal/Award Coordination and Management:**

- 6a. Management of annual project solicitation process to BADER Affiliates
  - 6b. Management of approved projects (financial, HR, administrative support)
  - 6c. Oversight of all subawards for technical and financial compliance
- Reviewed and approved invoices on subcontracts - subcontractors are reminded to bill on a regular basis.
  - Processed amendments to subawards for no cost extension as appropriate.

**Problem areas related to this task:**

- BADER projects and support are concluding as the EACE Research and Surveillance Division (RSD) continues to expand. This divergent pattern of EACE expansion is disadvantageous to junior investigators at the MTFs as critical resources that were available through BADER are discontinued. EACE leadership has expressed that infrastructure-building capabilities would propel and maximize the EACE RSD mission especially in the MTF environment where patient care, not research, is the primary mission. The EACE RSD indicated that a close BADER-EACE RSD partnership would offer the ability to harness the EACE organizational structures and BADER's direct support to the MTF embedded EACE research teams. As the BADER Consortium prepares to sunset, discussions about providing direct support to EACE RSD research teams has risen in light of the potential to reallocate un-spent BADER research project funds in this manner with the hope that such support would continue under the BADER-EACE extension JWRMP proposal.
- BADER recently submitted to CDMRP a notification of decision of non-renewal of a second no-cost-extension request for the **Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators** study (PI, Pruziner). Informing the decision for the non-renewal of the extension was a review of the project's current enrollment status and a discussion with EACE officials and with the MTF supervisor of the PI with regard to project performance. In anticipation of the unspent funds from this study, BADER and EACE initiated communications to generate ideas about how best to use these funds to further enhance EACE/MTF research capacity and capabilities while staying within the current BADER SOW.

**Task 7: Intellectual Property, Material Property, Inventions and Patents Management:**

- 7a. Management of IP, MP, Invention and Patent agreements
- 7b. Consult with legal experts as necessary for compliance

- No changes this report period

**Problem areas related to this task:**

- No problems reported

**Task 8: Evaluation:**

8a. Management of internal evaluation process

8b. Primary liaison with external evaluation service (AAAS)

- BADER Administration had presented to the MTF representatives, External Advisory Committee (EAC) and the Grants Officer Representative (GOR) a plan for having the American Association for the Advancement of Science (AAAS) perform a research evaluation for the BADER Consortium and provide consultation on a sustainment model. At this time, the AAAS evaluation has been placed on hold.

**Problem areas related to this task:**

- No problems reported

## Clinical Research Core (CRC)

### **Task 1: Facilitate approvals of protocols for the use of human subjects in research through local IRBs and through HRPO**

- 1a. Identify DoD requirements for the protections of Human Subjects in Research
  - 1b. Develop materials for and assist PIs in submitting protocols according to the United States Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) policies and procedures through the ORP for approval
- The CRC Manager continues to oversee the protocol approval process and assist with issues as they arise.

#### **Problem areas related to this task:**

- No problems reported

### **Task 2: Assist in the development, implementation, and monitoring of standard protocol/human subject research activities that will be instituted across MTFs and Clinical Study Sites throughout the BADER Consortium:**

- 2a. Compile detailed descriptions of all of the planned activities/ interventions/ testing sessions etc. in which subjects will participate in each study and identify existing research resources at MTFs and clinical study sites
  - 2b. Identify and hire Consortium Protocol and Data Coordinators Managers
  - 2c. Identify and hire On-site Protocol Managers and Technicians for MTFs and clinical study sites
  - 2d. Identify data storage needs and work with the Scientific Cores to set up policies and procedures relating to coding of research protocols, subjects and associated data across all MTFs and clinical study sites
  - 2e. Train Consortium Protocol and Data Coordinators in modeling protocols in Data Monitoring System
  - 2f. Implement the Protocol and Data Management System (PDMS)
- The CTDB Operations Core continues to engage with BADER investigators regarding the use of the CTDB as needed.

#### **Problem areas related to this task:**

- Investigators wish to continue having access to this resource, yet EACE is currently not staffed to assume management of this task.

### **Task 3: Provide training and oversight to On-site Protocol Managers, Technicians and other relevant personnel in study procedures:**

- 3a. Develop and provide training to On-site Protocol Managers and oversee the coordination and maintenance of Institutional Review Board and ORP approvals, including initial review and approval processes, continuing renewal processes, amendment, and addendum and termination approvals.

- 3b. Develop and provide training to On-site Protocol Managers, and oversee procedures to recruit subjects, track accrual, track human subjects compliance, schedule tests, and report adverse events to the ORP and local IRBs.
  - 3c. In conjunction with the Scientific Cores, develop and coordinate training for the Consortium Data Coordinators, On-site Research Directors and Technicians and other relevant personnel in data collection and management and quality control procedures
- This task is complete.

**Problem areas related to this task**

- No problems reported.

**Task 4: Monitor protocol activities and notify Administrative Core of inadequate study procedures, training or subject recruitment that requires input from the BADER Consortium Coordinating Center**

- 4a. Develop tools for reporting progress in of training activities, subject recruitment and testing, data analysis and quality control measures
  - 4b. Track study progress monthly and notify Administrative Core of underperforming sites and suggest solutions to improve performance
  - 4c. Provide input to Administrative Core for quarterly progress reports of clinical research studies
- The CRC Manager monitors site-specific protocol activities and coordinate with study PIs to address any inadequacies.
  - The CRC Manager and BADER PI (Dr. Stanhope) met with CDMRP officials to discuss one underperforming study and the study PIs request for a second no-cost extension.
  - For this same study, the CRC Manager and BADER PI (Dr. Stanhope) recently met with EACE officials and the MTF supervisor of the PI with regard to project performance and the study PIs request for a second no-cost extension.

**Problem areas related to this task**

- See Task 6 – Administrative Core.

**Task 5: Research Development (Dr. Stanhope)**

- 5a. Identify gap research areas.
- 5b. Identify and secure sources of external funding.
- 5c. Connect BCAs with potential collaborators.
- 5d. Create research pipeline of tech development to basic research to clinical trials.
- 5e. Support research development at MTFs.

- Continue to Mentor Mr. John Collins - stationed at the NMCS D as he works to compete his PhD in Biomechanics and Movement Science focused on the development of a generalized method for quantifying the sources and flow of mechanical work during the “push off” phase in normal, impaired and amputee walking.
- Coordinated BADER related activities at the 2018 MHSRS meeting.
- Using non-BADER funds, the Administrative Core staff coordinated with EACE leadership to prepare and submit application to the Joint Warfighter Medical Research Program Funding Opportunity Number: W81XWH-18-JWMP. If awarded, BADER Consortium will secure up to \$6,000,000 to conduct BADER sustainability and transition activities.
- Initiated discussions with EACE leadership regarding the use of unspent BADER-funded project award dollars toward supporting research development at the MTFs. To this end, BADER is conducting an internal audit of its budget to confirm unspent project award amounts.

**Problem areas related to this task:**

- No problems reported.

**Task 6: Development and Coordination of the Call for Proposals (Dr. Davis)**

- BADER completed Task 6 in Year 3. BADER has eight approved protocols completed or ongoing, meeting the original goal of funding 6-8 projects.

**Problem areas related to this task:**

- No problems reported.

## Scientific Technical Cores

### **Biomechanics Core (BC): C-Motion, Inc.**

*Funding for the Biomechanics Core ended September 29, 2016. See prior reports for complete details of work completed.*

### **Rehabilitation Outcomes Measurement (ROM) Core: University of Delaware**

#### **Task 1: Establish outcomes library and training libraries, develop infrastructure for working with investigators.**

- 1a. Submit relevant IRB related documents as necessary.
- 1b. Conduct literature reviews to identify relevant outcomes measurement tools related to orthopedic injuries.
- 1c. Build measurement library for utilization of relevant outcomes measures for research studies.
- 1d. Provide workshops, web-ex presentations, and seminars to train BADER personnel about Patient Reported Outcome (PRO) measures.
- 1e/f. Prepare training materials for data collection of patient reported outcomes. Prepare measurement platform for BADER proposals (develop Assessment Center or alternative method for data capture).

- Tasks completed; Deliverables under final year funding.

#### **Problem areas related to this task:**

- No problems reported.

#### **Task 2: Evaluate relevant outcomes measurement instruments and ensure relevance for use in BADER studies. Ensure that floor and ceiling is appropriate for the population. Develop new item content as appropriate.**

- 2a. Develop focus group guides to identify measurement issues.
- 2b. Prepare and execute focus group meetings at collaborating DoD sites (months 2-3)
- 2c. Transcribe focus group guides and prepare NVivo (qualitative software) coding guides (months 4-6)
- 2d. Code and reconcile focus group data (months 7-9)
- 2e. Develop new item content to increase measurement sensitivity/specificity of orthopedic injuries (months 10-12).

- Tasks completed.

#### **Problem areas related to this task:**

- No problems reported.

**Task 3: Consult and review study proposals for the BADER Consortium**

- 3a: Submit relevant IRB related documents as necessary.
- 3b: Work directly with prospective PIs of BADER projects. Provide consultation on outcomes measurement design issues and integration into proposals and research methodology.
- 3c: Review proposal ideas and provide feedback on outcomes design.
- 3d: Work with investigators to provide design measurement platforms and train research personnel.
- 3e: Develop new measurement techniques tailored for specific interventions as appropriate.

- Tasks completed.

**Problem areas related to this task:**

- No problems reported.

**Biostatistics Core: Christiana Care Health Systems (CCHS)**

The Biostatistics Core for the BADER Consortium is a fee for service model that provides services when requested. Due to changes in personnel at Christiana Care Health Systems, the Biostatistics Core will utilize resources available at the University of Delaware under the same fee for service model.

**Task 1: Participate in development of project specific aims and research design with investigators.**

- No updates for this task.

**Task 2: Develop statistical analysis plans (SAP) for each research project.**

- No updates for this task.

**Task 3: Assist in the design of datasets for analysis. Provide transfer capabilities and expertise.**

- No updates for this task.

**Task 4: Conduct statistical analyses.**

- No updates for this task.

**Task 5: Provide assistance in developing presentations, writing reports and manuscripts.**

- No updates for this task.

## **Progress Reports on Clinical Studies**

(please see Appendix C for updated Quad Charts)

## Progress Reports on Clinical Studies (BADER funded)

Summary table

|                                                | <b>2012.1 –<br/>Step2Step<br/>COMPLETED</b>  | <b>2012.2 –<br/>RETRAIN<br/>COMPLETED</b> | <b>2013.1 –<br/>ProLeg Rx<br/>COMPLETED</b> | <b>2013.2 –<br/>K2Power</b> | <b>2013.3 –<br/>QOL Toolbox<br/>COMPLETED</b>        | <b>2014.1<br/>MORE</b>                  | <b>2014.2<br/>Backpack</b>            | <b>2014.3<br/>Trauma<br/>Outcomes<br/>COMPLETED</b> |
|------------------------------------------------|----------------------------------------------|-------------------------------------------|---------------------------------------------|-----------------------------|------------------------------------------------------|-----------------------------------------|---------------------------------------|-----------------------------------------------------|
| <b>Proposal submitted</b>                      | Oct 2010                                     | Oct 2010                                  | Dec 2012                                    | Dec 2012                    | Dec 2012                                             | Nov 2013                                | Nov 2013                              | Dec 2012                                            |
| <b>Scientific Review</b>                       | May 2011                                     | May 2011                                  | December 2012                               | December 2012               | December 2012                                        | December 2013                           | December 2013                         | Dec 2012                                            |
| <b>GSC approval</b>                            | June 2012                                    | April 2012                                | March 18, 2013                              | March 18, 2013              | March 18, 2013                                       | February 28, 2014                       | February 28, 2014                     | Mar 2013                                            |
| <b>Contract negotiation docs sent to CDMRP</b> | June 2012                                    | July 2011                                 | August 2013                                 | August 2013                 | December 2014                                        | December 2014                           | December 2014                         | Jan 2015                                            |
| <b>CDMRP approval</b>                          | August 2012                                  | August 2012                               | February 2014                               | February 2014               | February 2015                                        | February 2015                           | February 2015                         | August 2012                                         |
| <b>Omnibus CRADA executed</b>                  | December 2012                                | October 2012                              | March 2014                                  | March 2015                  | February 2015                                        | April 2015                              | April 2015                            | February 2015                                       |
| <b>BADER PI agreement signed</b>               | August 2012                                  | October 2012                              | April 2013                                  | Not executed                | Not executed                                         | April 2014                              | March 2014                            | October 2014                                        |
| <b>IRB approvals</b>                           | August 2012                                  | June 2013                                 | Oct 2013                                    | March 2019                  | May 2015                                             | Dec 2018                                | March 2019                            | Nov 2017 (most recent site)*                        |
| <b>HRPO approval</b>                           | Sept-12 (aim 1)<br>Ap-13, (aim 2)            | June/July 2013                            | COMIRB approval Oct 2013                    | June 2014                   | Feb 2016                                             | June 2015                               | June 2015                             | *                                                   |
| <b>Subject pool</b>                            | *                                            | *                                         | 45                                          | 17                          | *                                                    | 200+                                    | 23                                    | *                                                   |
| <b>Subjects screened</b>                       | 46                                           | 12                                        | 32                                          | 15                          | *                                                    | 469 patients<br>36 therapists           | 20                                    | *                                                   |
| <b>Subjects enrolled</b>                       | 46<br>(Aim 1:22,<br>Aim 2:1<br>Aim 3: 23)    | 2                                         | 22                                          | 13                          | 60<br>(12 lower, 48<br>upper<br>extremity<br>injury) | 409<br>(390 patients,<br>19 therapists) | 17                                    | 90<br>(56 Patients<br>34 Providers)                 |
| <b>Subjects Completed</b>                      | 46                                           | 0                                         | 22                                          | 7                           | 59 (12 lower,<br>47 upper<br>injury)                 | 145                                     | 17                                    | 90                                                  |
| <b>Presentations</b>                           | 23                                           | 5                                         | 43                                          | 4                           | 6                                                    | 0                                       | 7                                     | *                                                   |
| <b>Publications</b>                            | 5 (plus 3 in<br>preparation;<br>2 submitted) | 0                                         | 5                                           | 0                           | 3                                                    | 0                                       | 1 (plus 1<br>submitted;<br>2 in prep) | *                                                   |

\* data not available

**2012.1 “Improving Step-To-Step Control of Walking in Traumatic Amputees”**

***“STEP2STEP”***

**THIS PROJECT HAS BEEN CLOSED. PLEASE SEE PRIOR REPORTS FOR COMPLETE PROJECT DETAILS**

**PLEASE REFER TO APPENDIX A FOR COMPLETE LIST OF PUBLICATIONS RESULTING FROM THIS WORK**

**Abstract:** Gait and balance training are essential for patients with lower limb amputation because of their high fall risk. However, little scientific evidence exists to guide efforts to develop such training programs. The purpose of this study is two-fold: to determine how step-to-step control strategies differ between patients with varying levels of amputation and to determine how these patients respond to a virtual reality based training intervention. Addressing these two issues will provide an essential foundation from which we can design more effective training protocols. Enhanced training will take place in a fully immersive virtual reality (VR) environment so we can apply well controlled and ecologically relevant motions to the walking surface. Effective VR-based gait training programs may provide significant advantages over traditional gait training, putting therapists in control of the training environment and allowing them to quantitatively monitor patient progress in real time. We expect this will yield significant generalization to real world walking. We will conduct a single-center study including 30 patients with varying degrees of lower limb amputation to determine the relative effects of VR based treatment on walking step-to-step control strategies. We will test each subject before, during, and after training as well as at an approximate 2-week follow-up while walking both in the VR environment and while walking over flat and uneven ground. Step-to-step control measures will then be compared across the group of patients using regression analyses against clinical performance measures to better understand the effects of physical ability on step-to-step control. Additional intra-subject analyses will be conducted to look at changes in walking over the course of the intervention.

|                          |                                                                                                                                                 |                                                                                                                                             |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Title:                   | 2012.1: “Improving Step-To-Step Control of Walking in Traumatic Amputees”                                                                       |                                                                                                                                             |
| Funded Amount:           | \$679,300                                                                                                                                       |                                                                                                                                             |
| Principal Investigators: | Jonathan Dingwell, PhD                                                                                                                          | Department of Kinesiology & Health Education, University of Texas at Austin, Austin, TX                                                     |
|                          | Jason Wilken, PhD                                                                                                                               | Military Performance Lab, Center for the Intrepid, Department of Orthopaedics & Rehabilitation, Brooke Army Medical Center, San Antonio, TX |
| Collaborators:           | Joseph P. Cusumano, Ph.D.                                                                                                                       | Pennsylvania State University, Department of Engineering Science & Mechanics                                                                |
| Accruals                 | Aim #1: 21 total subjects (9 patients + 13 controls)<br>Aim #2: 1 subject<br>Rehab Frogger Study: 23 total subjects (10 patients + 13 controls) |                                                                                                                                             |

|                                   |                                                                                                                                                                                                                                                                                                  |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IRB Approvals:                    | <p>Our IRB application for Specific Aim #1 was determined to qualify for “<i>exempt</i>” status so therefore no annual renewals are required.</p> <p>Our IRB application for Specific Aim #2 has been approved by BAMC IRB and has received HRPO approval. Approval expires: January 9, 2017</p> |
| Amendments to IRB                 | None reported.                                                                                                                                                                                                                                                                                   |
| Adverse events:                   | None reported.                                                                                                                                                                                                                                                                                   |
| Serious adverse events:           | None reported.                                                                                                                                                                                                                                                                                   |
| Problems or barriers to research: | None reported.                                                                                                                                                                                                                                                                                   |
| Finances:                         | <p>Awarded a no cost extension through September 2016</p> <p>Award amount: \$679,300</p> <p>Spent to date: \$677,707</p> <p>% spent to date: 99.7%</p> <p>% award period complete: 100%</p>                                                                                                      |

**2012.2 “Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”**  
**“RETRAIN”**

**THIS PROJECT HAS BEEN CLOSED. PLEASE SEE PRIOR REPORTS FOR COMPLETE PROJECT DETAILS**

**PLEASE REFER TO APPENDIX A FOR COMPLETE LIST OF PUBLICATIONS RESULTING FROM THIS WORK**

**Abstract:** Lower extremity amputations significantly impact a soldier’s gait function and their ability to return to active duty. Despite standard rehabilitative care that includes gait training, loading remains elevated in the intact extremity, increasing the risk for the development of degenerative joint disease. *The purpose of this study is to examine whether symmetry of loading can be improved in both walking and running using real-time feedback in individuals with unilateral, transtibial amputations.*

|                          |                                                                                                                                                                                                       |                                                                                                                                        |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------|
| Title:                   | 2012.2 “Return to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”                                                                                                        |                                                                                                                                        |
| STATUS:                  | <b>Project ended 09/30/2015</b>                                                                                                                                                                       |                                                                                                                                        |
| Funded Amount:           | \$708,524                                                                                                                                                                                             |                                                                                                                                        |
| Principal Investigators: | Irene Davis, PhD, PT                                                                                                                                                                                  | Spaulding Rehabilitation Hospital                                                                                                      |
|                          | Alison (Linberg) Pruziner, DPT, ATC                                                                                                                                                                   | Walter Reed National Military Medical Center                                                                                           |
| Collaborators:           | Steve Jamison, PhD<br>Matthew Ruder, MS<br>Devjani Saha, PhD                                                                                                                                          | Elizabeth Nottingham<br>Elizabeth Husson<br>Amanda Wingate, BA                                                                         |
| Accruals:                | <b>SNRC:</b><br>Potential subjects contacted: 23<br>Potential subjects screened (phone): 15<br>Lab screened: 6 (5 did not qualify)<br>Subjects enrolled: 1                                            | <b>WRNMMC:</b><br>Potential subjects contacted: 10<br>Potential subjects screened: 6<br>Subjects enrolled: 1<br>Subject withdrawals: 1 |
| Adverse events:          | None reported.                                                                                                                                                                                        |                                                                                                                                        |
| Serious adverse events:  | None reported.                                                                                                                                                                                        |                                                                                                                                        |
| Finances:                | Award amount: \$708,524<br>Spent to date: \$618,162<br>% spent to date: 87%<br>Project dates: 10/01/2012 – 09/30/2015<br>Dr. Davis was granted a no cost extension to 09/30/2015.<br>% complete: 100% |                                                                                                                                        |

**2012.3 A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma**

***"Trauma Outcomes"***

**THIS PROJECT HAS BEEN CLOSED. PLEASE SEE PRIOR REPORTS FOR COMPLETE PROJECT DETAILS**

**PLEASE REFER TO APPENDIX A FOR COMPLETE LIST OF PUBLICATIONS RESULTING FROM THIS WORK**

|                         |                                                                                                             |                        |
|-------------------------|-------------------------------------------------------------------------------------------------------------|------------------------|
| Title:                  | 2012.3: A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma     |                        |
| Funded Amount:          | Funded through Research Outcomes Measurement Core budget                                                    |                        |
| Principal Investigator: | David Tulskey, PhD                                                                                          | University of Delaware |
| Collaborators:          | Christopher Dearth, PhD                                                                                     | WRNMMC                 |
|                         | Marilynn Wyatt, MPT                                                                                         | NMCSD                  |
|                         | Jason Wilken, PhD                                                                                           | BAMC/CFI               |
| IRB Approvals:          | NMCSD IRB approval received (August 21, 2013). HRPO Approval received March 2014. HRPO Log Number A-17117.5 |                        |

**2013.2 Prosthetic Leg Prescription (ProLegRx):**  
**What is the optimal stiffness and height of a running-specific prosthesis?**  
***“The ProLegRx Study”***

**THIS PROJECT HAS BEEN CLOSED. PLEASE SEE PRIOR REPORTS FOR COMPLETE PROJECT DETAILS**

**PLEASE REFER TO APPENDIX A FOR COMPLETE LIST OF PUBLICATIONS RESULTING FROM THIS WORK**

**Abstract:** There are currently no science-based, objective methods for optimizing running-specific prosthesis (RSP) prescription. Existing practices can waste time, money, and resources and do not necessarily provide the best prosthetic prescription. Due to the severity of impairment caused by a leg amputation and the healthcare costs sustained over the lifetime of a person with an amputation, it is extremely important to improve RSP prescription so that Soldiers and Veterans with amputations can regain the greatest possible level of functional ability and return to active duty, if they choose. Our goal is to develop tools for clinicians to prescribe running-specific leg prostheses that facilitate optimal function for Soldiers and Veterans with transtibial amputations. We intend to systematically vary the stiffness and height of distance-running RSPs and measure the biomechanical and metabolic effects of running at the speed required for a subject's age/sex 50<sup>th</sup> percentile Physical Fitness Test (PFT) 2 mile run and at one standardized speed, 3 m/sec. We also intend to systematically vary the stiffness and height of sprint-running RSPs and measure the biomechanical and performance effects of running across a range of speeds. Then, we will combine results from distance-running and sprint-running prostheses to develop clinically relevant, quantitative algorithms for prosthetic stiffness and height prescription based on a subject's weight, amputation level, limb segment lengths, and desired running speed. The results of our research will be disseminated to clinicians and will improve RSP prescription for people with leg amputations. We hope to improve and expedite rehabilitation for Soldiers and Veterans with transtibial amputations and to save time, money, and resources. Optimizing RSP prescription would facilitate aerobic conditioning, reduce injury risk, improve running economy (the metabolic demand at a given running speed) and improve performance; thus improving the quality of life and reducing the healthcare needs of Soldiers and Veterans with leg amputations.

|                         |                                                                                                                            |                                                              |
|-------------------------|----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| Title:                  | 2013.1: Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis? |                                                              |
| Funded Amount:          | \$882,827                                                                                                                  |                                                              |
| Principal Investigator: | Alena Grabowski, PhD                                                                                                       | Dept. of Veterans Affairs Eastern Colorado Healthcare System |
| Collaborators:          | Rodger Kram, PhD                                                                                                           | Dept. of Integrative Physiology, University of Colorado      |
|                         | Ryan Stephenson, MD                                                                                                        | Dept. of Veterans Affairs Eastern Colorado Healthcare System |
|                         | Michael Litavish, CP                                                                                                       | Dept. of Veterans Affairs Eastern Colorado Healthcare System |
| Accruals:               | Potential subjects contacted: 45<br>Potential subjects screened: 32<br>Subjects enrolled: 22                               |                                                              |

|                                   |                                                                                                                                          |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
|                                   | Subjects completed: 22                                                                                                                   |
| IRB Approvals:                    | COMIRB: Expires August 21, 2018                                                                                                          |
| Amendments to IRB:                | We expanded the age range of participants to include people between 18-55 years old.                                                     |
| Adverse events:                   | None                                                                                                                                     |
| Serious adverse events:           | None                                                                                                                                     |
| Problems or barriers to research: | None reported                                                                                                                            |
| Finances:                         | Award amount: \$827,116<br>Spent to date: \$767,903<br>% spent to date: 93%<br>Project dates: 10/01/2013 – 12/31/2017<br>% complete: 95% |

#### **Updates:**

##### **Funding:**

We submitted four abstracts in support of the BADER consortium renewal. We have submitted proposals to the Defense Health Program CDMRP Peer Reviewed Orthopaedic Research Program and Orthotics and Prosthetics Outcomes Research Program Award Funding Opportunity to study the effects of running-specific prosthetic alignment on performance in athletes with transtibial amputations and the effects of running-specific prosthetic blade stiffness and knee articulation on athletes with transfemoral amputations. We were chosen as an alternate for the alignment project. We have also submitted a proposal to the DMRDP DHA Clinical Research Intramural Initiative, Military Women's Health Research Award to determine the optimal orthotic and prosthetic components for military women with limb salvage or transtibial amputations and received a notification of funding for this project. We recently submitted a pre-application to the Joint Warfighter's Military Research Program to develop advanced running-specific prostheses.

##### **Honors & Awards (BADER-related):**

Dr. Grabowski was invited to give a presentation at the International Research Forum on Biomechanics of Running-specific Prostheses in Tokyo, Japan. She was one of three invited US researchers. Dr. Grabowski was invited to be part of an international research team that analyzed the use of prostheses for the long jump and specifically if Markus Rehm should be allowed to compete in the Rio Olympics in 2016. She presented the results of this study at an International Press Conference in Cologne, Germany, "Markus Rehm about to jump to Rio 2016". She was one of three researchers and the only US researcher invited to contribute to this project. This study has been published: S Willwacher, J Funken, K Heinrich, R Müller, H Hobara, AM Grabowski, G-P Brüggemann, & W Potthast; Elite long jumpers with below the knee prostheses approach the board slower, but take-off more effectively than non-amputee athletes. *Scientific Reports*; 2017; 7: 16058; DOI:10.1038/s41598-017-16383-5.

Dr. Grabowski was invited to give a presentation to the NCAA Track and Field Rules Committee regarding her research and the participation of an athlete with bilateral transtibial amputations as a Division I scholarship athlete. This athlete was allowed to compete.

## **2013.2 “Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators”**

### ***“The K2POWER study”***

**Abstract:** Advances in lower limb prostheses have allowed for improvements in function and participation in activities for individuals with transtibial limb loss. Advancements in passive ankle prostheses are still limited in their ability to assist with forward progression and push-off because of their inability to produce positive network. Recent advancements to powered prostheses have proposed the potential to provide positive network, returning these individuals to a level of function and efficiency similar to those without limb loss. The objectives of this proposal are to identify differences in gait, efficiency, function, and quality of life between using a standard passive prosthesis versus a powered ankle prosthesis, and to see if changes remain stable for up to six months after the initial fitting. We wish to address these objectives in individuals with lower limb loss that are not capable of fully interacting in their environment and community. This proposed project will assist with prosthetic prescription decisions regarding individuals with transtibial limb loss with varying levels of function, as advanced technology is often not directed at the more disabled population, despite these individuals potentially having the most to gain from this technology.

Twenty individuals with transtibial limb loss will be recruited to participate in this longitudinal study: ten who function at a Medicare Functional Classification Level (MFCL) K2-level and ten who function at a MCFL K3-level. Participants will be evaluated in their current passive ankle prosthesis, be fit with a powered ankle prosthesis, and be followed during six visits over six months. Testing during these six months will include analyzing how the participants walk, how much energy they are using to walk, their balance and endurance, and subjective reports of how they feel and what they are able to do in the prosthesis. We expect results will show differences in walking measures that indicate a change in risk of secondary injury to the intact limb, such as osteoarthritis; will identify changes in efficiency with walking and in balance and endurance; and will measure the users satisfaction with the device and how the user is able to interact with his/her home and community lives, to indicate differences in ability to re-integrate into these roles.

Results from this proposal will have a short-term impact of helping drive prosthetic prescription of powered ankle prostheses for individuals with transtibial limb loss who are K2 and K3-level walkers. The long-term impact of results from this proposal will be the potential for increasing opportunities for lower level walkers to have access to advancements in technology, especially as these technologies expand to include more joints, such as the knee and hip. This proposal will be able to demonstrate the ability of a lower level walker to control and respond to a powered prosthetic device. Additionally, this proposal will allow us to determine if power makes any positive changes to the user’s walking, efficiency, balance, endurance, and ability to engage in their daily activities at home and within their community, and if any changes are sustainable.

|                         |                                                                                                   |                                              |
|-------------------------|---------------------------------------------------------------------------------------------------|----------------------------------------------|
| Title:                  | 2013.2: “Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators” |                                              |
| Funded Amount:          | \$1,529,718                                                                                       |                                              |
| Principal Investigator: | Alison A. Pruziner, DPT                                                                           | Walter Reed National Military Medical Center |

|                                   |                                                                                                                                                                                                                                                                                                                                                                                       |                                              |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| Collaborators:                    | Caitlin Mahon, MS                                                                                                                                                                                                                                                                                                                                                                     | Walter Reed National Military Medical Center |
|                                   | Joseph B. Webster, MD                                                                                                                                                                                                                                                                                                                                                                 | Hunter Holmes McGuire VA Medical Center      |
|                                   | Bradford Hendershot, PhD                                                                                                                                                                                                                                                                                                                                                              | Walter Reed National Military Medical Center |
|                                   | David S. Tulskey, PhD                                                                                                                                                                                                                                                                                                                                                                 | University of Delaware                       |
| IRB Approvals:                    | Expires March, 2019                                                                                                                                                                                                                                                                                                                                                                   |                                              |
| Amendments:                       | 1. Recruit participants with limb loss due to vascular causes but who are currently in a recovered/remission state in their disease.<br>2. Add an age-matched control group to serve as normative reference.                                                                                                                                                                          |                                              |
| Adverse events:                   | None reported                                                                                                                                                                                                                                                                                                                                                                         |                                              |
| Serious adverse events:           | One participant was withdrawn this quarter after being admitted for an amputation to the contralateral limb. The SAE was discussed with the Director of IRB Operations at WRNMMC to evaluate if the event met the criteria to be considered a UPIRTSO; it was determined this SAE should only be recorded on the Adverse Event log, and reported at the next study continuing review. |                                              |
| Problems or barriers to research: | None reported                                                                                                                                                                                                                                                                                                                                                                         |                                              |
| Recruitment:                      | Total number of subjects contacted: 17<br>Total number of potential subjects screened: 15<br>Total number of subjects enrolled: 13                                                                                                                                                                                                                                                    |                                              |
| Finances:                         | Award amount: \$1,529,718<br>Spent to date: \$899,157.25<br>% spent to date: 59%<br>Project dates: 03/01/2014 – 09/29/2018                                                                                                                                                                                                                                                            |                                              |

### **Research Progress Update:**

For each aim, describe: (a) what you have done, (b) what the next steps will be, (c) the administrative and scientific challenges you have experienced and (d) what you are doing to overcome them.

- a) Aim 1: During this quarter: Both enrolled participants initiated data collection. One of these participants completed both visits required to obtain data for analysis to address this aim, bringing the total to 9 data sets. The other participant unfortunately underwent an amputation on the contralateral limb before completing both visits, so this participant has been withdrawn from the study because he no longer qualifies for enrollment. One additional potential participant contacted the research team with interest for more information. He has been provided this information and is considering his ability to participate because of the time commitment. He has not been fully screened at this time to verify his eligibility, but this screening will be completed if he determined he is interested and available.

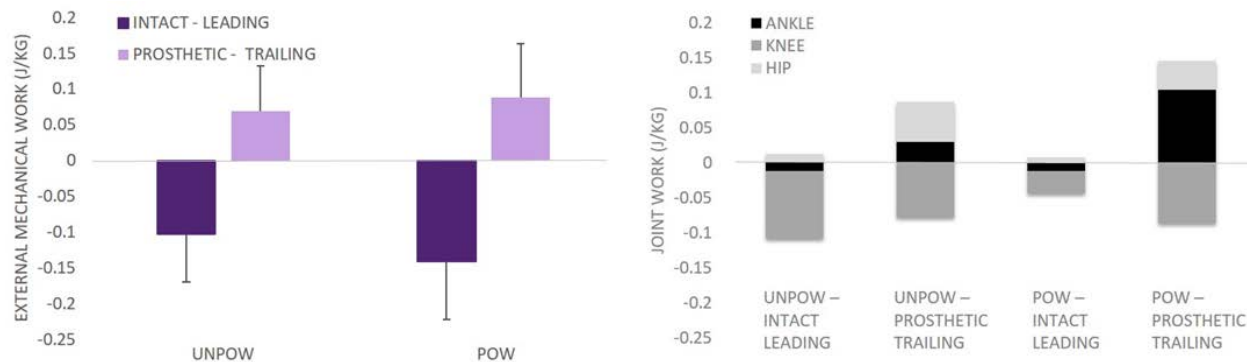
Aim 2: During this quarter, the remaining enrolled participant has completed follow-up testing that will result in 7 data sets for analysis to address this aim.

Both Aims: During this quarter, the research team presented data from this project at the World Congress of Biomechanics in Dublin, Ireland. This data was well received and fostered communication with additional teams working on similar efforts (both at the meeting and moving forward). During this quarter audit comments were received and addressed, and the amendment to add an age-matched control group to serve as a normative reference for the final data set was submitted. Finally, a request was sent to the sponsor to add the VAMC sites as collection sites.

- b) Both Aims: During the upcoming quarter, the research team will: 1) continue collections for the currently enrolled participant, 2) continue recruitment efforts through the Department of Rehabilitation at WRNMMC to help us meet our recruitment goals, 3) track modifications submitted to the IRB, 4) prepare for expansion of efforts to the VAMCs, if approved, 5) continued analysis and interpretation of collected data, looking into potential identification of participants as responders or non-responders based on differences in patterns observed in the data.
- c) Changes in local recruitment regulation has limited our recruitment opportunities to only DoD health care beneficiaries.
- d) A request has been made to the sponsor for approval to formally add both Hunter Holmes McQuire VAMC in Richmond, VA and the New York Harbor Healthcare System VAMC in New York, NY as recruitment and data collection sites. At this time, there are no plans to continue civilian recruitment locally at WRNMMC but, if expansion is approved, this recruitment method will be utilized at the VAMC sites.

### **Preliminary results:**

- Participants selected a similar ( $p=0.64$ ) over ground SSP (UNPOW =  $1.06 \pm 0.27$  m/s; POW =  $1.04 \pm 0.22$  m/s).
- Step-to-step transition work was not different between UNPOW and POW for the intact limb when leading ( $p=0.19$ ) or the prosthetic limb when trailing ( $p=0.37$ ; Figure 2a).
- Trailing prosthetic ankle work increased when using POW vs. UNPOW, but prosthetic-side hip work decreased and prosthetic-side knee work became more negative (Figure 2b).
- Metabolic efficiency was not different ( $p=0.48$ ) between conditions (UNPOW =  $0.255 \pm 0.087$  ml/kg/m; POW =  $0.259 \pm 0.084$  ml/kg/m).
- Overall user satisfaction did not change ( $p=0.20$ ) between conditions (UNPOW =  $80.7 \pm 9.8$ ; POW =  $86.4 \pm 11.8$ ).



## Conclusions

- In contrast to our hypotheses and previous work in high-functioning individuals, there was no difference in individual limb transitional work, nor metabolic efficiency between the POW v. UNPOW devices.
  - Though an increase (from UNPOW to POW) in negative leading intact limb external work (Figure 2a) may be due to soft-tissue or intact foot contributions, since summed intact limb joint work (Figure 2b) did not become more negative.
- Overall, these preliminary results suggest individuals with transtibial limb loss at lower (vs. higher) MFCL likely utilize different strategies when walking with a POW vs. UNPOW device.
  - However, alterations in lower-extremity motor control (e.g., redistribution of joint powers) with age or other deficits/pathologies [5,6] may necessitate unique considerations in device programming for this population.
- Additional participants and (comprehensive) longitudinal follow-ups will help clarify guidelines for initial prescription and fitting, as well as clinical expectations over the longer term.

**Study completion projection:** September 29, 2018

## **Presentations (BADER-related only):**

Pruziner AL. Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. *The BADER Consortium Government Steering Committee Meeting*. 19 February 2014.

Pruziner AL. Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. *The BADER Consortium Government Steering Committee Meeting*. 20 February 2015.

Wingate AF, Kisala PA, Pruziner AL, Dearth CL, Tulsy DS. Comparison of Patient-Reported to Performance-Based Functional Outcomes in Individuals with Unilateral Transtibial Amputation. *Military Health System Research Symposium*. 17-20 August 2015, Ft. Lauderdale, FL.

Pruziner AL, Mahon CE, Gladish JR, Hendershot BD. Kinetic and metabolic outcomes for Medicare Functional Classification Level-2 and 3 Individuals Wearing a Powered Ankle-foot Prosthesis. *World Congress of Biomechanics*. 8-12 July 2018, Dublin, Ireland.

**2013.3 “Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma”**  
***“QOL Toolbox”***

**THIS PROJECT HAS BEEN CLOSED. PLEASE SEE PRIOR REPORTS FOR COMPLETE PROJECT DETAILS**

**PLEASE REFER TO APPENDIX A FOR COMPLETE LIST OF PUBLICATIONS RESULTING FROM THIS WORK**

**Abstract:** As a result of Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND), an unprecedented number of wounded warriors have had combat-related major traumatic limb injuries that include amputation of one or more limbs. These wounded warriors are typically treated for long periods of time at Military Treatment Facilities (MTF) within the Department of Defense (DoD) and later, upon discharge from active duty, at Department of Veterans Affairs Medical Centers (VA) or civilian hospitals. Unfortunately, the health care that is provided across the DoD MTF sites and the VAs is not well coordinated. Individual clinicians and researchers use a wide variety of measurement tools to assess their patients and the lack of standardization across sites makes it difficult to track progress or compare functioning and outcomes across the major treatment facilities. This often results in a lack of coordination of medical care. From a research perspective, the lack of uniformity in measurement tools makes it difficult to compare patients across studies or follow individuals over time as they are transferred to and receive care from different medical facilities. This hinders our ability to study these injured service persons over time to better understand their course of recovery and identify the most effective types of treatments. Because upper limb injury was a rare occurrence prior to OEF/OIF/OND there have been few studies on this patient group and little evidence to inform the design of optimal clinical care guidelines.

People who have had upper extremity amputation of one or both hands and/or arms, major traumatic damage to their limbs without amputation, or who have had multi-limb amputations are understudied groups. When research is performed, the medical community has focused on assessment of patient physical functioning (e.g., limitations in an individual’s strength and their ability to walk and stand) and placed less emphasis on measuring the injured individual’s ability to return back to a healthy and productive life by participating in society, and resuming work and social relationships (known as community reintegration). Entire areas of functioning revolving around social participation have been largely ignored in clinical practice. Moreover, without coordination between the MTFs, the VAs, and civilian hospitals, researchers and clinicians at the different sites will use different measures, making it very difficult to accumulate data across sites. A coordinated approach to assessment for this population would help improve clinical care and allow research at different sites to be aggregated. This grant hopes to improve all of these things.

A central aim of this grant is to develop a “toolbox” of outcome assessments that is comprehensive and includes measures of community integration and quality of life, as well as assessments of physical activity and limitations in body functions. The proposed study is unique because it brings together a large group of clinicians and researchers from the major military treatment facilities that treat individuals with traumatic amputation (i.e., the Center for the Intrepid/San Antonio Military Medical Center, Naval Medical Center in San Diego, Walter Reed National Military Medical Center) and one of the largest VA hospitals and amputation centers (Tampa VA) and one of the oldest and largest civilian hospitals (Rusk Rehabilitation at New York University) along with leaders in

measurement from the University of Michigan and Providence VA. This grant will bring together a diverse team of stakeholders (individuals who have had catastrophic limb trauma, clinicians, policy makers, and research investigators) with many representatives from our participating sites to discuss and agree on a series of common measures and scales that can help bring standards and uniformity to the field.

Given the dearth of research on individuals with upper extremity amputation, we plan to validate the toolbox by administering the upper extremity toolbox measures to individuals who have had upper limb amputation at 3 MTFs, a VA, and a civilian hospital. The instrument will be reassessed to help us ascertain reliability and other psychometric properties. Through this collective work we will introduce a new level of cooperation and uniformity to the field. We will study individuals with upper extremity amputations, a subgroup of injured service people who have been underrepresented in research in the past. We will also emphasize the vital areas of community reintegration and quality of life assessment with MTF and VA clinical practice to improve the lives of individuals who have had these traumatic limb injuries. These efforts will ultimately result in improvements to clinical practice which will directly benefit persons with both combat and non-combat related limb trauma and amputation.

|                         |                                                                                                                                                         |                                             |
|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Title:                  | 2013.3: "Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma" |                                             |
| Funded Amount:          | \$2,059,000                                                                                                                                             |                                             |
| Principal Investigator: | David Tulskey, PhD                                                                                                                                      | University of Delaware                      |
| Collaborators:          | Alison Pruziner, DPT;<br>Christopher Dearth, PhD                                                                                                        | WRNMMC                                      |
|                         | Jill Cancio, PhD                                                                                                                                        | BAMC/CFI                                    |
|                         | Marilynn Wyatt, MPT                                                                                                                                     | NMCSD                                       |
|                         | Hilary Bertisch, PhD                                                                                                                                    | NYU Langone Medical Center                  |
|                         | Linda Resnik, PT, PhD                                                                                                                                   | Providence VA Medical Center                |
|                         | Gayle Latlief, DO                                                                                                                                       | James A. Haley Veteran's Hospital, Tampa FL |
|                         | Claire Kalpakjian, PhD                                                                                                                                  | University of Michigan                      |

|                             |                                                                                                                                 |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| Number of subjects enrolled | Focus groups: 56 patients, 34 providers<br><br>Toolbox administration: 59 participants (12 lower extremity, 47 upper extremity) |
| IRB Approvals               | Expires: November 25, 2017                                                                                                      |

## **2014.1 Maximizing Outpatient Rehabilitation Effectiveness (MORE)**

**Abstract:** In 2012, 31.7% of 20,452,769 outpatient visits recorded across the Department of Defense were for rehabilitation services associated with musculoskeletal disorders, the number one cause of disability among active duty service members. Data across all branches of the military indicate that the largest burden of injury from the Global War on Terror is extremity trauma, representing 64% of a projected \$1.9 billion in disability benefit costs, and causing the largest percentage of days on limited duty. Nearly 50% of all extremities injuries involve the lower limb and fewer than 25% of service members with extremities injuries returning to their previous occupation. Service members with lower extremity injuries commonly undergo several months of outpatient rehabilitation in an effort to improve motion, strength and function, and reduce pain and disability. The rehabilitation process for injured service members includes personnel from many different healthcare specialties. Physical Therapists play a major role in the recovery process typically spending more time with the patient than individuals from any other specialty. While treatments interventions are commonly focused on physical deficits, clinicians have long recognized that a multitude of additional factors can affect rehabilitation outcomes. Over the past decade, there has been an increased emphasis on determining which factors affect how well an individual recovers from their injury, how they improve or change during the course of rehabilitation, and whether or not they are likely to fully recover to pre-injury function. Given the current climate of high patient volumes and limited clinical resources, it is increasingly important to characterize persistent deficits and identify predictors of positive and negative rehabilitation outcomes.

In this study, we seek to “(d)etermine factors that predict ... successful treatment of musculoskeletal conditions following severe extremity trauma and/or deployment related musculoskeletal injuries.” This study will provide valuable information that can be used to “(d)etermine the optimal treatment strategies to minimize impairments, maximize function and performance, and/or optimize quality of life.” Findings from this study will also help lessen the overwhelming negative impact these injuries have on service members, their families, and our military healthcare system. The proposed study will be conducted with a large group of service members with lower extremity injuries receiving care at three physical therapy clinics at Fort Hood, TX and Joint Base San Antonio, TX. This patient subject group is the exact patient population this study is intended to positively affect, and will result in actionable information to improve current and future clinical care within the military. A range of measures that characterize physical deficits, functional limitations, activity restrictions, and health related quality of life will be collected by clinical research staff fully imbedded within the physical therapy clinics of Fort Hood, TX and Joint Base San Antonio, TX. This approach not only ensures that a large percentage of service members with extremity injuries at these clinics will be enrolled, but that also enhances the ecologic validity of this study. Physical, cognitive, and psychosocial measures will be administered in parallel with rehabilitative care. There are three primary sources of data in this proposed study: 1) self-report surveys, 2) participant medical records, and 3) physical assessments. Imbedded clinical research staff will directly observe, measure, record, and report functional changes that occur throughout the rehabilitation processes at each of these sites. Assessments metrics contained in the National Institutes of Health’s (NIH) Patient Reported Outcomes Measurement Information System (PROMIS) will be leveraged for this study and electronically collected with additional outcome metrics using computer tablets (i.e. Apple iPads). De-identified data will be entered into the BADER Clinical Trials Database system for analysis.

An improved understanding of the types and magnitudes of deficits present, and their relative contributions to treatment success, goal attainment, and health related quality of life in a military setting is needed to effectively guide the use of limited clinic resources and facilitate efforts to maximize outpatient rehabilitation effectiveness. As final study results become available, information will be directly shared with treating therapists through incorporation into educational programs to promote evidence based practice and accelerate patient recoveries.

|                         |                                                                   |                                                     |
|-------------------------|-------------------------------------------------------------------|-----------------------------------------------------|
| Title:                  | 2014.1: Maximizing Outpatient Rehabilitation Effectiveness (MORE) |                                                     |
| Funded Amount:          | \$1,487,036                                                       |                                                     |
| Principal Investigator: | Amy Bowles, MD                                                    | Brooke Army Medical Center, Center for the Intrepid |
| Collaborators:          | Jason Wilken, Pt, PhD                                             | University of Iowa                                  |
|                         | David Tulsy, PhD                                                  | University of Delaware                              |
|                         | COL Scott Shaffer, PhD                                            | Joint Base San Antonio TX                           |
|                         | MAJ Sean Suttles, PT, DPT, OCS                                    | Fort Hood, TX                                       |
|                         | Paul Kolm, PhD                                                    | Christiana Care, Newark Delaware                    |
|                         | MAJ Owen T. Hill, PhD                                             | Center for the Intrepid, Joint Base San Antonio     |

|                                   |                                                                                                                                                                                                                                                                                                                                                                                         |  |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Subject Accruals:                 | Potential subjects contacted: 200+<br>Potential subjects screened: 469 patients, 36 therapists<br>Subjects enrolled: 409 total (390 patients, 19 therapists)                                                                                                                                                                                                                            |  |
| IRB Approvals:                    | Expires December 19, 2018                                                                                                                                                                                                                                                                                                                                                               |  |
| Amendments:                       | Amendment 9 submitted to add Scott Shaffer to the study, change the CRDAMC site PI to Mathew Frazier since MAJ Sean Suttles will be retiring in the months ahead, update project coordinator location and logistics for receiving identifiable data from other study sites, and add responsibilities to Molly Pacha and Pam Jahelka, Submitted June 18, 2018, Approved August 21, 2018. |  |
| Adverse events:                   | One reported previously                                                                                                                                                                                                                                                                                                                                                                 |  |
| Serious adverse events:           | None reported                                                                                                                                                                                                                                                                                                                                                                           |  |
| Problems or barriers to research: | None reported                                                                                                                                                                                                                                                                                                                                                                           |  |
| Finances:                         | Award amount: \$1,529,718<br>Spent to date: \$835,268.65<br>% spent to date: 51%<br>Project dates: 03/01/2014 – 09/29/2019                                                                                                                                                                                                                                                              |  |

#### **Research Progress Update:**

**Specific Aim 1: To determine factors that predict clinical outcomes following outpatient rehabilitation in a military setting.** Information collected at the initial visit and early in the treatment process will each be used to predict and identify factors that influence discharge values for 1) patient and therapist reported improvements and goal attainment, 2) objective measures of physical capacity/ability and 3) health related quality of life. Measures include impairment level variables (e.g. strength and range of motion), performance on objective tests of physical activity, psychosocial factors (e.g. self-efficacy) and therapist related factors (e.g. experience).

- a) Enrollment of therapist and patient participants and subsequent data collection is ongoing at all orthopedic and physical therapy clinics. Due to the lack of participant population at Joint Base San Antonio and to ensure timely completion of the study, recruitment and data collection is no longer taking place at this site. Subject recruitment and data collection are ongoing at Fort Hood and the University of Iowa. Data review and quality checks are ongoing.
- b) New personnel have been hired to the study staff at Fort Hood. Recruitment and data collection have significantly improved with the current and new staff working together. Identifying and recruiting study subjects into the study will be a primary focus of activities for the next quarter.
- c) Dropout rate is higher than initially estimated. We intend to more closely examine the dropout rate and reasons for dropout over the coming year.
- d) Please see above

**Specific Aim 2: To determine the extent to which patient reported and observed outcomes change and covary during the course of outpatient rehabilitation.** Function of the limb, objective assessments (impairment and physical activity measures) and subjective reports of physical ability along with symptomatology are used to assess recovery following musculoskeletal injury. The extent to which these measures and psychosocial factors co-vary and change during the course of rehabilitation is largely unknown. We will use data from the initial visit, quarter-point, half-point and discharge to determine the extent to which measures change over the course of care and determine if between-measure associations change over the course of care.

- a) See above Aim 1a.
- b) See above Aim 1b.
- c) See above Aim 1c.

**Specific Aim #3. To determine the magnitude of residual deficits following completion of outpatient rehabilitation.** Military physical therapists typically work with their patients until they can successfully return to their desired activities and/or have reached a maximal level of recovery. However, the decision to conclude therapy is most commonly made using therapist and patient self-reflection with limited data establishing the expected or maximal rehabilitation outcome for individuals with similar injury characteristics. We will use data collected at the completion of care to determine the prevalence of residual biopsychosocial deficits.

- a) See above Aim1 a.
- b) See above Aim1 b.
- c) See above Aim1 c.

**Study Completion Projection:** 9/30/2019 with a second 2-year NCE. The University of Iowa has been added to the study as a site for enrollment to achieve desired study numbers. Andrew Valentine re-joined the Fort Hood site to assist with enrollment and data collection which has improved greatly since his return. The NCE will be required to complete collection, data analysis and finalization of study activities.

Significant delays associated with the human subjects regulatory process, when added to the delay in receipt of funds, put the project behind schedule. As a result, it will take the entirety of the no-cost extension to complete the study. Although, as described in the proposal, many efforts were completed prior to receipt of funds, several factors have prevented timely progress. In addition to systemic regulatory delays associated with the loss of IRBNet, the local IRB failed to send our initially approved protocol to HRPO for second tier review delaying initiation of patient recruitment. The initiation of a new eIRB system and then subsequent dissolution of the system resulted in additional regulatory delays. Staff turn over , difficulty recruiting new staff, and low census at one site has slowed the ability to recruit subjects. However, we currently are actively enrolling participants and have added staff and another site to make up for lost time.

**2014.2 Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation**

***“Backpack”***

**ABSTRACT:** Our work is motivated by the lack of objective criteria for evaluating and prescribing prosthetic ankle-foot components for Service Members with transtibial amputations wishing to perform load carriage and other physically demanding tasks. Healthy intact ankle-foot systems adapt to added load by maintaining similar ankle motion and effective rocker shapes during walking. In contrast, most prosthetic feet are spring-like and continue to bend with added load, suggesting they may not mimic the physiologic system they are trying to replace during weighted walking. Additionally, there are currently no data to suggest which types of prosthetic feet will be most resistant to breakage during impact loading (e.g. loads that would be experienced when jumping off of a Humvee). We expect that mechanical testing will show a large diversity of mechanical properties of prosthetic feet based on marketing materials (some companies market extreme flexibility while others market limited flexibility). For the testing in Aim 2, we expect that the more flexible prosthetic foot (one that deforms considerably with added weight) will lead to increased loading on the intact limb during walking compared with the less flexible prosthetic foot. The planned testing will provide quantitative data to support the selection of prosthetic feet for highly active Service Members with lower-limb amputations, including data on impact durability and response to added loads above body weight. Prosthetic feet that can reduce loading to the intact limb may be prescribed to reduce the chances for long-term secondary complications of the intact limb (e.g. knee osteoarthritis). Although studies have been conducted on weighted walking in able-bodied persons and persons with lower-limb amputations, none have examined the effects of different prosthetic foot properties on gait. This study is innovative in that it combines the use of mechanical testing, functional testing, and clinical testing of prosthetic feet for persons in the highest functional levels. This comprehensive investigation should greatly improve our knowledge of these types of prosthetic feet and have direct implications for their prescription.

|                         |                                                                                                                |                                                                                     |
|-------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Title:                  | 2014.2: Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation |                                                                                     |
| Funded Amount:          | \$398,735                                                                                                      |                                                                                     |
| Principal Investigator: | Barri Schnall, MPT                                                                                             | Walter Reed National Military Medical Center                                        |
| Collaborators:          | Andrew Hansen, PhD                                                                                             | Minneapolis VA, University of Minnesota                                             |
|                         | Bradford Hendershot, PhD                                                                                       | Walter Reed National Military Medical Center                                        |
|                         | Joan Bechtold, PhD                                                                                             | University of Minnesota                                                             |
| IRB                     | Expires: March 25 2019                                                                                         |                                                                                     |
| Subject Accruals:       | Minneapolis VA:<br>Patients contacted: 3<br>Patients screened: 3<br>Patients enrolled: 3                       | WRNMMC:<br>Patients contacted: 20<br>Patients screened: 17<br>Patients enrolled: 14 |

|                                   |                                                                                                                                                                                                                                                                                                                                                                                         |  |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
| Amendments:                       | Amendment 9 submitted to add Scott Shaffer to the study, change the CRDAMC site PI to Mathew Frazier since MAJ Sean Suttles will be retiring in the months ahead, update project coordinator location and logistics for receiving identifiable data from other study sites, and add responsibilities to Molly Pacha and Pam Jahelka, Submitted June 18, 2018, Approved August 21, 2018. |  |
| Adverse events:                   | None reported                                                                                                                                                                                                                                                                                                                                                                           |  |
| Serious adverse events:           | None reported                                                                                                                                                                                                                                                                                                                                                                           |  |
| Problems or barriers to research: | None reported                                                                                                                                                                                                                                                                                                                                                                           |  |
| Finances:                         | Award amount: \$398,735<br>Spent to date: \$334,909.97<br>% spent to date: 84%<br>Project dates: 03/01/2014 – 04/29/2019 (check)                                                                                                                                                                                                                                                        |  |

### **Research Progress Update:**

For each aim, describe: (a) what you have done, (b) what the next steps will be, (c) the administrative and scientific challenges you have experienced and (d) what you are doing to overcome them.

**Specific Aim 1:** Determine mechanical characteristics and durability of current prosthetic feet intended for highly functional transtibial prosthesis users.

- a) **We have completed Major Task 1** – Mechanical stiffness characterization of prosthetic feet. **We have completed Major Task 2** – Roll-over shape characterization of prosthetic feet. **We have completed Major Task 3** – The drop tester device has been completed and validation results have been analyzed and submitted as an abstract. Prosthetic feet have been dropped from various heights, with additional measurements obtained using the impact load cell.
- b) We have now published data from major tasks 1-3 in PLOS One and JPO (see section 12 below).
- c) n/a
- d) n/a

**Specific Aim 2:** Compare biomechanical and functional outcomes between prosthetic feet with linear and non-linear mechanical properties (“stiffness”) during weighted walking and high-intensity (CHAMP) activities.

- a) **We have completed Major Task 4** – In total, seventeen participants have been consented, 14 have been fully collected (1 was not included in data analysis, and 2 withdrew from the study). Initial data collection has thus been completed.
- b) Now that the manuscript for Tasks 1&2 is published, we are now finalizing this manuscript for submission in October (likely also to PLOS One, or J Biomech).
- c) Preliminary analyses thus far indicate the tactical athlete can perform well on different components. Evaluating biomechanics of walking with and without a load, however, only provides part of the picture of the human-component interaction. As such, other essential tasks should be studied.
- d) An amendment to the currently approved protocol has been submitted to

further investigate militarily relevant tasks, potentially generating preliminary data for future grant submissions.

**Pending Support:**

DoD Congressionally Directed Joint Warfighter Medical Research Program- “Developing Impact Testing Standards for Prosthetic Feet: Applications for Military Readiness” (W81XWH-18-JWMRP).

**Publications in Refereed Journals (BADER-related only):**

Koehler-Nicholas, S.R., Nickel, E.A., Barrons, K., Blaharski, K.E., Schnall, B.L., Hendershot, B.D., Hansen, A.H., 2018. Mechanical Characterization of Prosthetic Feet for Weighted Walking. PLOS One 13, e0202884.

Nickel, E., Voss, G., Morin, S., Koehler-McNicholas, S., Hendershot, B.D., Schnall, B.L., Barrons, K., Mion, S., Hansen, A.H. Impact Testing of Prosthetic Feet for High Activity Prosthesis Users. Prosthetics and Orthotics International, Accepted.

**Presentations:**

Golyski, P.R., Schnall, B.L., Hendershot, B.D. Biomechanical Implications of Prosthetic Foot Stiffness For Loaded Walking. Poster presentation at Walter Reed National Military Medical Center 9<sup>th</sup> Annual National Capital Region Research Competition

Golyski, P.R., Schnall, B.L., Hansen, A.H., Koehler-McNicholas, S.R., Dearth, C.L., Hendershot, B.D. Biomechanical Outcomes of Prosthetic Foot Stiffness During Weighted Walking. Poster presentation at 41<sup>st</sup> Annual Meeting of the American Society of Biomechanics

Eric Nickel, Steve Morin, Gregory Voss, Sara Koehler-McNicholas, and Andrew Hansen. Impact Testing of Prosthetic Feet for High Activity Prosthesis Users. Poster presentation at Military Health System Research Symposium.

Golyski, P.R., Schnall, B.L., Hansen, A.H., Koehler-McNicholas, S.R., Dearth, C.L., Hendershot, B.D. Biomechanical Implications of Prosthetic Foot Stiffness for Walking with Added Load. Poster presentation at Military Health System Research Symposium.

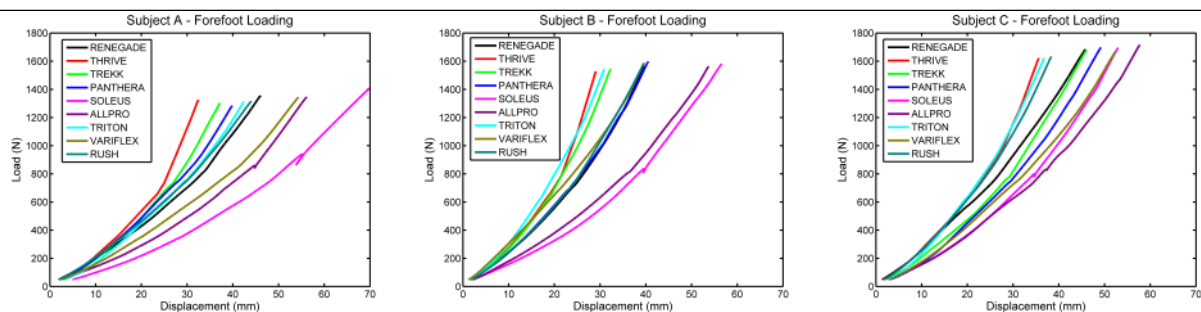
Eric Nickel, Steve Morin, Gregory Voss, Sara Koehler-McNicholas, and Andrew Hansen. Impact test for Prosthetic Feet. Podium presentation at 2017 O&P World Congress.

Dellamano, C.A., Ray, S.F., Schnall, B.L., Hendershot, B.D., Koehler-McNicholas, S.R., Hansen, A.H., 2018. Energy Return in Prosthetic Feet for High Activity Users during Weighted Walking and Unweighted Walking. In American Society of Biomechanics. Rochester, Minnesota.

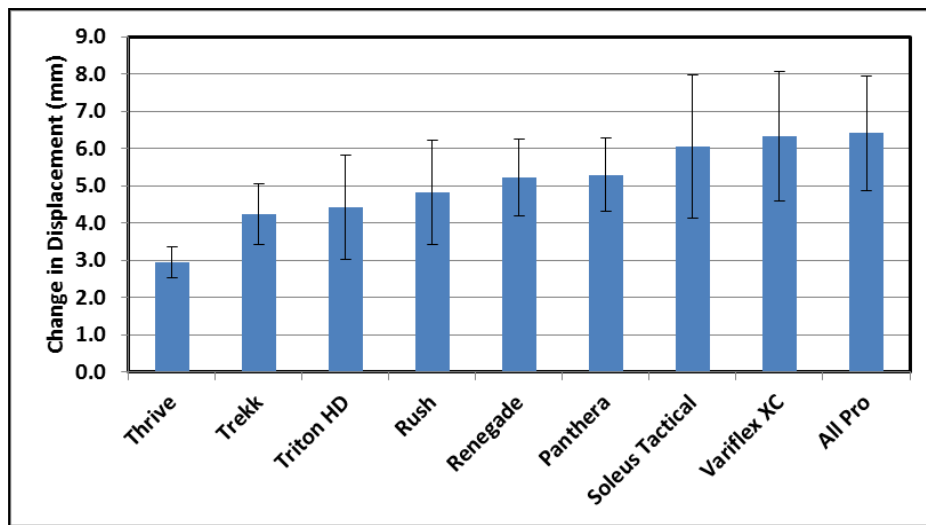
**Preliminary results:**

**We have completed Major Task 1** - Major Task 1 (Mechanical stiffness characterization of prosthetic feet) was accomplished at Excelen Biomechanics Laboratory in Minneapolis, Minnesota; with data analysis completed at the Minneapolis VA. The images below show the testing set-up for forefoot loading

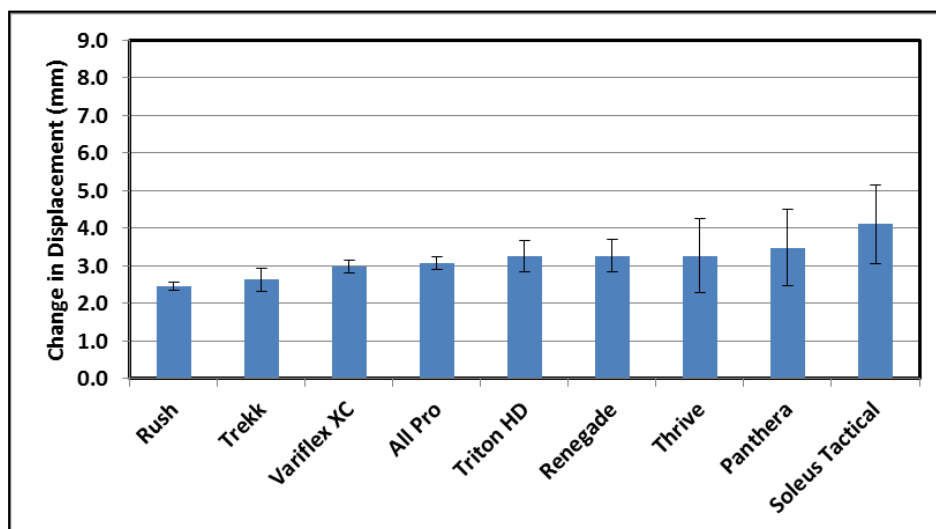
within an MTS load frame. All 27 prosthetic feet were tested within military boots. Forefoot sections of prosthetic feet were tested at a 20 degree angle and heels were tested at a 15 degree angle to mimic the ISO 10328 testing standard. As expected, we found a high variance in forefoot stiffness properties.



In addition, we have determined the change in displacement associated with adding 49lbs of added weight:



Change in displacement due to 49lbs of added load to the forefoot (loading angle = 20 degrees)

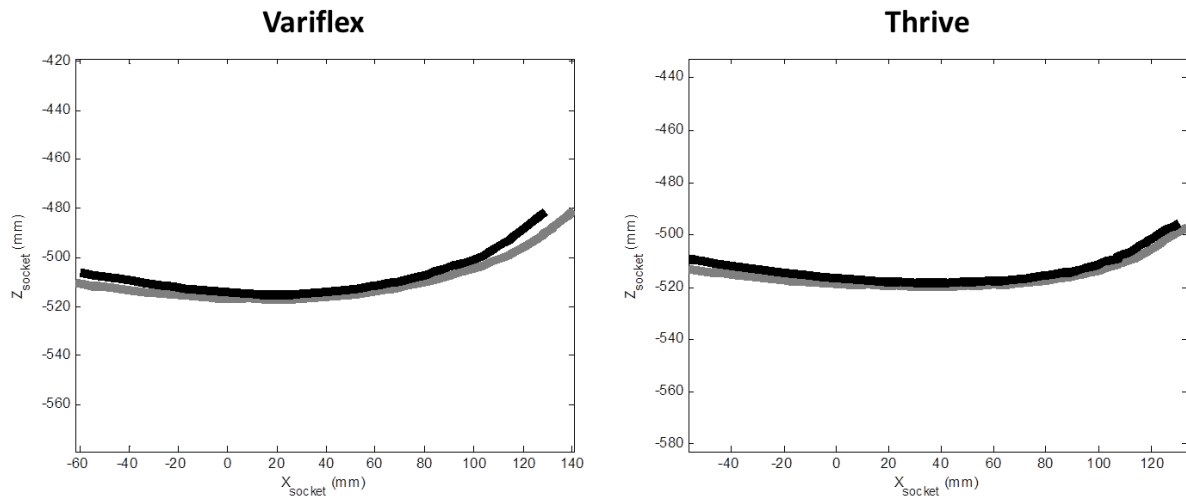


Change in displacement due to 49lbs of added load to the heel (loading angle = 15 degrees)

The results suggest that there are larger changes in forefoot properties between feet compared with heel properties. As expected, the Thrive prosthetic foot yields the lowest additional forefoot displacement when loaded above body weight. All Pro, Variflex, and Soleus Tactical have the largest additional displacements on the forefoot when loading above body weight.

**We have completed Major Task 2** - We have completed subtask 2.1 – Rollover shape measurements of 3 Veterans with unilateral transtibial amputations, each using 9 different types of feet, while loaded and unloaded. The data have also been processed

and fitted with circular arc models. Milestone 2 (Roll-over shape data collected for 27 prosthetic feet for loaded and unloaded walking) has been completed. Two examples are shown below:

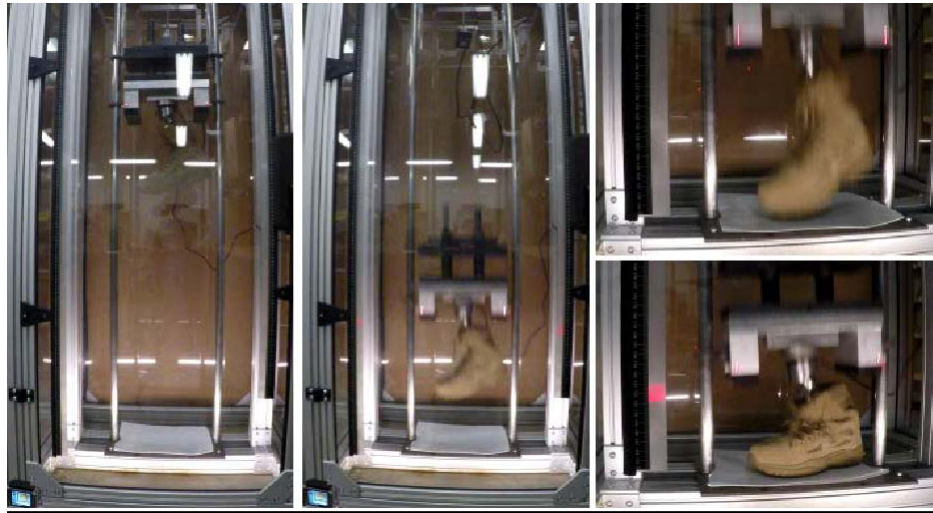


There is a trend for a reduction in radius of the roll-over shapes due to added weight carriage; however, the amount of change in radius does not seem to correlate with changes in displacement due to the added weight. This suggests that the small changes in mechanical properties are either not important or that the user is adapting to differences in mechanical properties to maintain similar roll-over shape radii between foot conditions. The larger study in Aim 2 should help to further our understanding.

Based on the results of the mechanical testing, we are recommending use of the Thrive as the “non- linear” prosthetic foot in Aim 2. We are also recommending the use of either the All Pro, Variflex, or Soleus Tactical as the more linear foot in Aim 2. Discussions within our groups have swayed toward using only Major Tasks 1 and 2 results to determine the prosthetic feet to use in the study. The reason for this approach is that the Aim 2 study at Walter Reed will inform our understanding of prosthetic foot mechanical properties on function of the user. Durability issues that may arise with current designs will influence prosthetic choices later and may lead to design revisions, but these issues should not interfere with our study aimed at gaining an understanding between mechanical and functional properties of feet. We believe that finding the best functioning foot for return-to-duty is important and that any durability issues that may arise with a best-functioning foot may be addressable through future design revisions.

**Major Task 3:** The drop tester for assessing impact durability characterization of prosthetic feet has been constructed. Validation results demonstrate the device effectively replicates free fall – Standard deviation of drop height measurement was

0.06mm within 1 rater, and 1.4mm between 3 raters.



Prostheses failed at a drop heights ranging from 0.4m to 1.0 m. At the lowest drop height, the difference between potential energy at the drop and impact energy calculated using velocity at impact was 4.7%. Additional results using the impact load cell are forthcoming.

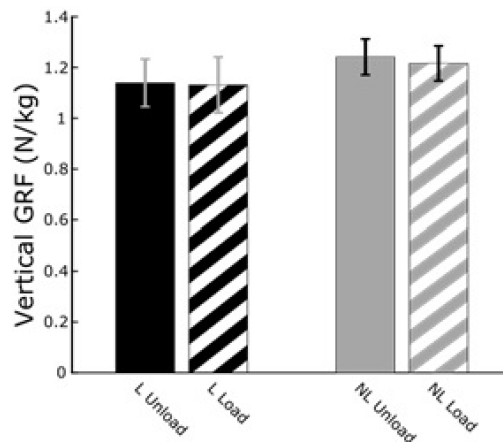
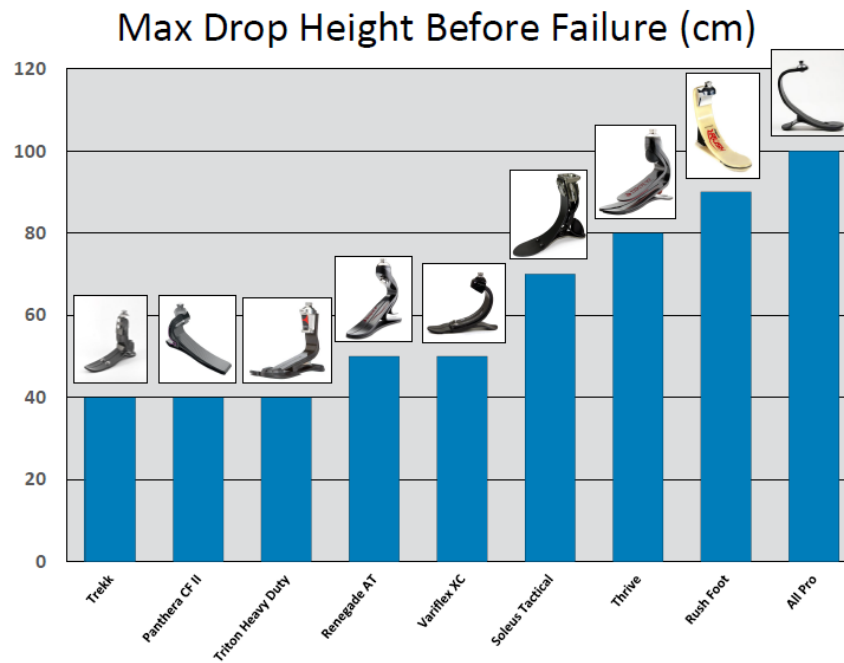


Figure 1. Contralateral limb vGRF (a) was greater with the nonlinear foot ( $p=0.006$ ) and at faster speeds ( $p<0.001$ ), and had no effect of load. Data shown for 1.34 m/s condition only.

**Major Task 4:** Full biomechanical and functional data from Specific Aim 2 are processed/analyzed for all 14 participants. In contrast to our hypotheses, results indicate larger first peak vertical ground reaction forces on the intact limb with the foot with non-linear (Thrive) vs. linear (Soleus Tactical) stiffness, while first peak prosthetic limb loads did not differ by foot. However, the mechanical characterization of the two prosthetic feet accomplished in Major Task 1 may explain this observation, since the non-linear foot

(vs. linear foot) exhibited larger stiffness values both below and above body weight. Such larger stiffnesses can translate to decreased energy storage and return over stance and decreased push-off on the prosthetic foot, which has been associated with larger intact limb loads. An analysis of prosthetic foot power further substantiates this revised hypothesis. Intact limb vertical ground reaction forces and prosthetic foot powers from the 14 fully processed study participants are shown below:



## **Key Research Accomplishments Per Project Year**

## **BADER Consortium**

**W81-XWH-11-2-0222**

### **Key Research Accomplishments per project year**

#### **Key Accomplishments in the seventh year of performance (September 30 2017 – September 29 2018):**

- The BADER consortium publication count reached 158 published abstracts/presentations and 42 published manuscripts. Additionally, one (1) manuscript is in review, two (2) have been submitted and six (4) are in preparation.
- Continue to engage with and monitor three BADER-funded protocols. Updated quad charts for all active BADER funded studies are included in Appendix C.
- During this period of performance, grant applications related to BADER funding were submitted and awarded. To date, the submissions have resulted in 17 awards, 14 of which total \$15.5 million in external funding. The BADER Consortium has nearly eight million dollars in research proposals among various agencies pending review and awarding.
- One of the submitted applications proposes to continue the BADER Consortium. The application was submitted to the Joint Warfighter Medical Research Program Funding Opportunity Number: W81XWH-18-JWMP. If awarded, BADER Consortium will secure up to \$6,000,000 to continue implementing its powerful Research Competitiveness Enhancement Model to exclusively support EACE/RSD efforts to further establish impactful research partnerships, an efficient technology translational pipeline, and EACE/RSD investigator goals of obtaining research independence by obtaining PI status on externally-funded grants.
- Integral to the above mentioned JWMP application is a renewed, highly interactive and productive partnership with the Extremity Trauma and Amputation Center of Excellence (EACE) in particular, its Research and Surveillance Division (RSD).
- One immediate partnership activity proposed by the Director of the EACE is the adoption of the RSD steering committee as a new structure for the BADER Consortium and consisting of a central leadership team comprising EACE/RSD lead scientists and BADER leaders with appropriate Administrative Core support. An award from JWMP will propel this steering committee into the role of oversight and policy hub for joint EACE/RSD and BADER continuation activities.

#### **Key Accomplishments in the sixth year of performance (September 30 2016 – September 29 2017):**

- The BADER consortium publication count reached 84 published abstracts/presentations and 21 published manuscripts this year. Additionally, 1 manuscript is in revision and 4 are in process.
- Three CRC staff (Wingate, Hiebert, Hulcher) presented abstracts at the MHSRS conference August 2017.
- Updated quad charts for all BADER funded studies are included in Appendix D.
- Dr. Jason Wilken resigned from the CFI and with the assistance of the BADER Consortium, completed his transition to the University of Iowa. The BADER Consortium will continue to work with all affected

project PIs to implement desired and required project administrative adjustments to affected BADER funded projects.

- In spite of staff cutbacks, the BADER Consortium provided support for 16 Military Treatment Facility (MTF) non-BADER funded research projects and 7 related activities (see Appendix C). Other contributions of the BADER Consortium towards MTF research capabilities included drafting protocols for both CAREN and gait labs, creating an Access database for tracking projects and products, preparing reports for the Extremity Amputee Center of Excellence (EACE), assisting with literature searches, conducting of training sessions on equipment and performance measures.
- The BADER Consortium led efforts to establish, edit and publish the Military Medicine supplement, Volume 181, November/December 2016, pp. 1-80 titled "Raising the Bar: Extremity Trauma Care".
- The BADER Consortium currently coordinates and manages Institutional Review Board (IRB) documentation activities for 23 protocols (15 active; across 9 investigators).
- The BADER Consortium established a method for holding virtual consensus meetings. As a result, 47 individuals from across the country – including MTF sites - were able to simultaneously participate in a major BADER funded Measurement Consensus Meeting.
- The Outcomes Measurement Library for BADER-relevant outcomes measures has been established. The library has been updated with recent publications. This information has been provided to the BADER CTDB team to see how this work could be integrated with the Clinical Trials Database and used as a central research and patient care tool. Permissions have been obtained for 22 of the measures to be included thus far.
- During this period of performance, several grants related to BADER funding were submitted and awarded. The BADER Consortium has nearly seven million dollars in research proposals among various agencies pending review and awarding.
- Dr. Tulskey's BAA "Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments" has been awarded in the amount of \$4 million
- This year, the BADER Consortium supported the submission of 17 grant applications across three of the MTF sites (NMCP, WRNMMC, and NMCSO). Not having oversight authority, the BADER Consortium receives little submission detail and follow-up information on these applications. In contrast, non-DoD investigators appear to provide substantial details.

#### **Key Accomplishments in the fifth year of performance (September 30 2015 – September 29 2016):**

- Spearheaded two AMSUS Publications for Military Medicine
- Established relationship with Thought Leadership Innovation Foundation
- Supported the submission of two BAA proposals
- Established agreement to use NIH BRICS system – a more robust protocol and data management system
- MORE project fully modeled in CTDB
- BADER Consortium highlighted in Military Medicine Supplement
- Clinical Research Core staff coordinated 20 protocols at Center for the Intrepid
- Clinical Research Core staff supported 38 research projects and 11 related activities at the MTFs

- Clinical Research Core staff submitted four abstracts to the 2016 MHSRS call for abstracts
- Supported continuing education for CRC staff – two in the Masters in Public Administration Program and one in the MBA program.
- Biomechanics Core published a new gait symmetry index in the Journal of Applied Biomechanics based on work done with the BADER Consortium
- Outcomes Measurement Core completed systematic review of 32 measures of physical functioning
- Outcomes Measurement Core established a measurement library for BADER relevant outcomes measures
- Outcomes Measurement Core delivered training materials related to PROMIS
- The BADER Consortium began showing signs indicating significant maturation and advancement of research efforts at our partner MTF and VA sites.
- This quarter, greater than \$7.1M in grant proposals were submitted.
- Research support provided by BADER Clinical Research Core staff – located at each MTF site – expanded to include research support for 37 non-BADER-funded studies.
- The BADER Consortium received approval from HRPO to start the eighth BADER-funded project (Ruck-Foot at WRNMMC).
- With only one completed BADER-funded project, BADER has produced five published manuscripts and 44 published abstracts.
- The BADER Consortium has been asked to facilitate engaging MTF sites in industry sponsored and FDA approved clinical trials.
- NMCP team has fully established a novel research paradigm for studying the occurrence and rehabilitation of musculoskeletal injuries under an aircraft carrier deployment model.
- The biofeedback paradigm tested under the return-to-run BADER-funded study has been transitioned to use in the clinic at WRNMMC.
- The gait stability research initiative has officially launched. It is based on findings from the Step2Step BADER-funded project. Results from the Step2Step project indicate the “Rehab Frogger” paradigm is an effective rehabilitation training intervention to enhance the ability of patients to optimize their stepping control strategies to maximize both stability and maneuverability. The gait stability research initiative has substantially advanced - receiving an R01 award this quarter from the NIH to further study the impact of the “Rehab Frogger” paradigm.
- In addition, the gait stability team has recently launched a new initiative to develop and investigate the effectiveness of a low-cost and clinically applicable (CAREN-light) version of the CAREN system located at several of the MTF sites. The initiative involves MTFs, industry and academia. The CAREN-light system will provide MTF and VA clinics access to the “Rehab Frogger” paradigm.
- The RAPIDFab initiative began as a 3D printing AFO study that was originally proposed by the BADER Consortium - but not allowed to proceed by the Government Steering Committee.
- The RAPIDFab initiative has generated over \$3.5M in subsequent grant awards, six publications and thirteen published abstracts. The RAPIDFab team, led by Dr. Wilken at the CFI, is planning its next major grant submission.
- The Outcomes Core is preparing to execute an outcomes consensus conference expected to attract a global sample of rehabilitation outcomes experts.

- In addition, the Outcomes Core has developed and submitted a BAA proposal for substantially advancing the tool box of identified outcomes measures as agency wide research and patient care tools.
- The BADER supplement to Military Medicine – International Journal of AMSUS was published in February 2016. The supplement reports on activities related to the first, “WARfighters Receiving Innovative Orthopedic Rehabilitation (WARRIOR) Symposium: Research and Treatment of Patients with Extremity Trauma and Amputation,” which was sponsored by the BADER Consortium and held in San Antonio, Texas on 30 November to 4 December in conjunction with the 2015 AMSUS Meeting.
  - [http://publications.amsus.org/pb-assets/Supplements/181\\_2\\_Supplement.pdf](http://publications.amsus.org/pb-assets/Supplements/181_2_Supplement.pdf)
- With the news that the proposal to continue BADER efforts was not recommended for funding, BADER transitioned to the new BADER committee structure that positions Drs. Wilken and Kaufman as co-chairs of the BADER Consortium Committee. The committee is focused on completion of current projects and sustainment efforts centered on the further establishment of externally funded research initiatives and the termination or transition of BADER components to EACE or MTF management.
- BADER has begun eliminating staff and terminating support for core resources in alignment with its sustainment and transition plan.
- Successful AMSUS meeting and creation of strong partnership.
- Discussions with EACE to strengthen partnership.
- Worked with MTF staff to develop a universal research support and capacity building model.
- Identified several large scale research initiatives.
- Worked with MTF representatives to develop an adapted Statement of Work and No Cost Extension budget.
- Established enhanced partnership with NIH for the use of the BRICS system.

#### **Key Accomplishments in the fourth year of performance (September 30 2014 – September 29 2015):**

- Eight identified BADER funded studies are active and collecting subject data.
- BADER Scientific Technical Cores supported six MTF proposals.
- BADER Clinical Research Core staff are supporting 64 projects at the MTFs. This is a combination of BADER-funded and non-BADER funded projects.
- The CTDB now has six active protocols for Consortium funded projects and study data for seven subjects has been entered.
- The Collaboration Agreement between the UD and the NIH for use of the CTDB was renewed for an additional two years.
- Training materials related to the CTDB were finalized and uploaded to a secure site for staff use.
- CRC staff member Dr. Steve Jamison submitted his first white paper to the Fall 2014 CDMRP call for proposals and was invited to submit a full proposal.
- MTF representatives have embraced the concept of creating a large-scale, nationwide Human Subject Recruitment Campaign.
- Dr. David Tulskey relocated to the University of Delaware to lead Outcomes Measurement initiatives.

- Policies are being developed at the University of Delaware to allow non-University personnel to be PIs on research proposals submitted through UD.
- Four Clinical Research Core staff had abstracts accepted for the 2015 MHSRS Conference.
- Eight abstracts were submitted to MHSRS.
- Received Subaward with NYU on the NMCP project **“A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries.”**
- Fully executed subcontract with the first BADER-METRC Collaboration **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees.”**

#### **Key Accomplishments in the third year of performance (September 30 2013 – September 29 2014):**

- Approval of two additional BADER funded research projects bringing the total to 8.
  - Project 2014.1 – Maximizing Outpatient Rehabilitation Effectiveness (MORE)
  - Project 2014.2 – Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower Limb Amputation
- Successfully filled all vacant BADER funded staff positions at the MTFs.
- Provided research support to over 24 non-BADER funded on-site protocols at the MTFs.
- Began exclusive partnership with Leidos on Homeland Defense TATs IDIQ mechanism.
- Established a collaborative agreement with NIH for the use of the CTDB and modeled two protocols in the system.
- Presented the BADER Consortium to the Defense Health Board, Health Care Delivery Subcommittee on May 21, 2014.
- Enrolled first MTF staff member into Biomechanics and Movement Science PhD program at the University of Delaware.
- Established a policy at the University of Delaware for external PIs.
- Developed a process for receiving donations for research support.
- Multiple (n=6) BADER-supported proposals recommended for funding.
- First BADER-METRC Collaboration proposal recommended for funding.
- Omnibus CRADA dramatically streamlining project initiation.
- IRB – HRPO process is improved.
- CTDB being implemented on a large scale across Consortium.
- WRNMMC received approval to recruit non-military, civilian human subjects.
- Initiating nationwide Human Subjects Recruitment Initiative.
- Realized an uptick in additional grant submissions and funded projects across the Consortium.
- Planning underway for Orthopaedic Rehabilitation Research Annual Meeting.
- BADER Operations model finalized.

## **Key Accomplishments in the second year of performance (September 30 2012 – September 29 2013):**

- Approval of three additional BADER funded research projects bringing the total to 5:
  - Project 2012.2 – Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback.
  - Project 2012.1 – Improving Step-To-Step Control of Walking in Traumatic Amputees.
  - Project 2013.1 – Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?
  - Project 2013.2 - Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.
  - Project 2013.3 - Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.
- Recruited all eight BADER funded positions at the MTFs.
- Provided research support to nine on-site MTF research projects.
- IT and videoconference infrastructures.
- Continue to increase the ranks of BADER Consortium Affiliates (n=96).
- Support NMCS D with use of UD Power Segment technique.
- Streamlined the IRB approval process by establishing blanket Institutional Award Agreement (IAA).
- In concert with the MTFs, began development of a central research subject repository.
- Held the first BADER Consortium annual meeting.
- Providing valuable research support through Consortium funded on-site employees.
- On-boarded multiple agencies to the omnibus CRADA to reduce administrative hurdles and allow rapid execution of research studies.
- Established a research related travel support policy and supported travel expenses for collaborators to visit MTF sites and two MTF personnel to present at the American Society of Biomechanics (ASB) scientific meeting.
- Supporting multiple proposals for external funding.
- Strengthen research collaborations and partnerships between MTFs, VA and research focused institutions.
- The live instance of the NIH supplied Protocol and Data Management System (PDMS) is up and running on BADER servers.
- Development of table and announcement for alternative project funding models.
- Strategizing with NIH officials.
- Outreach and meetings with VA.
- BADER Consortium Web-site development continues:
  - Secure log-in to the website completed
  - Core services request form completed
  - Additional enhancements being explored

**Key Accomplishments in the first year of performance (September 30 2011 – September 29 2012):**

- Approval and establishment of two clinical research projects.
- HRPO clearance and start of first project (Dingwell).
- Initiated the development of first IRB of record outside the MTFs (Davis).
- Initiated the development of partnership with Nike, USA (Davis).
- Development and implementation of an Omnibus Cooperative Research and Development Agreement (CRADA).
- Established a consortium-wide protocol and data management system.
- Partnered with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE).
- Worked with the EACE to develop research focus (gap) areas for the BADER Consortium call for proposals.
- Established a complete process for the call, submission, review and selection of Consortium funded projects.
- Published the BADER Consortium call for clinical research proposals.
- Established the BADER Consortium web site and standard operating procedures (SOPs).
- Initiated the hiring of eight research support staff to be placed onsite at MTFs.
- Open communication with all MTFs and partners through bi-weekly teleconferences.
- Established partnerships with the VA and NIH.

**Reportable Outcomes**  
**Through Year 7**

## ***Reportable Outcomes to date***

### ***Research Projects:***

#### **BADER Funded Projects:**

Dingwell, J., and Wilken, J. **“Improving Step-To-Step Control of Walking in Traumatic Amputees”** \$679,300. Sites: University of Texas Austin, Brooke Army Medical Center/Center for the Intrepid.

Davis, I., and Pruziner, A. **“Returning to High-Level Performance: Walk to Run Training with Realtime Kinetic Feedback”** \$708,524. Sites: Spaulding Rehabilitation Hospital, Walter Reed National Military Medical Center.

Grabowski, A., Kram, R., Stephenson, R., Litavish, M. **“Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?”** \$882,827. Sites: Eastern Colorado Healthcare System – Department of Veterans Affairs, Jewell Regional Amputation Clinic.

Pruziner, A., Webster, J., Tulskey, D. **“Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators.”** \$1,529,718. Sites: Walter Reed National Military Medical Center, Hunter Holmes McGuire VA Medical Center.

Tulskey, D., Wilken, J., Wyatt, M., Bushnik, T., Resnik, L., Latlief, G., Kalpakjian, C., Kisala, P. **“Development of an Assessment Toolbox to Measure Community Reintegration, Functional Outcomes and Quality of Life After Major Extremity Trauma.”** \$2,059,000. Sites: New York University, University of Michigan, Walter Reed National Military Medical Center, Brooke Army Medical Center/Center for the Intrepid, Naval Medical Center San Diego, NYU Langone Medical Center, Providence VA Medical Center, James A. Haley Veterans Hospital, Tampa FL.

Wilken, J., Tulskey, D., Shaffer, S., Houck, K., Hill, O. **“Maximizing Outpatient Rehabilitation Effectiveness (MORE)”**. \$1,487,036. Sites: Joint Base San Antonio, TX; Ft. Hood, Killeen TX; University of Delaware.

Schnall, B., Hansen, A., Hendershot, B., Bechtold, J. **“Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation.”** \$398,735. Sites: Walter Reed National Military Medical Center; University of Minnesota; Minneapolis VA.

#### **BADER Scientific Technical Core Supported projects:**

Tulskey, D., Wyatt, M., **“A Qualitative Study of Patient Reported Outcomes Measures in Individuals with Major Limb Trauma.”** Sites: University of Michigan, Naval Medical Center San Diego, Brooke Army Medical Center/Center for the Intrepid.

### **Externally Funded Projects Supporting BADER Activities or Supported by BADER:**

Arch, E., "Objective Clinical Prescription of Passive-Dynamic Ankle-foot Orthoses to Optimize Patient Outcomes" \$500,000

Deluzio, K., Selbie, W., "Statistical Models for Establishing a Control Data set for Biomechanical Gait Analysis" Natural Sciences and Engineering Research Council of Canada \$25,000

Gillespie, J., et al. "Rapid Prototyping of Advanced Passive Dynamic Ankle-Foot Orthoses Designs for Wounded Warriors." Sites: University of Delaware. Funded by: DARPA \$3,000,000

Grabowski, A., CDMRP DHA-17-CR11-MWHRA (Wyatt); Department of Defense Clinical Research Intramural; 01/01/2018 - 12/31/2021; Initiative Military Women's Health Research Award; Optimizing Orthotic and Prosthetic Components for Military Women with Limb Salvage or Amputation \$750,000

Kaufman, K. "Comparison of 3-D Gait Analysis Data Across Department of Defense Sites." Funded by: Center Rehabilitation Sciences Research (CRSR). Support by Biomechanics Scientific Technical Core.

May, 2016 – May, 2021 Research Project Grant (R01): "Improving Lateral Stepping Control to Reduce Falls in the Elderly", National Institutes of Health (NIA), 1-R01-AG049735-01A1, (PI: J.B. Dingwell) \$1,937,057

Morshed, S., Kaufman, K. "The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans- tibial Amputees" \$137,044

Tulsky, David; BAA proposal titled "Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury: Development of Patient Reported Outcomes Assessment Instruments." awarded Aug 2017 \$4.1M

Whittlesey, S., Selbie, W.S. "Development of a Low Cost, Real-time Biofeedback Gait Retraining System" Funded by: NIH, Phase I – SBIR \$149,995

Ziemke, G, Campello, M.; Hiebert, R., Faulkner, DF. Backs to work study –BUMED \$500,000

Ziemke, G., Campello, M., "A pilot study to test the efficacy of psychologically based physical therapy training for treating deployed US Sailors and Marines with musculoskeletal injuries." Proposal to CDMRP/PRORP, July 2013. (3 years) \$279,858

Ziemke, G., Campello, M., Hiebert, R., Faulkner, DF ACDA/ACDF study – BUMED \$350,000

Ziemke, G., Campello, M., Hiebert, R., Faulkner, DF Attrition study – BUMED \$120,000

Ziemke, G., Campello, M., Hiebert, R., Faulkner, DF Carrier study – CRM RP \$1,200,000

### **Pending Proposals for External Funding Supported by BADER:**

Grabowski, A., CDMRP PRORP W81XWH-17-PRORP-ATA (Grabowski); Department of Defense; Total award amount: \$749,585; Optimizing prosthetic prescription for running in Service members with transfemoral amputations.

Grabowski, A., Effects of leg prosthetic stiffness on uphill and downhill running performance. 2017-21; \$1,317,096 VA Merit Review.

### **Manuscripts, abstracts, presentations**

### **BADER Staff, Funded Projects and Cores**

#### ***Publications (N=28):***

Beck, O., and Grabowski, A. (2018). Case studies in physiology: The biomechanics of the fastest sprinter with a unilateral amputation. *Journal of Applied Physiology*; 124: 641–645.

Hsieh, K.L., Sheehan, R.C., Wilken, J.M., and Dingwell, J.B. (2018). Healthy individuals are more maneuverable when walking slower while navigating a virtual obstacle course. *Gait & Posture*, 61: 466-472. (Published on line 02/14/18: <https://doi.org/10.1016/j.gaitpost.2018.02.015>).

Koehler-Nicholas, S.R., Nickel, E.A., Barrons, K., Blaharski, K.E., Schnall, B.L., Hendershot, B.D., Hansen, A.H., 2018. Mechanical Characterization of Prosthetic Feet for Weighted Walking. *PLOS One* 13, e0202884.

Arch ES and Stanhope SJ. (2017). Orthotic Device Research. In *Full Stride: Advancing the State of the Art in Lower Extremity Gait Systems*. Springer, New York, NY.

Beck, O., Taboga, P., and Grabowski, A. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations? *J.R. Soc. Interface* 14:20170230.

Beck, O.N., Taboga, P., and Grabowski, A.M. Prosthetic model, but not stiffness or height, affects the metabolic cost of running for athletes with unilateral transtibial amputations. *J Appl Physiol* 123: 38-48, 2017.

Beck, O.N., Taboga, P., and Grabowski, A.M. Reduced prosthetic stiffness lowers the metabolic cost of running for athletes with bilateral transtibial amputations. *J Appl Physiol* 122: 976-984, 2017.

Ebrahimi, A., Collins, J., Kepple, T., Takahashi, K., Higginson, J., and Stanhope, S. (2017). A mathematical analysis to address the 6 degree-of-freedom segmental power imbalance. *Journal of Biomechanics*, 66. p186-193. [doi.org/10.1016/j.jbiomech.2017.10.034](https://doi.org/10.1016/j.jbiomech.2017.10.034)

Ebrahimi, A., Goldberg, S., Wilken, J., and Stanhope, S. (2017). Constituent lower extremity work (CLEW) approach: A novel tool to visualize joint and segment work. *Jul*;56:49-53. doi: 10.1016/j.gaitpost.2017.04.024.

Mazzone, B, Yoder, A, Zalewski, B, Wyatt, M, Sheu, R. (2017). Comprehensive Treatment Strategy for Chronic Low Back Pain in a Patient with Bilateral Transfemoral Amputations Integrating Changes in Prosthetic Socket Design. *Journal of Prosthetics and Orthotics*, 00(00).

Resnik, L., Borgia, M. and Silver, B. (2017). Measuring community integration in persons with limb trauma and amputation: A Systematic Review. *Archives of Physical Medicine and Rehabilitation*; <https://doi.org/10.1016/j.apmr.2016.08.463>.

Resnik, L., Borgia, M., Silver, B., and Cancio, J. (2017). Systematic review of measures of impairment and activity limitation for persons with upper limb trauma and amputation. *Archives of Physical Medicine and Rehabilitation*. PMID: 28209508. DOI: 10.1016/j.apmr.2017.01.015.

- Salinas, M.M., Wilken, J.M., and Dingwell, J.B. (2017). How humans use visual optic flow to control step variability in treadmill walking. *Gait & Posture*, 57: 15-20. (Published on line 05/08/17: <https://doi.org/10.1016/j.gaitpost.2017.05.002>).
- Beck, O., Taboga, P., and Grabowski, A. (2016). Characterizing the mechanical properties of running-specific lower-limb prostheses. *Plos One*, December 14, 2016 <http://dx.doi.org/10.1371/journal.pone.0168298>.
- Bothum, K., Bogan-Brown, K., and Cecere, F. (2016). Proceedings of the AMSUS Summit for Federal and Civilian Orthopedic Rehabilitation Programs Military Medicine, 2016 Feb;181(S2):3-10.
- Cecere, F., and Oldham, B. (2016). Raising the bar in extremity trauma care: A story of collaboration and innovation. Editorial. *Military Medicine* 2016 Nov;181,11/12:1-2.
- Cecere, F., Stanhope, S., Kaufman, K., Oldham, B., Shero, J., and Mundy, J., guest editors, Raising the Bar: Extremity Trauma Care. *Military Medicine* supplement 2016 Nov;181(S4):1-80.
- Dingwell, J.B., and Cusumano, J.P. (2016). Error correction and the structure of inter-trial fluctuations in a redundant movement task. *PLoS Computational Biology*, 12(9): e1005118. (Published on line 09/19/16: <http://dx.doi.org/10.1371/journal.pcbi.1005118>).
- Farrokhi, S, Mazzone, B, Yoder, A, Grant, K, Wyatt, M. (2016). A Narrative Review of the Prevalence and Risk Factors Associated with Development of Knee Osteoarthritis After Traumatic Unilateral Lower Limb Amputation. *Military Medicine*. Manuscript, 181, 11/12:38.
- Kaufman, K., Miller, E., Kingsbury, T., Russell Esposito, E., Wolf, E, Wilken, J., & Wyatt, M. Reliability of 3D gait data across multiple laboratories. *Gait posture*, 2016, Sep; 49(375-381).
- Kaufman, K., Stanhope, S., Oldham, B., Cecere, F., guest editors. The New Normal Military Medicine, 2016 Feb;181(S2):1-24.
- Miller, E., Kaufman, K., Kingsbury, T., Wolf, E., Wilken, J., & Wyatt, M. (2016). Mechanical testing for three-dimensional motion analysis reliability. *Gait Posture*, Oct;50:116-119.
- Resnik, L., Borgia, M., Silver, B. (2016). Measuring community integration in persons with limb trauma and amputation: A systematic review. *Archives of Physical Medicine and Rehabilitation*. <http://dx.doi.org/10.1016/j.apmr.2016.08.463> PMID: 27612941.
- Sheehan, R.C., Rylander, J.H., Wilken, J.M., and Dingwell, J.B. (2016). Use of perturbation-based gait training in a virtual environment to address mediolateral instability in an individual with unilateral transfemoral amputation. *Physical Therapy*, 96(12): 1896-1904. (Published on line 06/08/16: <http://dx.doi.org/10.2522/ptj.20150566>).
- Stanhope SJ, Wilken JM, Pruziner AL, Dearth CL, Wyatt M, Ziemke GW, Strickland R, Milbourne SA, Kaufman KR. The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium: Reaching in Partnership for Optimal Orthopaedic Rehabilitation Outcomes. *Military Medicine* 2016 Nov; 181(S4):13-19.
- Dingwell JB, Cusumano JP. Identifying Stride-To-Stride Control Strategies in Human Treadmill Walking *PLoS ONE*, 2015;10(4): e0124879. (Published on line 04/24/15: <http://dx.doi.org/10.1371/journal.pone.0124879>).
- Schrank, E., Stanhope, S., (2011). Dimensional accuracy of ankle-foot orthoses constructed by an automated fit customization and rapid manufacturing framework. *Journal of Rehabilitation Research & Development*; 48(1):31-42. PMID:21328161.
- Takahashi, K., Kepple, T., Stanhope, S. (2011). A unified deformable (UD) segment model for quantifying total power of anatomical and prosthetic below-knee structures during stance in gait. *Journal of Biomechanics* 2012;45:2662-2667. PMID:22939292.

**In Revision (N=1)**

Nickel, E., Voss, G., Morin, S., Koehler-McNicholas, S., Hendershot, B.D., Schnall, B.L., Barrons, K., Mion, S., Hansen, A.H. Impact Testing of Prosthetic Feet for High Activity Prosthesis Users. Prosthetics and Orthotics International.

**Submitted (N=2)**

Dingwell, J.B., and Cusumano, J.P. Humans Use Multi-Objective Control to Regulate Lateral Foot Placement When Walking. Submitted to PLoS Computational Biology.

Sheehan, R.C., Ruble, M.D., Dingwell, J.B., and Wilken, J.M. Individuals with Lower Limb Trauma Prioritize Stability over Maneuverability When Navigating a Virtual Obstacle Course. Submitted to Gait & Posture.

**In Preparation (N=4):**

Dingwell, J., and Cusumano, J. Strategies for controlling lateral stepping movements in human walking. In preparation for submission to PLoS Computational Biology.

Dingwell, J.B., Rylander, J.H., Cusumano, J.P., and Wilken, J.M. Frontal Plane Step-To-Step Control Strategies in Persons With Transtibial Amputation. To submit to Journal of Biomechanics.

Ray, S.F., Golyski, P.R., Schnall, B.L., Koehler-McNicholas, S.R., Hansen, A.H., Dearth, C.L., Hendershot, B.D. Overall Prosthetic Foot Stiffness May Influence Biomechanical Outcomes more than Stiffness Linearity during Weighted Walking.

Sheehan, R.C., Ruble, M.D., Dingwell, J.B., and Wilken, J.M. Individuals with Lower Limb Trauma Prioritize Stability over Maneuverability When Navigating a Virtual Obstacle Course. To be Submitted to Archives of Physical Medicine & Rehabilitation.

**Abstracts/Presentations/Invited Talks (N=140):**

Brennan, T, Campello, M, Hiebert, R, Lis, A, Ziemke, G, Faulkner, D, Lashbaugh, M, Weiser, S. Mechanism of injury for musculoskeletal injuries in active duty service members (ADSM) reporting to physical therapy aboard two United States air craft carriers. Military Health System Research Symposium, Kissimmee, FL August 2018.

Brennan, T, Campello, M, Hiebert, R, Lis, A, Ziemke, G, Faulkner, D, Lashbaugh, M, Weiser, S. Musculoskeletal incidence in deployed navy active duty service members (ADSM) reporting musculoskeletal injuries aboard two United States air craft carriers. Military Health System Research Symposium, Kissimmee, FL August 2018.

Cancio, J, Pruziner, A, Wyatt, M, Slotkin, J, Tyner, C, Boulton, A, Dearth, C, Wilken, J, Tulskey, D. Test-Retest Reliability for Clinically Administered Outcome Measures for Use After Upper or Lower Extremity Trauma. MHSRS, August 22, 2018.

Dellamano, C.A., Ray, S.F., Schnall, B.L., Hendershot, B.D., Koehler-McNicholas, S.R., Hansen, A.H., 2018. Energy Return in Prosthetic Feet for High Activity Users during Weighted Walking and Unweighted Walking. In American Society of Biomechanics. Rochester, Minnesota.

Dingwell, J.B., and Cusumano, J.P. Choose Wisely: How Humans Regulate Lateral Stepping in Walking. Proceedings of the American Society of Biomechanics East Coast Meeting, Reading, PA, April 20-21, 2018.

Grabowski, A. Invited to organize a symposium on the broad topic of "Exoskeletons and Prosthetics". International Society of Biomechanics Annual Meeting 2019. Calgary, BC.

Grabowski, A. Invited to speak (1 of 2 speakers) and highlight CU's research, "Implications of scientific research on fairness and inclusion for Paralympic and Olympic track and field competition in 2020". University of Colorado Boulder Chancellor's Global Ambassador Meeting 2018 Tokyo, Japan.

Grabowski, A. Invited to speak (1 of 3 speakers) for a symposium, "Do prosthetic legs enhance or hinder running performance?" European College of Sport Science Congress 2018. Dublin, Ireland.

Grabowski, A. Invited to speak at a regular meeting, ""Implications of scientific research on fairness and inclusion for Paralympic and Olympic track and field competition in 2020". Boulder Flatiron Rotary Club 2018. Boulder, CO.

Grabowski, A. Invited to speak at the University of Delaware Department of Kinesiology & Applied Physiology Seminar 2018. "The effects of using running prostheses for athletes with transtibial amputations and implications for inclusion in Olympic track & field competition". University of Delaware. Newark, DE.

Grabowski, A. Invited to speak (1 of 2 speakers) for the Hay Award symposium given to Rodger Kram. The biomechanical & performance effects of prostheses on running, sprinting & jumping. American Society of Biomechanics 2018. Rochester, MN

Pruziner AL, Mahon CE, Gladish JR, Hendershot BD. Kinetic and metabolic outcomes for Medicare Functional Classification Level-2 and 3 Individuals Wearing a Powered Ankle-foot Prosthesis. World Congress of Biomechanics. 8-12 July 2018, Dublin, Ireland.

Schnall, B.L.; Ray, S.F., Golyski, P.R.; Koehler-McNicholas, S.R; Hansen, A.H.; Dearth, C.L.; Hendershot, B.D. (2017). Biomechanical Implications of Prosthetic Foot Stiffness For Loaded Walking. Walter Reed National Military Medical Center 10th Annual National Capital Region Research Competition.

Southern, E.K., Beck, O.N., Taboga, P., and Grabowski, A.M. Running-Specific Prosthetic Model Affected Top Sprinting Speed in Athletes with Unilateral Transtibial Amputations. Rocky Mountain American Society of Biomechanics 2018. Estes Park, CO.

Southern, E.K., Beck, O.N., Taboga, P., and Grabowski, A.M. Running-Specific Prosthetic Model Affected Top Sprinting Speed in Athletes with Unilateral Transtibial Amputations. American Society of Biomechanics 2018. Rochester, MN.

Taboga, P. Beck, O.N. and Grabowski, A. International Research Forum on Biomechanics of Running-Specific Prostheses 2018. Tokyo, Japan. Sprint biomechanics of athletes with bilateral transtibial amputations using different prosthetic configurations.

Taboga, P. Beck, O.N. and Grabowski, A. Rocky Mountain American Society of Biomechanics 2018. Estes Park, CO. Running-Specific Prosthetic Model Affected Top Sprinting Speed in Athletes with Unilateral Transtibial Amputations.

Taboga, P., Beck, O., and Grabowski, A. Sprint biomechanics of athletes with bilateral transtibial amputations using different prosthetic configurations. International Research Forum on Biomechanics of Running-Specific Prostheses 2018. Tokyo, Japan.

Tulsky, D, Slotkin, J, Tyner, C, Resnik, L, Wyatt, M, Pruziner, A, Cancio, J, Kalpakjian, C, Bertisch, H, Kisala, P, Dearth, C, Wilken, J. Development of a Toolbox to Assess Functioning, Community Reintegration and Quality of Life after Major Extremity Trauma. MHSRS, August 22, 2018.

Beck, O., and Grabowski, A. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations? Military Health System Research Symposium. Kissimmee, FL.

Beck, O., and Grabowski, A. Is the metabolic cost of running different for athletes with unilateral versus bilateral transtibial amputations? American College of Sports Medicine 2017. Denver, CO.

Beck, O., Taboga, P., and Grabowski, A. How do prosthetic stiffness, height, and running speed affect the biomechanics of athletes with bilateral transtibial amputations? Rocky Mountain American Society of Biomechanics 2017. Estes Park, CO.

Dingwell, J.B. and Cusumano, J.P. Multi-Objective Control of Lateral Foot Placement While Walking. Proceedings of the Annual Meeting of the Society for Neuroscience, Washington, DC, November 11-15, 2017.

Dingwell, J.B., and Cusumano, J.P. Multi-Objective Control of Lateral Stepping While Walking. Proceedings of the 2017 Annual Meeting of the American Society of Biomechanics, Boulder, CO, Aug. 8-11, 2017.

Dingwell, J.B., and Cusumano, J.P. Step-to-Step Regulation of Walking Movements Is Redundant, Multi-Objective, and Adaptable. Proceedings of the Symposium on Advances in Motor Learning and Motor Control, (<http://motor-conference.org/openconf.php> ), Washington, DC, November 10, 2017.

Golyski, P.R., Schnall, B.L., Hansen, A.H., Koehler-McNicholas, S.R., Dearth, C.L., Hendershot, B.D. (2017). Biomechanical Implications of Prosthetic Foot Stiffness for Walking with Added Load. Abstract accepted as poster to Military Health System Research Symposium.

Golyski, P.R., Schnall, B.L., Hansen, A.H., Koehler-McNicholas, S.R., Dearth, C.L., Hendershot, B.D. (2017). Biomechanical Outcomes of Prosthetic Foot Stiffness During Weighted Walking. Abstract accepted as poster to 41st Annual Meeting of the American Society of Biomechanics.

Golyski, P.R., Schnall, B.L., Hendershot, B.D. (2017). Biomechanical Implications of Prosthetic Foot Stiffness For Loaded Walking. Poster submitted to Walter Reed National Military Medical Center 9th Annual National Capital Region Research Competition.

Grabowski, A. The biomechanical and metabolic effects of using of powered and compliant leg prostheses on performance during human locomotion. International Conference on Intelligent Robots and Systems Invited to speak (1 of 8 speakers) for a symposium "On the Energy Economy of Robotic and Biological Systems". Vancouver, British Columbia, Canada.

Grabowski, A. American Orthotic & Prosthetic Association 2017. Invited to speak (1 of 8 speakers) for a symposium, "Power in Prosthetics" Las Vegas, NV.

Grabowski, A. Do leg prostheses provide an advantage or disadvantage for running, sprinting, & jumping? Boulder Valley School District Arapahoe Campus 2017. Boulder, CO.

Grabowski, A. Do leg prostheses provide an advantage or disadvantage to Paralympic athletes? USOC Paralympic Ambulatory Sprints and Jumps Coaches Summit 2017. Colorado Springs, CO.

Grabowski, A. Does the use of a leg prosthesis provide an advantage or disadvantage to Paralympic athletes? CU Athletics Department Sports Governance Center 2017. Boulder, CO.

Grabowski, A. Effects of Leg Prostheses on Running, Sprinting, and Jumping. Human Movement Variability Conference 2017. Omaha, NE.

Grabowski, A. How do leg prostheses effect the running, sprinting & long jump performance of Paralympic athletes? American Academy of Orthotists and Prosthetists Annual Meeting 2017. Chicago, IL.

Grabowski, A. The effects of leg prostheses during walking, running, and sprinting. Department of Veterans Affairs Eastern Colorado Healthcare System Jewell Clinic Amputee Team Meeting 2017. Denver, CO.

Mazzone B, Eskridge S, Shannon K, Hill O, Moore J, Farrokhi S. Early Physical Therapy Utilization Patterns and Incidence of Secondary Musculoskeletal Conditions after Lower Limb Amputation. Accepted for platform presentation at APTA Combined Section Meeting 2017. February 2017.

Mazzone B, Schmitz K, Eskridge S, Shannon K, Hill O, Moore J, Farrokhi S. Physical Therapy Practice Patterns of the Military Amputee Patient. Accepted for platform presentation at APTA Combined Section Meeting 2017. February 2017.

Nickel, E., Morin, S., Voss, G., Koehler-McNicholas, S., and Hansen, A. (2017). Impact Testing of Prosthetic Feet for High Activity Prosthesis Users. Abstract accepted as poster to Military Health System Research Symposium.

Nickel, E., Morin, S., Voss, G., Koehler-McNicholas, S., and Hansen, A. (2017). Impact test for Prosthetic Feet. Podium presentation at 2017 O&P World Congress.

Nickel, E., Morin, S., Voss, G., Koehler-McNicholas, S., and Hansen, A. Impact test for Prosthetic Feet. Abstract accepted as podium presentation to 2017 O&P World Congress.

Sheehan, R.C., Ruble, M.D., Dingwell, J.B., and Wilken, J.M. Individuals With Lower Limb Trauma Prioritize Stability Over Maneuverability When Navigating A Virtual Obstacle Course. Proceedings of the 2017 Annual Meeting of the American Society of Biomechanics, Boulder, CO, Aug. 8-11, 2017.

Takahashi, K., Stanhope, S., and Grabowski, A. Locomotion on springs: from biological limbs to prosthetic devices. International Research Forum on Biomechanics of Running-Specific Prostheses 2017. Tokyo, Japan.

Tulsky, D. Development of the BADER Toolbox for measuring major extremity trauma outcomes in a military service member population. MHSRS, August 28, 2017.

Tyner, C. Psychosocial Challenges Affecting Patients with Major Limb Trauma. Rehabilitation Psychology Conference, February 18, 2017 (Albuquerque, NM).

Beck, O., and Grabowski, A. Characterizing the Stiffness of Running-Specific Prostheses. American Orthotic & Prosthetic Association, Boston, MA, 2016.

Beck, O., Taboga, P., and Grabowski, A. Asymmetric Forces Increase the Metabolic Cost of Running for Individuals with a Unilateral Leg Amputation. American Society of Biomechanics Annual Meeting, OH, 2015.

Beck, O., Taboga, P., and Grabowski, A. Characterizing the Stiffness of Lower-Limb Running- Specific Prostheses. American Society of Biomechanics Annual Meeting, Raleigh, NC, 2016.

Benjamin Darter, PT, PhD; Erik Wolf, PhD; Elizabeth Husson, BS, CCRC. (2016 February). Gait Adaptability in Persons with Traumatic Transtibial Amputation. Platform presentation at the Combined Sections Meeting, American Physical Therapy Association. Anaheim, CA.

Dingell, J.B., Cussumano, J.P., Rylander, J.H. & Wilken, J.M. (2016). Frontal plane stepping control and lateral balance in human walking. Proceedings, 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Dingwell, J., Cusumano, J., Rylander, J., and Wilken, J. How Humans Regulate Lateral Stepping Movements and Balance While Walking. 2016 Biomechanics and Neural Control of Movement Conference, Mt. Sterling, OH, June 12-16, 2016.

Djafar T, Sharp K, Kingsbury T, Collins JD, Wyatt M. The Effect of Digital Filtering Procedures on Total Power Below the Knee during Overground Running. Poster at American Society of Biomechanics. August 2016.

Elizabeth M. Husson BS, CCRC, Brad D. Hendershot, PhD, Amanda F. Wingate, BA, Irene S. Davis PT, PhD, Alison L. Pruziner, PT, DPT. (2016 May). The Effectiveness of Real-time Biofeedback Retraining in Reducing Vertical Impact Peaks During Running in a Servicemember with Unilateral Transtibial Limb Loss. Oral poster session presented at the 8th Annual National Capital Region Research Competition. Bethesda, MD. \*Finalist in the case report category.

Grabowski, A. Biomechanical comparison of the long jump of athletes with and without a below the knee amputation. Cologne, Germany. International Press Conference - Markus Rehm about to jump to Rio 2016. 1 of 3 researchers and the only US researcher invited to contribute.

Grabowski, A. Can leg prostheses augment walking & running performance? Northern Arizona University Biology Department Seminar 2016. [https://twitter.com/cbi\\_nau/status/702989123976495106](https://twitter.com/cbi_nau/status/702989123976495106) Flagstaff, AZ.

Grabowski, A. Do leg prostheses augment walking, running, sprinting or jumping? Keynote at CU Boulder Research Administrators Breakfast 2016. Boulder, CO.

Grabowski, A. Do leg prostheses provide an advantage or disadvantage to Paralympic athletes? CU Athletics Department Sports Governance Center 2016. Boulder, CO.

Grabowski, A. Effects of leg prostheses on walking, running, sprinting, & jumping. University of Colorado Boulder Integrative Physiology Department Colloquium 2016. Boulder, CO.

Grabowski, A. Effects of running-specific leg prostheses on performance. International Research Forum on Biomechanics of Running-Specific Prostheses 2016. Tokyo, Japan. 1 of 3 researchers invited from the US.

Grabowski, A. The effects of using running-specific leg prostheses on the performance of athletes with transtibial amputations. NCAA Track and Field Rules Committee 2017. Indianapolis, IN.

Hendershot, B.D., Bell, E.M., & Wolf, E. Biofeedback-induced modulation of vertical ground reaction force impulse within a virtual reality environment. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Kingsbury T, Marks M, Mazzone B, Wyatt M. Initial Effects of the IDEO on the Gait Quality of Limb Preservation Patients with Different Usage Needs. Poster at American Society of Biomechanics. August 2016.

Kingsbury T, Marks M, Mazzone B, Wyatt M. Initial Effects of the IDEO on the Gait Quality of Limb Preservation Patients with Different Usage Needs. Poster at Military Health System Research Symposium. August 2016.

Kingsbury T, Marks M, Mazzone B, Yoder A, Wyatt M. Initial Effects of the IDEO Brace on the Gait Quality of Limb Preservation Patients with Different Usage Needs. Poster at Gait and Clinical Movement Analysis Society. May 2016.

Mazzone B, DePratti A, Farrokhi S, Wyatt M. Improved High-Level Performance with the IDEO after Return to Run Clinical Pathway. Podium at Military Health System Research Symposium. August 2016.

Mazzone B, Farrokhi S, Eskridge S, Shannon K, Hill O. Timing of lower limb amputation after trauma and its association with manifestation of secondary musculoskeletal conditions. Platform presentation. Military Health System Research Symposium, Kissimmee, FL August 2016.

Mazzone B, Farrokhi S, Eskridge S, Shannon K, Hill O. Timing of Lower Limb Amputation after Trauma and its Association with Secondary Musculoskeletal Conditions. Podium at Military Health System Research Symposium. August 2016.

Mazzone B, Yoder A, Wyatt M. Temporal-Spatial Parameters before and after a Delayed Transtibial Amputation. Poster at Gait and Clinical Movement Analysis Society. May 2016.

Mazzone B, Yoder A, Wyatt M. Temporal-spatial parameters before and after delayed transtibial amputation. Gait and Clinical Movement Analysis Society, Memphis, TN, May 2016.

Quacinella M. Mazzone B, Wyatt M, Kuhn K. Spatiotemporal Gait Improvements after Pilon fracture using the Intrepid Dynamic Skeletal Orthosis. Podium at Society of Military Orthopaedic Surgeons. December 2016.

Salinas, M., and Dingwell, J. Balancing Competing Task Goals During Treadmill Walking. 2016 Gait & Clinical Movement Analysis Society Annual Meeting, Memphis, TN, May 17-20, 2016.

Salinas, M., and Dingwell, J. Goal-Relevant Correction of Conflicting Goals During Treadmill Walking. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, Aug. 2-5, 2016.

Sheehan, R., Rylander, J., Wilken, J., and Dingwell, J. Lower Limb Trauma Alters the Priority of Stability and Maneuverability While Navigating a Virtual Obstacle Course. 2016 Gait & Clinical Movement Analysis Society Annual Meeting, Memphis, TN, May 17-20, 2016.

Sheehan, R., Wilken, J., and Dingwell, J. Perturbation Based Gait Training May Improve the Tradeoff of Stability and Maneuverability in Patients with Lower Limb Injury. XXIIth Congress of the International Society of Electrophysiology and Kinesiology, Chicago, IL, July 5-8, 2016.

Sheu R, Mazzone B, Zalewski B, Wyatt M. Comprehensive Treatment Strategy for Chronic Low Back Pain in a Patient with Bilateral Transfemoral Amputations Integrating Changes in Prosthetic Socket Design. Federal Advanced Amputation Skills Training, Long Beach, CA, July 2016.

Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Gait Analysis, Quality of Life and Overall Outcomes in Patients Who Have Undergone Late Amputation After Failed Limb Preservation. Platform presentation. Academic Research Competition, April 2016.

Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Gait Analysis, Quality of Life and Overall Outcomes in Patients Who have Undergone Limb Amputation after Failed Limb Salvage. Podium at NMCSA Academic Research Competition. January 2016.

Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Quality of Life, Spatiotemporal Gait Parameters and Overall Outcomes in Patients with Elective Delayed Amputation after Failed Limb Preservation. Accepted for podium presentation. Society of Military Orthopaedic Surgeons Annual Meeting (SOMOS) 2016. December 2016.

Spahn K, Mazzone B, Yoder A, Wyatt M, Kuhn K. Spatiotemporal Gait Parameters, Quality of Life and Overall Outcomes in Patients Who Have Undergone Late Amputation After Failed Limb Preservation. Poster presentation. Military Health System Research Symposium, Kissimmee, FL August 2016.

Sturdy, J.T., Sessoms, P.H., Wyatt, M.P., Grabiner, M.D., & Kaufman, K.R. Prevalence of anticipatory gait modifications prior to treadmill-induced simulated trip while walking in a CAREN virtual environment. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Takahashi, K. Z., Sharp, K., Taboga, P., Wyatt, M., and Grabowski, A. Energy storage and return of running specific prostheses. International Research Forum on Biomechanics of Running-Specific Prostheses 2016. Tokyo, Japan.

Tulsky, T. and Cohen, M. Selection of Common Assessment Instruments and Data Elements for Individuals with Major Extremity Trauma and/or Amputation. Military Health System Research Symposium (MHSRS), August 18, 2016 (Kissimmee, FL).

Tulsky, T. BADER Toolbox Overview. EACE, San Antonio, TX, May 17, 2016.

Weiser S, Campello M, Lis A, Ziemke G, Hiebert R, Faulkner, DC, Brennan, T, Iveson B, “Feasibility of Training Physical Therapists to Implement a Psychologically-based Physical Therapy Program for Deployed US Sailors and Marines with Musculoskeletal Injuries”. Poster Session presented at Military Health System Research Symposium, Kissimmee, FL, August 2016.

Yoder A, Mazzone B, Farrokhi S, Wyatt M. Changes in Intersegmental Knee Joint Forces During Walking Before and After Delayed Transtibial Amputation. Poster presentation. Military Health System Research Symposium, Kissimmee, FL August 2016.

Yoder A, Mazzone B, Wyatt M, Farrokhi S. Symmetry of Ground Reaction Forces Before and After Delayed Transtibial Amputation. Poster presentation. American Society of Biomechanics, Raleigh, NC, August 2016.

Beck, O., Taboga, P., and Grabowski, A. Asymmetric Forces Increase the Metabolic Cost of Running for Individuals with a Unilateral Leg Amputation. Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015.

Beck, O., Taboga, P., and Grabowski, A. Lower Prosthetic Stiffness Minimizes the Metabolic Cost of Running for Individuals with Bilateral Leg Amputations. American Society of Biomechanics Annual Meeting, OH, 2015.

Beck, O., Taboga, P., and Grabowski, A. Lower Prosthetic Stiffness Minimizes the Metabolic Cost of Running for Individuals with Bilateral Leg Amputations. Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015.

Dingwell, J., Rylander, J., Cusumano, J., and Wilken, J. Control Models of Lateral Stepping in Human Walking. Proceedings of the 2015 Dynamic Walking Meeting, Columbus, OH, July 20-24, 2015. (Podium Presentation).

Elizabeth M. Husson BS, CCRC, Erik J. Wolf, PhD, Irene S. Davis PT, PhD, Alison L. Pruziner, PT, DPT. (2015 August). A Case Report on the Effect of Real Time Biofeedback Training During Running in a Servicemember with a Unilateral Transtibial Amputation. Poster session presented at the Military Health System Research Symposium. Fort Lauderdale, FL.

Givens, D.L., Freisinger, G.M., Lewis, J., McNally, Jamison, S.T., & Chaudhan, A.M.W. Relationship between thoracic and lumbar spinal curvature during unsupported sitting. American Society of Biomechanics 39th Annual Meeting Columbus, Ohio August 5-8, 2015.

Grabowski, A. Can leg prostheses restore function during running and/or sprinting? Naval Medical Center San Diego 2015. San Diego, CA.

Grabowski, A. The effects of using leg prostheses during walking & running – Can we augment performance? University of Colorado Boulder Integrative Physiology Department Colloquium 2015. Boulder, CO.

Grabowski, A. Wearable active and passive leg prostheses; Can we augment performance in people with an amputation? American Society of Biomechanics Symposium 2015. Columbus, OH.

Husson, E., Wolf, E., Wingate, A., Davis, I., Pruziner, A. A Case Report on the Effect of Real Time Biofeedback Training During Running in a Servicemember with a Unilateral Transtibial Amputation. Accepted for poster presentation at Military Health System Research Symposium, August 2015.

Jamison, S.T. and Davis, I.S. (2015). Validation of determining stance time using accelerometer data. American Society of Biomechanics 39th Annual Meeting. Columbus, Ohio August 5-8, 2015

Kingsbury T, Yoder A, Wyatt M. Reliability of Temporal-Spatial Gait Data Across Multiple Laboratories. Poster at Gait and Clinical Movement Analysis Society. March 2015.

Mahon, C.E., Hendershot, B.D., Wolf, E.J., & Pruziner, A.L. Individual limb transition work during walking in service members with transfemoral amputation. American Society of Biomechanics 39th Annual Meeting Columbus, Ohio August 5-8, 2015.

Pruziner, A., Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. The BADER Consortium Government Steering Committee Meeting. 20 February 2015.

Rice, H., Jamison, S., Pruziner, A., Davis, I. Gait retraining to improve stance time asymmetry reduces knee external adduction moments: a case study of a unilateral transtibial amputee. Accepted as a thematic poster for presentation at the American Society of Biomechanics Annual Meeting, Columbus, Ohio, August 2015.

Rice, H., Jamison, S., Pruziner, A., Davis, I. Gait-retraining to improve stance time asymmetry reduces knee external adduction moments: a case study of an individual with a unilateral transtibial amputation. Accepted for poster presentation at Military Health System Research Symposium, August 2015.

Ruder, M.C., Atimetin, P., Jamison, S.J., Davis, I. The effect of highly cushioned shoes on tibial acceleration in runners. American Society of Biomechanics 39th Annual Meeting Columbus, Ohio August 5-8, 2015.

Rylander, J., Cusumano, J., Wilken, J., and Dingwell, J. Frontal Plane Stepping Control in Persons with Transtibial Amputation. Proceedings of the 39th Annual Meeting of the American Society of Biomechanics, Columbus, OH, Aug. 5-8, 2015.

Salinas, M., Wilken, J., and Dingwell, J. How Humans Use Visual Optic Flow to Regulate Stepping Movements. Proceedings of the 39th Annual Meeting of the American Society of Biomechanics, Columbus, OH, Aug. 5-8, 2015.

Sheehan, R., Rylander, J., Wilken, J., and Dingwell, J. A Virtual Reality Rehabilitation Program Improves Mediolateral Stability in a Patient with Unilateral Transfemoral Amputation. Proceedings of the 2015 American Orthotic & Prosthetic Association National Assembly, San Antonio, TX, Oct. 7-10, 2015.

Sheehan, R., Rylander, J., Wilken, J., and Dingwell, J. Lower Limb Trauma Impairs Lateral Walking Transitions in a Virtual Obstacle Course. Proceedings of the 39th Annual Meeting of the American Society of Biomechanics, Columbus, OH, Aug. 5-8, 2015.

Taboga, P., Beck, O., and Grabowski, A. Optimal Running Prostheses for Sprinters with Bilateral Leg Amputations. Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015.

Taboga, P., Beck, O., and Grabowski, A. Optimal Running Prostheses for Sprinters with Unilateral Leg Amputations. American Society of Biomechanics Annual Meeting, OH, 2015.

Wingate AF, Kisala PA, Pruziner AL, Dearth CL, Tulskey DS. Comparison of Patient-Reported to Performance-Based Functional Outcomes in Individuals with Unilateral Transtibial Amputation. Military Health System Research Symposium, August 2015.

Wingate, A., Kisala, P., Pruziner, A., Dearth, C., and Tulskey, D. Comparison of Patient-Reported to Performance-Based Functional Outcomes in Individuals with Unilateral Transtibial Amputation. Military Health System Research Symposium. 17-20 August 2015, Ft. Lauderdale, FL.

Wolf EJ, Darter BJ, Saha D. Ankle Kinematics of Service Members With and Without Transtibial Amputation while Walking on a Split Belt Treadmill. Presented at American Society of Biomechanics, Columbus, OH, from August 5-8, 2015.

Ziemke G., Campello M., Hiebert R., Schecter-Weiner S., Rennix C., Nordin M. (August 2015) Does a coordinated, multidisciplinary Spine Team limit medical attrition related to work disabling spine conditions in the US Navy? Poster session presented at the Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL. August 2015.

Jamison, S.T., McNally, M.P., Yedimenko, J.A., & Onate, J.A. Validation of a novel clinical to measure frontal plane pelvis motion during walking. Seventh World Congress of Biomechanics, Boston, MA July 6-11, 2014.

Lewis, J., Freisinger, G., McNally, M., Jamison, S.T., & Givens, D. Validation of a device for measuring seated pelvic position. Seventh World Congress of Biomechanics, Boston, MA July 6-11, 2014.

McNally, M., Lewis, J., Freisinger, G., Jamison, S., Chaudhari, A., & Givens, D. Effect of pelvic position feedback on maintenance of seated pelvic posture. Seventh World Congress of Biomechanics, Boston, MA July 6-11, 2014.

Pruziner, A., Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators. The BADER Consortium Government Steering Committee Meeting. 19 February 2014.

Rylander, J., Beltran, E., Wilken, J., and Dingwell, J. Healthy Persons with Unilateral Amputation and Able Bodied Controls Respond Similarly To Visual Field Perturbations While Walking. Proceedings of the 60th Annual Meeting of the Orthopaedic Research Society, New Orleans, LA, March 15-18, 2014.

Rylander, J., Wilken, J., Cusumano, J., and Dingwell, J. Strategies for controlling lateral stepping movements in human walking. Proceedings of the 2014 Society for Neuroscience Annual Meeting, Washington, DC, Nov. 15-19, 2014.

Salinas, M., and Dingwell, J. How Humans Use Visual Optic Flow To Regulate Stepping Movements During Walking. Proceedings of the 7th World Congress of Biomechanics, Boston, MA, July 6-11, 2014.

Sheehan, R., Rylander, J., Wilken, J., and Dingwell, J. A virtual reality obstacle course to improve lateral balance control in lower limb trauma patients. Proceedings of the 2014 Society for Neuroscience Annual Meeting, Washington, DC, Nov. 15-19, 2014.

Cusumano, J., and Dingwell, J. On the Role of Perception in Regulating Stride-To-Stride Walking Dynamics. Proceedings of the 2013 Dynamic Walking Meeting, Pittsburgh, PA, June 10-13, 2013.

Dingwell, J., and Cusumano, J. Using Perceptual Cues to Regulate Walking From Stride- to-Stride. Proceedings of the 43rd Annual Meeting of the Society for Neuroscience, San Diego, CA, November 9-13, 2013.

Khattra NS, Tierney JJ, Yarlagadda S, Shevchenko N, Gillespie JW, Schrank ES, Stanhope SJ. Carbon fiber based custom orthoses for augmenting net ankle moment in gait. (Proceedings) Society for the Advancement of Material and Process Engineering, 2013.

Kingsbury T, Marks M, Thesing N, Myers G, Isken M, Wyatt M. Use of an Amputee Gait Score to Assess Rehabilitation Progress. Podium at American Society of Biomechanics. September 2013.

Rylander, J., Cusumano, J., Wilken, J., and Dingwell, J. Coronal Plane Treadmill Stepping Control Strategies in Individuals with Transtibial Amputation. Proceedings of the 43rd Annual Meeting of the Society for Neuroscience, San Diego, CA, November 9-13, 2013.

Samaan, C., Schwartz, J., Graf, E., Davis, I., Rainbow, M. A Standing Alignment System Improves Between-Session Repeatability in gait Kinematics: A Preliminary Study. Proceedings of the Annual Meeting of the American Society of Biomechanics, Omaha, NE, September 4-7, 2013.

Thesing N, Kingsbury T, Myers G, Wyatt M. Comparison of Functional Outcome Measures between Patients with Knee Disarticulation and Trans-Femoral Amputations Due to Trauma. Poster at American Society of Biomechanics. September 2013.

Wyatt M, Unfried B, Sessoms P, Myers G, Grabiner M, Kaufman K. Does Novel Fall-Prevention Program Improve Gait Parameters in Unilateral Transtibial Amputees? Podium presentation, Gait and Clinical Movement Analysis Society (GCMAS) Annual Conference, Cincinnati, Ohio May 2013.

Razzook A, Gleason C, Willy R, Fellin R, Davis I, Stanhope S. Average Ankle Dynamic Joint Stiffness During Heel Strike Running. (Proceedings) American Society of Biomechanics, 2012.

Schrank ES, Higginson JS, Stanhope SJ. A Repeatable and Predictable method to Rapidly Manufacture Function-Customized Passive-Dynamic Ankle Foot Orthoses. Proceedings of the ASME, 2012

Takahashi KZ, Stanhope SJ. Net Efficiency of the Combined Ankle-Foot System in Normal Gait: Insights for passive and Active Prosthetics. (Proceedings) American Society of Biomechanics, 2012.

Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. A proposed method for PD- AFO stiffness prescription procedure. (Proceedings) Center for Biomedical Engineering Research Symposium, University of Delaware, 2011.

Guinn LD, Takahashi KZ, Razzook AR, Schrank ES, Stanhope SJ. Ankle Pseudo-Stiffness is Greatest During Gait Initiation. (Proceedings) Gait and Clinical Movement Analysis Society Conference, 2011.

Guinn, L., Takahashi, K., Razzook, A., Schrank, E., Stanhope, S., A proposed method for PD- AFO stiffness prescription procedure. (Proceedings) Center for Biomedical Engineering Research Symposium, University of Delaware, 2011.

Guinn, L., Takahashi, K., Razzook, A., Schrank, E., Stanhope, S., Ankle Pseudo-Stiffness is Greatest During Gait Initiation. (Proceedings) Gait and Clinical Movement Analysis Society Conference, 2011.

Razzook AR, Takahashi KZ, Guinn LD, Schrank ES, Stanhope SJ. Predictive Model for Natural Ankle Stiffness During Walking: Implications for Ankle Foot Orthosis Prescription. (Proceedings) Gait and Clinical Movement Analysis Society Conference, 2011.

Schrank, E., Higginson, J., Stanhope, S., Compensatory Muscle Control Strategies when Walking with a Customized PD-AFO. (Proceedings) American Society of Biomechanics, 2011.

Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Kepple TM, Stanhope SJ. Unified Deformable Segment Model of the Combined Ankle-Foot System that Does Work. (Proceedings) American Society of Biomechanics, 2011.

Takahashi KZ, Razzook AR, Guinn LD, Schrank ES, Stanhope SJ. A Model of Normal Gait Roll-Over Dynamics One Step Closer to Customizing Prosthetic Ankle-Foot Components. (Proceedings) Gait and Clinical Movement Analysis Society Conference, 2011.

#### **Patents:**

None at this time

#### **BADER Supported and Related Projects**

##### ***Publications (N=14):***

Andrews, A.M., Deehl, C., Rogers, R.L., et al. Core temperature in service members with and without traumatic amputations during a prolonged endurance event. *Military Medicine* 181 11/12:61, 2016.

Farrokhi, S., Mazzone, B., Yoder, A., Grant, K., and Wyatt, M. (2016). A narrative review of the prevalence and risk factors associated with development of knee osteoarthritis after traumatic unilateral lower limb amputation. *Military Medicine* 2016 Nov;181, 11/12:38-44.

Highsmith, M.J., Kahle, J.T., Miro, R.M., et al. Differences in military obstacle course performance between three energy-storing and shock-adapting prosthetic feet in high-functioning transtibial amputees: a double-blind randomized controlled trial. *Military Medicine* 181 11/12:45, 2016.

Highsmith, M.J., Nelson, L.M., Carbone, N.T., et al. Outcomes associated with the Intrepid Dynamic Exoskeletal Orthosis (IDEO): A systematic review of the literature. *Military Medicine* 181 11/12:69, 2016.

Hill, O., Bulathsinhala, L., Eskridge, S.L., et al. Descriptive characteristics and amputation rates with use of Intrepid Dynamic Exoskeleton Orthosis. *Military Medicine* 181 11/12:77, 2016.

Isaacson, B.M., Hendershot, B.D., Messinger, S.D., et al. The Center for Rehabilitation Sciences Research: Advancing the rehabilitative care for service members with complex trauma. *Military Medicine* 181 11/12:20, 2016.

Mangan, KI, Kingsbury, TD, Mazzone, BN, Wyatt, MP, Kuhn, KM. (2016). Limb Salvage Versus Transtibial Amputation: A comparison of Functional Gait Outcomes. *Journal of Orthopaedic Trauma*, 30(12).

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Rabago, C.A., Clouser, M., Dearth, C.L., et al. The Extremity Trauma and Amputation Center of Excellence: Overview of the Research and Surveillance Division. *Military Medicine* 181 11/12:3, 2016.

Rabago, C.A., Wilken, J.M. The prevalence of gait deviations in individuals with transtibial amputation. *Military Medicine* 181 11/12:30, 2016.

Randolph, B.J., Nelson, L.M., and Highsmith, M.J. A review of unique considerations for female veterans with amputation. *Military Medicine* 181 11/12:66, 2016.

Salinas, M., and Dingwell, J. How Humans Use Visual Optic Flow To Regulate Stepping Movements During Walking. *Gait&Posture* 57 (2017):15-20.

Schnall, B.L., Chen, Y.T., Bell, E.M., et al. Functional outcomes of service members with bilateral transfemoral and knee disarticulation amputations resulting from trauma. *Military Medicine* 181 11/12:55, 2016.

Stinner, D.J. Improving outcomes following extremity trauma: The need for a multidisciplinary approach. *Military Medicine* 181 11/12:26, 2016.

### ***Abstracts and Presentations (N=18):***

Bohnsack-McLagan, N.K., Cusumano, J.P., & Dingwell, J.B. How humans regulate variability at walk-to-run transition speeds. ND.

Chopra, P., Castelli, D.M., & Dingwell, J.B. Texting while walking: cognitive capacity predicts obstacle avoidance. ND.

Ikeda, A.J., Ferguson, J.R., Westbrook, A.E., & Wilken, J.M. Effects of heel wedge properties on gait with the Intrepid Dynamic Exoskeletal Orthosis (IDEO). ND.

Westbrook, A.E., Russell Esposito, E., Rabago, C.A., Sheehan, R.C., & Wilken, J.M. Ankle foot orthosis users demonstrate impaired pelvis-trunk coordination during walking. ND.

Angiolillo, A.L., and Grabowski, A. Independent contributions of weight and mass to the metabolic cost of walking uphill and downhill. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Brown, S.E., Russell Esposito, E., Ikeda, A., Ferguson, J., Caldwell, R., Fatone, S., & Wilken, J.M. Effect of socket design and suspension on walking mechanics. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Capobianco, R.A., Feeney, D.F., Jeffers, J.R., Enoka, R.M., & Grabowski, A.M. Sit-to-stand biomechanics of individuals with sacroiliac joint pain compared to normal healthy persons. 2016. Rocky Mountain American Society of Biomechanics, At Estes Park, CO.

Devine, M.R., and Dingwell, J. Trial-to-trial model control dynamics in redundant reaching tasks. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Grabiner, M.D., Marone, J.R., Wyatt, M., & Kaufman, K.R. Step width during treadmill walking is statistically persistent. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Meling, L., Rabago, C.A., Hosterler, Z., Smith, M., Wilken, J.M., & Rylander, J. Assessment of limb tracking within a serious game for rehabilitation. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Ohm, K.A., Russell Esposito, E., Ranz, E.C., Neptune, R., R., & Wilken, J.M. Ankle-foot orthosis bending axis influences running mechanics. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Pickly, N.T., Wilken, J.M., Aldridge Whitehead, J.M., Westbrook, A.E., & Silverman, A.K. Comparison of inverted pendulum models during walking on slopes: application to prosthesis performance. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Russell Esposito, E. and Wilken, J.M. A powered ankle-foot orthosis for patients with plantarflexor weakness. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Sheehan, R.C., Allen, C., Deyle, G., Wilken, J.M., & Gill, N. Symptom relief improves stumble recovery in individuals with knee osteoarthritis: A case series. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Westbrook, A.E., Russell Esposito, E., Rabago, C.A., Sheehan, R.C., & Wilken, J.M. Ankle foot orthosis users demonstrate impaired pelvis-trunk coordination during walking. 40th Annual Meeting of the American Society of Biomechanics, Raleigh, NC, USA, August 2nd – 5th, 2016.

Dingwell, J.B., & Wilken, J.M. Integrating virtual reality and motion capture for clinical assessment and rehabilitation. Seventh World Congress of Biomechanics, July 6-11, 2014, Boston MA.

Rylander, J.H., Wilken, J.M., Cusumano, J.P., & Dingwell, J.B. Able bodied persons and individuals with transtibial amputation employ similar control strategies in the frontal plane during treadmill walking. Seventh World Congress of Biomechanics, July 6-11, 2014, Boston MA.

Salinas, M.M., & Dingwell, J.B. How humans use visual optic flow to regulate stepping movements during walking. Seventh World Congress of Biomechanics, July 6-11, 2014, Boston MA.

**Informatics such as databases and animal models:**

- The Consortium, through the Clinical Research Core, has executed a Collaboration Agreement with the National Institute of Child Health and Human Development (NICHD) for partnering on the use of the NICHD Clinical Trials Data Base (CTDB) as the Consortium PDMS system. This unique partnership is supported by leadership at both NIH and UD and brings substantial opportunities to both parties for future development and now offers the Consortium a secure and dedicated instance of the NIH Clinical Trials Database.

**Employment or research opportunities applied for and/or received based on experience/training supported by this award:**

- John Collins, a biomechanist in the gait analysis laboratory at NMCSD, currently holds a BS in Bioengineering from UC San Diego and a MA in Kinesiology with an emphasis in Biomechanics from San Diego State. He has completed his third year of studies in the University of Delaware Biomechanics and Movement Science program and returned to NMCSD in January 2016 to work on his research project. He anticipates completion of degree requirements in May 2019.
- Clinical Research Core staff have all found positions outside of BADER (due to funding being depleted) that were greatly facilitated by the opportunities supported by this award including research experiences, conference support and University of Delaware degree-granting and certificate programs.

## Conclusion

## Administrative Overview:

As we complete the fourth quarter of year 7 (second yr no cost extension) period of performance, efforts continue to be focused on the “Engagement” phase. BADER is actively working on the successful accomplishment of tasks as outlined in the proposed statement of work.

BADER Continues progress in the following areas:

MTF and research initiative team building: EACE engagement. Regular meetings of MTF and BADER personnel will continue and focus on engagement and sustainability efforts of the Consortium. Through these meetings and continued support of the MTF needs, initiative focused teams are forming and evidence of impact and sustainability is mounting – see appendices for summary of accomplishments.

Proposal submission:

Effort will continue in support of the submission of new proposals as requested for funding that builds on and/or extends current research efforts across the Consortium.

MTF Centric Coordination and Management:

BADER will effectively leverage existing networks and establish new partnerships to identify research teams to seek external funding opportunities for sustainability of the Consortium. During this quarter, BADER Consortium submitted a full application to the Joint Warfighter Medical Research Program Funding Opportunity Number: W81XWH-18-JWMP. If awarded, this will bring an additional \$6M to support the continuation of BADER Consortium for an additional four years. The BADER Consortium continuation proposes to exclusively support EACE/RSD efforts at MTF sites to further establish impactful research partnerships, an efficient technology translational pipeline, and EACE/RSD investigator goals of obtaining research independence by obtaining PI status on externally-funded grants.

Collaborations with other Consortia/Initiatives:

Leaders of the BADER Consortium have been working diligently to establish strong collaborations with other Department of Defense, VA and NIH initiatives. By collaborating with these initiatives, the BADER Consortium believes it can create extraordinary research infrastructures across the DoD and VA.

Partnership with EACE:

Leadership from BADER met with EACE leadership and MTF representatives most recently during the MHSRS meeting in Orlando, FL. Key points of conversation focused on continued support of the EACE/MTF needs.

Veteran’s Affairs (VA):

BADER leadership continues to engage the VA. A strong partnership with the VA is essential for sustainability efforts of the Consortium.

National Institutes of Health (NIH):

The Consortium is currently working under a Collaboration Agreement with the National Institute of Child Health and Human Development (NICHD) for partnering on the use of the NICHD Clinical Trials Data Base (CTDB) as the Consortium PDMS system. This Collaboration Agreement has been extended through September 29, 2019.

Post baccalaureate training:

John David Collins (NMCSD) continues to progress toward his PhD in Biomechanics and Movement Sciences at the University of Delaware and returned to NMCSD in January 2016 to continue his research to complete his degree requirements. Mr. Collins anticipates completion of degree requirements by May 2019.

## **Conclusion**

As we complete year 7 (second yr no cost extension) period of performance, efforts continue to be focused on the “Engagement” and “Sustainability” phases. BADER is actively working on the successful accomplishment of tasks as outlined in the proposed statement of work.

BADER will continue to effectively leverage existing networks and establish new partnerships to identify research teams to seek external funding opportunities for sustainability of Consortium activities.

Regular meetings of EACE, MTF and BADER personnel will continue and focus on engagement efforts of the Consortium. Through these meetings and continued support of the MTF needs, initiative focused teams are forming and evidence of impact and sustainability is mounting. As requested, we will continue to engage BADER Consortium Affiliates into forming large research teams to compete for large scale, impactful clinical grants.

BADER will maximize the remaining and unobligated project funds to further support MTF-identified activities that promote their orthopaedic rehabilitation research efforts.

Using non-BADER award funds, Consortium staff prepared application to the Joint Warfighter Medical Research Program Funding Opportunity Number: W81XWH-18-JWMP in August 2018.

We look forward to continuing our work in strengthening orthopaedic rehabilitation research at MTF and VA sites to bolster their efforts to bring all Wounded Warriors back to optimal function.

## APPENDICES

## APPENDIX A: Affiliations

### ***Affiliations:***

#### Government partners:

- CDMRP
- Brooke Army Medical Center
- Naval Medical Center Portsmouth
- Naval Medical Center San Diego
- Walter Reed National Military Medical Center
- National Institutes of Health
- Department of Veterans Affairs
- Denver Rehabilitation Institute
- ECBC/ADM
- Extremity Trauma and Amputation Center of Excellence (EACE)

#### Academic partners:

- University of Delaware
- Spaulding Rehabilitation Hospital
- Mayo Clinic
- University of Texas Austin
- University of Colorado
- University of Michigan
- New York University
- Christiana Care Health System
- Vanderbilt University
- University of Iowa
- Simbex, LLC

#### Industry partners:

- C-Motion, Inc
- Independence Prosthetics and Orthotics
- BiOM
- Ossur
- Otto-Bock
- Hanger Orthopedics

#### Non-Profit partners:

- Amputee Coalition
- Agrability

## APPENDIX B: BADER Consortium Affiliates

| <b>Aldridge, Jennifer</b>               | <b>BADER Consortium Affiliate</b>                              | <b>San Antonio Military Medical Center (SAMMC)</b> |
|-----------------------------------------|----------------------------------------------------------------|----------------------------------------------------|
| <b>Archer, Kristin R., PhD, PT, DPT</b> | BADER Consortium Affiliate, Research Advisory Committee Member | Vanderbilt                                         |
| <b>Bonato, Paolo, PhD</b>               | BADER Consortium Affiliate, Research Advisory Committee Member | Spaulding Rehabilitation Hospital                  |
| <b>Brown, Douglas</b>                   | BADER Consortium Affiliate                                     | Naval Medical Center San Diego (NMCS D)            |
| <b>Buchanan, Thomas S., PhD</b>         | BADER Consortium Affiliate                                     | University of Delaware                             |
| <b>Campello, Marco, PhD</b>             | BADER Consortium Affiliate                                     | New York University                                |
| <b>Carney, Joseph</b>                   | BADER Consortium Affiliate                                     | Naval Medical Center San Diego (NMCS D)            |
| <b>Casler, Rick</b>                     | BADER Consortium Affiliate                                     | BiOM                                               |
| <b>Cella, David, PhD</b>                | BADER Consortium Affiliate                                     | Northwestern University                            |
| <b>Childs, John D., PT, PhD, MBA</b>    | BADER Consortium Affiliate, Research Advisory Committee Member | Dept. of the Army                                  |
| <b>Collins, John-David</b>              | BADER Consortium Affiliate                                     | Naval Medical Center San Diego (NMCS D)            |
| <b>Crandell, David, MD</b>              | BADER Consortium Affiliate                                     | Spaulding Rehabilitation Hospital                  |
| <b>Dankmeyer, Charles H., CPO</b>       | BADER Consortium Affiliate                                     | Dankmeyer, Inc.                                    |
| <b>Davis, Irene Sprague, PhD, PT</b>    | Director, Clinical Research - BADER Consortium                 | Spaulding Rehabilitation Hospital                  |
| <b>Davis, Samuel, PhD</b>               | BADER Consortium Affiliate                                     | Naval Medical Center Portsmouth (NMCP)             |
| <b>de Lateur, Barbara J., MD, MS</b>    | BADER Consortium Affiliate, Research Advisory Committee Member | Johns Hopkins Medicine                             |
| <b>Dingwell, Jonathan B., PhD</b>       | BADER Consortium Affiliate                                     | Pennsylvania State University                      |

|                                      |                                                                |                                                       |
|--------------------------------------|----------------------------------------------------------------|-------------------------------------------------------|
| <b>Dromsky, David</b>                | BADER Consortium Affiliate                                     | Naval Medical Center San Diego (NMCSD)                |
| <b>Evans, Boyd</b>                   | BADER Consortium Affiliate                                     | Oak Ridge National Labs                               |
| <b>Farrell, Todd R., PhD</b>         | BADER Consortium Affiliate                                     | Liberating Technologies, Inc.                         |
| <b>Fatone, Stefania</b>              | BADER Consortium Affiliate                                     | Northwestern University                               |
| <b>Ferguson, John</b>                | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC)           |
| <b>Ficke, James R., PhD</b>          | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC)           |
| <b>Fitzgerald, G. Kelley, PhD</b>    | BADER Consortium Affiliate                                     | University of Pittsburgh                              |
| <b>Friedman, Matthew J., MD, PhD</b> | BADER Consortium Affiliate, Research Advisory Committee Member | Dartmouth                                             |
| <b>Gard, Steven A., PhD</b>          | BADER Consortium Affiliate                                     | Northwestern University                               |
| <b>Gill, Norman "Skip" LTC</b>       | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC)           |
| <b>Gillespie, John W., PhD</b>       | BADER Consortium Affiliate                                     | University of Delaware                                |
| <b>Grabowski, Alena, PhD</b>         | BADER Consortium Affiliate                                     | University of Colorado Boulder                        |
| <b>Greenwald, Rick, PhD</b>          | BADER Consortium Affiliate, Research Advisory Committee Member | Simbex                                                |
| <b>Groer, Shirley, PhD</b>           | BADER Consortium Affiliate, Research Advisory Committee Member | Department of Veterans Affairs                        |
| <b>Hansen, Andrew, PhD</b>           | BADER Consortium Affiliate                                     | Department of Veterans Affairs                        |
| <b>Hendershot, Brad</b>              | BADER Consortium Affiliate                                     | Walter Reed National Military Medical Center (WRNMMC) |
| <b>Hicks, Gregory E., PhD, PT</b>    | BADER Consortium Affiliate, Research Advisory Committee Member | University of Delaware                                |

|                                              |                                                                |                                                       |
|----------------------------------------------|----------------------------------------------------------------|-------------------------------------------------------|
| <b>Hopkins, Mark S., PT, CPO, MBA</b>        | BADER Consortium Affiliate                                     | Dankmeyer, Inc.                                       |
| <b>Hsu, Joseph, PhD, LTC</b>                 | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC)           |
| <b>Jarzombek, Sandi</b>                      | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC)           |
| <b>Kaufman, Kenton R., PhD, PE</b>           | Director, Scientific Cores                                     | Mayo Clinic                                           |
| <b>Kelley, Kevin</b>                         | BADER Consortium Affiliate                                     | Ottobock                                              |
| <b>Kingsbury, Trevor</b>                     | BADER Consortium Affiliate                                     | Naval Medical Center San Diego (NMCSD)                |
| <b>Klute, Glenn K., PhD</b>                  | BADER Consortium Affiliate                                     | University of Washington                              |
| <b>Kolm, Paul, PhD</b>                       | BADER Consortium Affiliate, Director, Biostatistics Core       | Christiana Care Health Services, Inc.                 |
| <b>Kram, Rodger, PhD</b>                     | BADER Consortium Affiliate, Research Advisory Committee Member | University of Colorado                                |
| <b>Kuiken, Todd, MD, PhD</b>                 | BADER Consortium Affiliate, Research Advisory Committee Member | Rehabilitation Institute of Chicago                   |
| <b>Pruzier, Alison</b>                       | MTF Representative, BADER Consortium Affiliate                 | Walter Reed National Military Medical Center (WRNMMC) |
| <b>Loggerstedt, David, PT, PhD, MPT, SCS</b> | BADER Consortium Affiliate                                     | University of Delaware                                |
| <b>Ludewig, Paula M.</b>                     | BADER Consortium Affiliate                                     | University of Minnesota                               |
| <b>Milbourne, Suzanne A., PhD</b>            | Clinical Research Core Manager, BADER Consortium Affiliate     | University of Delaware                                |
| <b>Miller, Ross H., PhD</b>                  | BADER Consortium Affiliate                                     | University of Maryland                                |
| <b>Mulroy, Sara, PhD, PT</b>                 | BADER Consortium Affiliate                                     | Rancho Los Amigos National Rehabilitation Center      |
| <b>Neptune, Rick</b>                         | BADER Consortium Affiliate                                     | University of Texas at Austin                         |

|                                        |                                                         |                                                       |
|----------------------------------------|---------------------------------------------------------|-------------------------------------------------------|
| <b>Nordin, Margareta</b>               | BADER Consortium Affiliate                              | New York University                                   |
| <b>Nowinski, Cindy, MD, PhD</b>        | BADER Consortium Affiliate                              | Northwestern University                               |
| <b>Owens, Johnny, PT</b>               | BADER Consortium Affiliate                              | San Antonio Military Medical Center (SAMMC)           |
| <b>Pasquina, Paul, COL</b>             | BADER Consortium Affiliate                              | Uniformed Services University of the Health Sciences  |
| <b>Powers, Christopher M., PhD, PT</b> | BADER Consortium Affiliate                              | University of Southern California                     |
| <b>Rabago, Chris</b>                   | BADER Consortium Affiliate                              | San Antonio Military Medical Center (SAMMC)           |
| <b>Resnick, Linda, PhD</b>             | BADER Consortium Affiliate                              | Brown University                                      |
| <b>Richards, James G., PhD</b>         | BADER Consortium Affiliate                              | University of Delaware                                |
| <b>Ritland, Bradley, CAPT</b>          | BADER Consortium Affiliate                              | Walter Reed National Military Medical Center (WRNMMC) |
| <b>Rodriguez, Kelly</b>                | BADER Consortium Affiliate                              | San Antonio Military Medical Center (SAMMC)           |
| <b>Rosenthal, Michael D., CAPT</b>     | BADER Consortium Affiliate                              | Naval Medical Center San Diego (NMCSD)                |
| <b>Royer, Todd, PhD</b>                | BADER Consortium Affiliate                              | University of Delaware                                |
| <b>Sacher, Richard S</b>               | BADER Consortium Affiliate                              | University of Delaware                                |
| <b>Schaffer, Scott, LTC</b>            | BADER Consortium Affiliate                              | San Antonio Military Medical Center (SAMMC)           |
| <b>Schnall, Barri</b>                  | BADER Consortium Affiliate                              | Walter Reed National Military Medical Center (WRNMMC) |
| <b>Scoville, Charles</b>               | BADER Consortium Affiliate                              | Walter Reed National Military Medical Center (WRNMMC) |
| <b>Selbie, William Scott, PhD</b>      | BADER Consortium Affiliate, Director, Biomechanics Core | C-Motion, Inc.                                        |
| <b>Sessoms, Pinata</b>                 | BADER Consortium Affiliate                              | Naval Medical Center San Diego (NMCSD)                |

|                                             |                                                                |                                             |
|---------------------------------------------|----------------------------------------------------------------|---------------------------------------------|
| <b>Shim, Jae Kun, PhD</b>                   | BADER Consortium Affiliate                                     | University of Maryland                      |
| <b>Silverman, Anne</b>                      | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC) |
| <b>Sluka, Kathleen A., PT, PhD</b>          | BADER Consortium Affiliate, Research Advisory Committee Member | University of Iowa Health Care              |
| <b>Snyder-Mackler, Lynn, PT, PhD, FAPTA</b> | BADER Consortium Affiliate                                     | University of Delaware                      |
| <b>Stanhope, Steven J., PhD</b>             | Director, BADER Consortium                                     | University of Delaware                      |
| <b>Swiontkowski, Marc F., MD</b>            | BADER Consortium Affiliate, Research Advisory Committee Member | University of Minnesota                     |
| <b>Takahashi, Kota, PhD</b>                 | BADER Consortium Affiliate                                     | University of Nebraska Omaha                |
| <b>Thesing, Nancy</b>                       | BADER Consortium Affiliate                                     | Naval Medical Center San Diego (NMCSD)      |
| <b>Tulsky, David, PhD</b>                   | BADER Consortium Affiliate, Director, Outcome Measures Core    | University of Delaware                      |
| <b>Vernon, Michael</b>                      | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC) |
| <b>Ward, Samuel R., PT, PhD</b>             | BADER Consortium Affiliate                                     | University of California, San Diego         |
| <b>Weir, Richard, PhD</b>                   | BADER Consortium Affiliate                                     | University of Colorado                      |
| <b>Wilken, Jason, PhD, MPT</b>              | MTF Representative                                             | University of Iowa                          |
| <b>Wyatt, Marilyn</b>                       | MTF Representative                                             | Naval Medical Center San Diego (NMCSD)      |
| <b>Yack, John</b>                           | BADER Consortium Affiliate                                     | San Antonio Military Medical Center (SAMMC) |

## APPENDIX C: Quad Charts for active BADER-funded research projects

# Characterization of Prosthetic Feet for the Weighted Walking in Service Members with Lower-Limb Amputations

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award

W81XWH-11-2-0222

PI: **Schnall, Barri**

Org: Walter Reed National Military Medical Center

Award Amount: \$398,735



## Study/Product Aim(s)

To provide objective criteria for evaluating and prescribing prosthetic ankle-foot components for Service Members with transibial amputations wishing to perform load carriage and other physically demanding tasks

## Approach

- Determine mechanical characteristics and durability of current prosthetic feet intended for highly functional transibial prosthesis users
- Compare the biomechanical effects and functional outcomes between prosthetic feet with linear and non-linear mechanical properties during weighted walking and high-intensity activities.

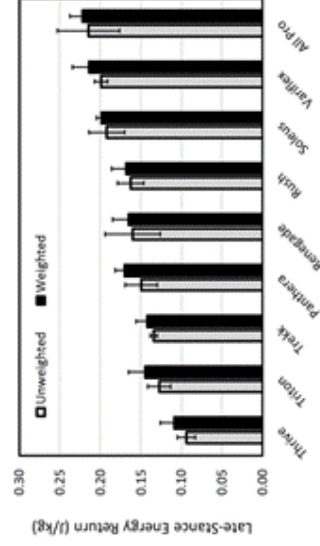


Figure 1. Mean (± 1 standard deviation) late-stage energy return across all subjects sorted from the least (left) to most (right) unweighted energy return.

- 1) Koehler-Nicholas, S.R., Nickel, E.A., Barrons, K., Blaharski, K.E., Schnall, B.L., Hendershot, B.D., Hansen, A.H., 2018. Mechanical Characterization of Prosthetic Feet for Weighted Walking. *PLOS One* 13, e0202884.
- 2) Nickel, E., Voss, G., Morin, S., Koehler-McNicholas, S., Hendershot, B.D., Schnall, B.L., Barrons, K., Mion, S., Hansen, A.H. Impact Testing of Prosthetic Feet for High Activity Prosthesis Users. *Prosthetics and Orthotics International*, Accepted.

## Timeline and Cost

| Activities                   | FY | 15   | 16     | 17    | 18    |
|------------------------------|----|------|--------|-------|-------|
| IRB Approval                 |    |      |        |       |       |
| Mechanical testing of feet   |    |      |        |       |       |
| Collect and Process Subjects |    |      |        |       |       |
| Publications                 |    |      |        |       |       |
| Estimated Budget (\$K)       |    | 100K | \$197K | \$59K | \$70K |

Updated 24 Sept 2018

## Goals/Milestones

- FY15 Goals** – IRB Approval
- ☒ Minneapolis VA Health Care System (MVAHCS)
  - ☒ Obtain IRB approval WRNMMC
  - ☒ Begin mechanical testing of feet and VA participants
- FY16 Goals** – Data collection / publication
- ☒ Publish preliminary results
  - ☒ Data collection at WRNMMC
  - ☒ Publish final results
- FY17 Goals** – Data publication
- ☒ Data collection at WRNMMC
  - ☒ Complete CR
  - ☒ Submit Addendum
  - ☐ Publish final results
- FY18 Goals** – Data publication
- ☒ Request additional subjects for drop landing assessment
  - ☒ Submit application for additional funding through DoD JWMRP
  - ☐ Complete data analysis and closure report
  - ☐ Publish final results

# Maximizing Outpatient Rehabilitation Effectiveness (MORE)

OR100017 PRORP: Orthopaedic Rehabilitation Clinical Consortium Award  
W81XWH-11-2-0222; subaward # 39170



PI: Amy Bowles

Org: SAMMC

Award Amount: \$1.36 M

## Study/Product Aim(s)

- AIM #1: To determine factors that predict clinical outcomes following outpatient rehabilitation in a military setting.
- AIM #2: To determine the extent to which patient reported and observed outcomes change and covary during the course of outpatient rehabilitation.
- AIM #3: To determine the magnitude of residual deficits following completion of outpatient rehabilitation.

## Approach

- Participants: Individuals who have experienced lower limb injury.
- Prospective collection of objective outcomes data throughout the course of rehabilitative care at Ft Hood, SAMMC, and the University of Iowa.
- Measures will be used to assess physical, cognitive, and psychosocial health and function every three weeks.



An improved understanding of the types and magnitudes of deficits present, and their relative contributions to treatment success, goal attainment, and health related quality of life is needed to effectively guide the use of limited clinic resources and facilitate efforts to maximize outpatient rehabilitation effectiveness.

## Timeline and Cost

| Activities                      | CY       | 14        | 15         | 16         | 17         | 18         | 19 |
|---------------------------------|----------|-----------|------------|------------|------------|------------|----|
| Regulatory Approval, Purchasing |          |           |            |            |            |            |    |
| Hire and Train Staff            |          |           |            |            |            |            |    |
| Enrollment and Data Collection  |          |           |            |            |            |            |    |
| Data analysis and dissemination |          |           |            |            |            |            |    |
| <b>Estimated Budget (\$K)</b>   | <b>0</b> | <b>58</b> | <b>202</b> | <b>249</b> | <b>237</b> | <b>344</b> |    |

Updated: SEPT 2018

## Goals/Milestones

**CY14-15 Goal** – Receipt of funds, Regulatory, Hiring and System tests  
☒ IRB protocol submitted, data collection framework under development, training materials in preparation.

☒ Purchase study equipment, hire and train staff.

**CY16-18 Goals** – Subject Enrollment and Data Collection

☐ Enroll over 1,000 participants.

☐ Collect complete data on over 90% of participants.

**CY18-19 Goal** – Data analysis and dissemination of findings

☐ Complete data audit and statistical analysis.

☐ Presentation of results to clinical staff and manuscript submission.

## Comments/Challenges/Issues/Concerns

Dropout rate is higher than initially estimated. We intend to more closely examine the dropout rate and reasons for dropout over the coming year.

## Budget Expenditure to Date

Projected Expenditure: \$1.36M

Actual Expenditure: \$938K

# Sustainable Benefits of a Powered Ankle Prosthesis for Transtibial K2 and K3 Ambulators



OR100017 PRORP: Orthopaedic Rehabilitation Consortium Award W81XWH-11-2-0222

PI: Alison L. Pruziner Org: DoD-VA Extremity Trauma and Amputation Center of Excellence (WRNMMC) Award Amount: \$1,529,718

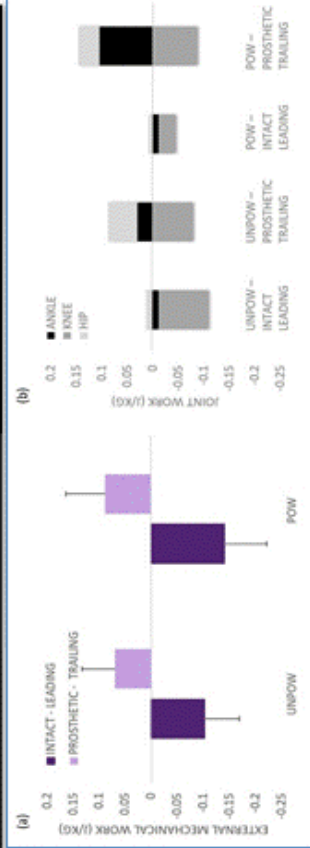
## Study/Product Aim(s)

Aim 1: Identify biomechanical, metabolic, functional, and/or subjective differences between using a passive versus a powered ankle prosthesis in individuals with unilateral transtibial limb loss, who function at a Medicare Functional Classification Level K2 and K3.

Aim 2: Identify stability of biomechanical, metabolic, functional, or subjective measures over time when wearing a powered ankle prosthesis in individuals with unilateral transtibial limb loss, who function at a Medicare Functional Classification Level K2 and K3.

## Approach

- Biomechanical, metabolic, functional, and subjective measures will be compared between a standard passive and powered ankle prosthesis
- Comparisons will be tracked over a six-month time period to evaluate stability of measures.
- It is hypothesized that outcomes will be improved with the application of a powered ankle prosthesis and that these improvements will be maintained for the study duration.



In contrast to our hypotheses and previous work in high-functioning individuals, there was no difference in individual limb transitional work, nor metabolic efficiency between the POW v. UNPOW devices. Overall, these preliminary results suggest individuals with transtibial limb loss at lower (vs. higher) MFCL likely utilize different strategies when walking with a POW vs. UNPOW device.

Accomplishment: An interim analysis has been completed and an abstract was accepted to be present at the World Congress of Biomechanics, in Dublin, Ireland in July 2018. Figure of results above.

## Timeline and Cost

| Activities FY          | 13 | 14   | 15  | 16  | 17  | 18   | 19   |
|------------------------|----|------|-----|-----|-----|------|------|
| Study preparation      |    |      |     |     |     |      |      |
| Recruitment            |    |      |     |     |     |      |      |
| Data Collection        |    |      |     |     |     |      |      |
| Data Analysis          |    |      |     |     |     |      |      |
| Manuscript Preparation |    |      |     |     |     |      |      |
| Budget (\$K)           | 0  | 3.42 | 405 | 186 | 191 | 122* | 416* |

\* Estimate of costs

Updated: 15 September 2018

## Goals/Milestones

FY13-16 Goal – Study prep and initiation

- ☒ Submission of IRB application
  - ☒ Hiring of key study personnel
  - ☒ Recruitment of K2 and K3 ambulators
  - ☒ Initiation of data collection
  - ☒ Initiate data analysis and interpretation
- FY17-18 Goal – Data collection and analysis
- ☐ Continue recruitment, collection, and analysis
  - ☐ Add VAMCs as a data collection sites
- FY19 Goal – Dissemination
- ☐ Complete data collection and analysis
  - ☐ Draft grant proposal for potential follow-on funding
  - ☐ Disseminate information through presentations and publications

## Comments/Challenges/Issues/Concerns

- Goals pushed back due to delays in release of funding and recruitment

## Budget Expenditure to Date

Projected Expenditure: \$ 1778 K

Actual Expenditure: \$ 1365 K



## APPENDIX D: Select Manuscripts and Presentations

RESEARCH ARTICLE

# Characterizing the Mechanical Properties of Running-Specific Prostheses

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## OPEN ACCESS

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**Data Availability Statement:** The authors confirm that all data underlying the findings are fully available without restriction. All relevant data are within the paper and its Supporting Information files.

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## Abstract

The mechanical stiffness of running-specific prostheses likely affects the functional abilities of athletes with leg amputations. However, each prosthetic manufacturer recommends prostheses based on subjective stiffness categories rather than performance based metrics. The actual mechanical stiffness values of running-specific prostheses (i.e. kN/m) are unknown. Consequently, we sought to characterize and disseminate the stiffness values of running-specific prostheses so that researchers, clinicians, and athletes can objectively evaluate prosthetic function. We characterized the stiffness values of 55 running-specific prostheses across various models, stiffness categories, and heights using forces and angles representative of those measured from athletes with transtibial amputations during running. Characterizing prosthetic force-displacement profiles with a 2<sup>nd</sup> degree polynomial explained 4.4% more of the variance than a linear function ( $p < 0.001$ ). The prosthetic stiffness values of manufacturer recommended stiffness categories varied between prosthetic models ( $p < 0.001$ ). Also, prosthetic stiffness was 10% to 39% less at angles typical of running 3 m/s and 6 m/s ( $10^\circ$ - $25^\circ$ ) compared to neutral ( $0^\circ$ ) ( $p < 0.001$ ). Furthermore, prosthetic stiffness was inversely related to height in J-shaped ( $p < 0.001$ ), but not C-shaped, prostheses. Running-specific prostheses should be tested under the demands of the respective activity in order to derive relevant characterizations of stiffness and function. In all, our results indicate that when athletes with leg amputations alter prosthetic model, height, and/or sagittal plane alignment, their prosthetic stiffness profiles also change; therefore variations in comfort, performance, etc. may be indirectly due to altered stiffness.

## Introduction

Running is a bouncing gait that is well-characterized by a spring-mass model [1–3]. The spring-mass model portrays the stance leg as a mass-less linear spring supporting a point mass representing the runner's center of mass. Upon ground contact, the leg spring compresses and stores elastic energy until mid-stance, and then returns mechanical energy from mid-stance through the end of ground contact [4]. In this model, the leg spring is completely elastic, however the structures of a biological leg are viscoelastic and therefore only a portion of the stored

**Competing Interests:** The authors have declared that no competing interests exist.

potential elastic energy is returned (due to hysteresis). The spring-like action of the leg conserves a portion of the runner's mechanical energy, theoretically mitigating the additional muscular force and mechanical energy input necessary to maintain running speed [4,5]. The magnitude of the stored and returned mechanical energy is inversely related to leg stiffness (resistance to compression), and is influenced by the magnitude and orientation of the external force vector acting on the leg [1]. Simply modeled as a linear spring, leg stiffness ( $k_{leg}$ ) equals the quotient of the peak applied force ( $F$ ) and the change in leg length ( $\Delta l$ ) from touchdown to mid-stance [2]:

$$k_{leg} = \frac{F}{\Delta l} \quad (1)$$

Inspired by the spring-like nature of running, passive-elastic running-specific prostheses (RSPs) were developed to enable athletes with lower-limb amputations to run. These carbon-fiber devices are attached to the sockets that encompass the residual limbs, are in-series with the residual limbs, and mimic the mechanical energy storage and return of tendons during ground contact. Unlike biological ankles, RSPs cannot generate mechanical power anew and only return 63% to 95% of the stored elastic energy during running [6–8]. For context, biological ankles generate mechanical power through use of elastic structures as well as muscles, and thus appear to “return” 241% of the energy stored while running at 2.8 m/s [7].

Athletes with leg amputations may adapt similar leg spring mechanics as non-amputees by using RSPs that emulate biological lower leg stiffness. Individually, non-amputees adopt a constant [2,9,10], metabolically optimal leg stiffness during running [11–13]. Non-amputee runners maintain leg stiffness across speeds by exhibiting constant ankle joint stiffness (sagittal plane torsional stiffness) [14,15]. It has been assumed that prosthetic stiffness is also constant across speeds [8,16–18], which if true, RSPs would act like that of biological ankles [14,15]. Yet, McGowan et al. [16] reported that the affected leg stiffness of athletes with transtibial amputations decreases as speed increases from 3.0 m/s to top speed (the range of top speeds achieved were 7.0 m/s to 10.8 m/s), indicating that prosthetic stiffness and/or affected leg knee stiffness may be inversely related with speed. Moreover, Dyer et al. [19] mechanically tested two Elite Blade RSPs (Chas A Blatchford & Sons Ltd. Basingstoke, UK) in a materials testing machine and reported that the RSPs have curvilinear force-displacement profiles, suggesting that prosthetic stiffness is non-constant and force dependent. Due to conflicting evidence in the literature, coupled with insufficient information provided by manufacturers regarding prosthetic stiffness profiles, it is unknown whether the force-displacement profiles of RSPs are linear, or curvilinear, which would infer that stiffness is contingent upon the applied force magnitude.

Prosthetic manufacturers do not report the stiffness values of RSPs (e.g. in kN/m). Instead, they classify RSPs into predetermined stiffness categories (e.g. categories 1 to 7), which are recommended to users based on body mass and intended activity (slow or fast running) [20–22]. Larger/heavier athletes with amputations are generally prescribed RSPs with numerically greater stiffness categories, which are presumably stiffer than numerically lower stiffness categories. Additionally, some prosthetic models are recommended at greater stiffness categories for fast running than for slow running [20,21], whereas other models are recommended at the same stiffness category irrespective of intended running speed [23,24]. These inconsistencies in prosthetic stiffness recommendations persist despite the potential influence of stiffness on running mechanics and performance. Therefore, it is imperative to quantify and disseminate stiffness values to further understand prosthetic function.

To accurately quantify prosthetic stiffness, it seems obvious to evaluate RSPs using forces and angles indicative of those produced during the respective activity. When athletes with

transtibial amputations run, they generate peak vertical ground reaction forces (GRFs) with their affected legs that are 2.1 to 3.3 times body weight at speeds of 2.5 m/s to 10.8 m/s [8,18,25,26]. During running, peak resultant GRFs typically occur around mid-stance and are oriented vertically. At the same instant, the proximal end of the stance leg's RSP is rotated forward in the sagittal plane relative to the peak resultant GRF vector. Therefore, the proximal bending moment acting on shorter RSPs may be less than that on taller RSPs for a given applied force, due to a reduced moment arm length. A smaller moment (torque) associated with shorter RSPs may reduce vertical displacement, and in turn increase prosthetic stiffness. Nonetheless, the peak resultant GRF magnitudes and sagittal plane orientations relative to RSPs are unknown, as is the influence of prosthetic height on stiffness.

Since prosthetic stiffness and hysteresis likely affect running performance, we aimed to 1) characterize the force-displacement profiles of RSPs, 2) quantify and compare prosthetic stiffness and 3) hysteresis values across prosthetic models, stiffness categories, and heights using angles and forces that replicate those exhibited during running, and 4) determine whether prosthetic height affects stiffness. Such information will enable accurate and objective comparisons between RSPs, subsequently allowing for potential improvements in prosthetic design, prescription, and athletic performance. Based on the predominant assumption that prosthetic stiffness is constant during running [8,16–18]; we hypothesized that the force-displacement profiles of RSPs would be linear. We hypothesized that for a given body mass and running speed, manufacturer recommended prosthetic stiffness would be similar between models. We also hypothesized that the magnitude of prosthetic hysteresis would not differ across testing conditions. Lastly, we hypothesized that shorter RSPs would be stiffer than taller RSPs.

## Methods

### Testing Procedure

We measured GRFs and sagittal plane angles of RSPs relative to the peak resultant GRFs from 11 athletes (5 males and 6 females; mean  $\pm$  SD; age:  $27.8 \pm 5.7$ ; standing height:  $1.74 \pm 0.08$  m; body mass:  $68.9 \pm 15.3$  kg) with unilateral transtibial amputations while they ran at 3 m/s and 6 m/s on a force-measuring treadmill. Each athlete used their own personal RSP. 3 m/s represents a typical distance running speed [27–29] and 6 m/s represents the fastest speed that all of our participants could achieve. The Intermountain Healthcare IRB, Colorado Multiple IRB, and the USAMRMC Office of Research Protection, Human Research Protection Office approved this study. Prior to participating, nine athletes provided informed written consent in accordance with the Intermountain Healthcare IRB and two participants provided informed written consent in accordance with the Colorado Multiple IRB and USAMRMC Office of Research Protection, Human Research Protection Office. Data collection took place in two separate labs.

We placed reflective markers on the lateral proximal and distal ends of each RSP's longitudinal axis and measured segment motion during each trial using a motion capture system (Motion Analysis Corporation, Santa Rosa, CA, USA, or Vicon Nexus, Oxford, UK) at 240 Hz (lab 1) or 200 Hz (lab 2) and implemented a 4<sup>th</sup> order low-pass Butterworth filter with a cutoff frequency of 6 Hz (Visual 3D, C-motion, Inc., Germantown, MD, USA) (Fig 1). The longitudinal axis was defined by a line through the center of the pylon connecting each socket to the corresponding C-shaped RSP, and along the center of the proximal, longitudinal section of each J-shaped RSP (Fig 1). Four athletes used a C-shaped RSP, and seven used a J-shaped RSP. We recorded GRFs via force-measuring treadmills (Treadmetrix, Park City, UT, USA) at 2400 Hz (lab 1) or 1000 Hz (lab 2) and applied a 4<sup>th</sup> order low-pass Butterworth filter with a cutoff frequency of 30 Hz using a custom MATLAB script (MathWorks Inc, Natick, MA, USA). Our

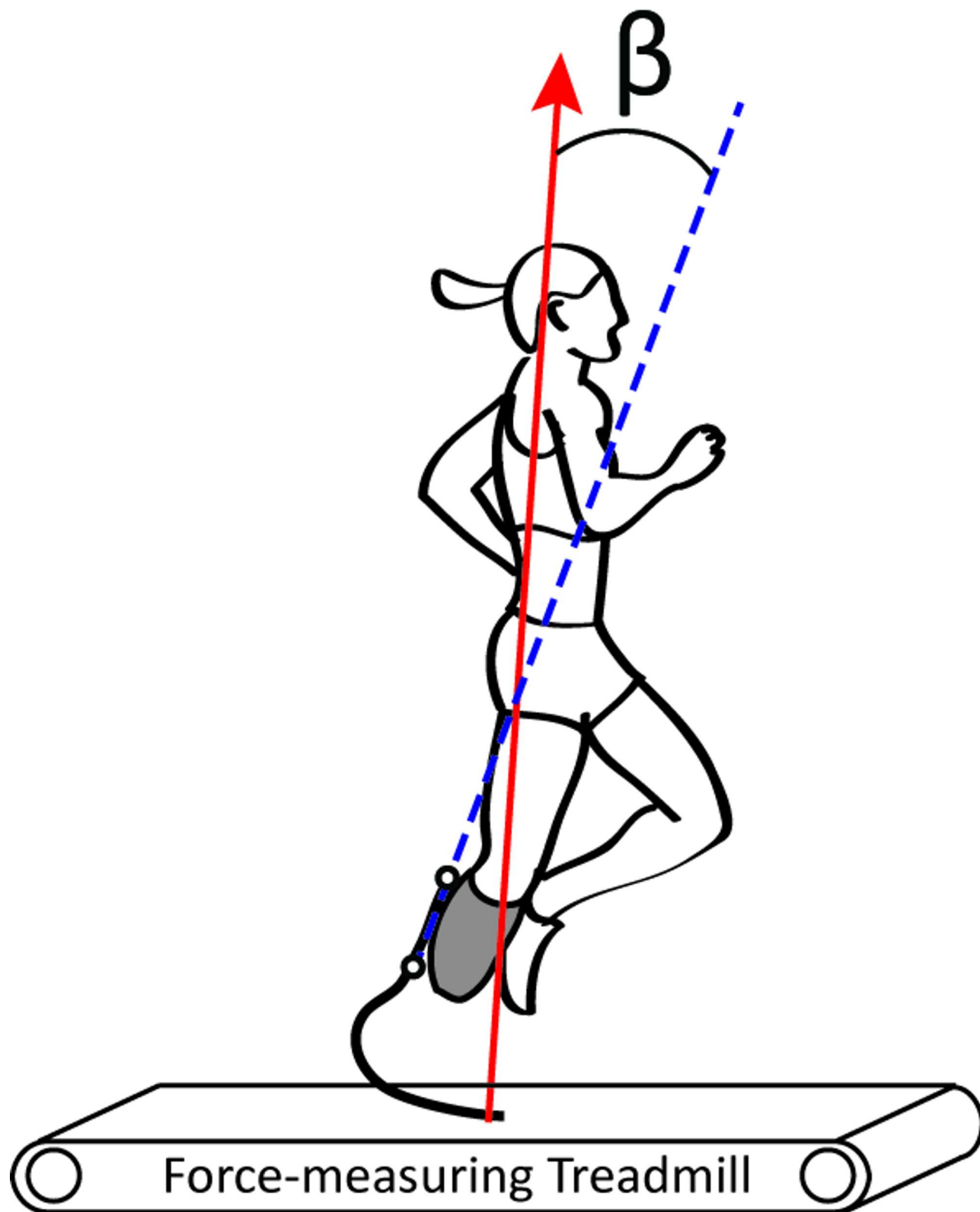


**Fig 1. Biomechanics of running.** Illustration of the calculated angle ( $\beta$ ) between the longitudinal axis of the running-specific prosthesis (dashed blue line) and the peak resultant GRF vector (solid red arrow).

doi:10.1371/journal.pone.0168298.g001

data were comparable because each participant ran both speeds at one lab, and due to the implementation of the same filtering process.

We determined the peak GRF magnitude, as well as the average sagittal plane angle of the longitudinal axis for each athlete's RSP relative to the peak resultant GRF vector from 10 consecutive ground contacts with the affected leg. We assessed the average angles for trials performed with C-shaped RSPs at 3 m/s ( $\alpha_3$ ) and 6 m/s ( $\alpha_6$ ), and with J-shaped RSPs at 3 m/s ( $\beta_3$ ) and 6 m/s ( $\beta_6$ ). When the RSP's longitudinal axis is parallel to the peak resultant GRF vector, the RSP is at 0°. Positive angles indicate that the proximal longitudinal axis was rotated forward in the sagittal plane relative to the peak resultant GRF vector (Fig 1). Sequentially, we implemented the measured angles ( $\alpha_3$ ,  $\alpha_6$ ,  $\beta_3$ , and  $\beta_6$ ) and peak resultant GRF magnitudes into our prosthetic testing procedure.

## Running-Specific Prostheses

Three prosthetic manufacturers, Össur (Reykjavik, Iceland), Freedom Innovations (Irvine, CA, USA), and Ottobock (Duderstadt, Germany) donated a combined total of 55 RSPs for use in our study. We characterized prosthetic stiffness profiles and hysteresis magnitudes from 14 C-shaped Össur Flex-Run prostheses (stiffness categories 3 low–7 high), 12 C-shaped Freedom Innovations Catapult FX6 prostheses (stiffness categories 2–7), 14 J-shaped Ottobock 1E90 Sprinter prostheses (stiffness categories 1–5), and 15 J-shaped Össur Cheetah Xtend prostheses (stiffness categories 2–7) (Fig 2) (Table 1). The unique design of the Catapult prosthesis allows for stiffness modifications via interchangeable carbon-fiber supports (PowerSprings) that are designed to supplement overall stiffness [20] (Fig 2). PowerSprings have designated stiffness categories based on the manufacturer's categorization. We tested each Catapult with the PowerSpring of the matching stiffness category (e.g. a category 2 Catapult with a category 2 PowerSpring).

## Stiffness Testing

To assess prosthetic stiffness and hysteresis at conditions that matched those of our analyzed running data, we fabricated an aluminum attachment to secure the RSPs on to the force transducer of our materials testing machine (Instron Series 5859, Norwood, MA, USA) (Fig 2). We also constructed an aluminum rotating base and fixed it under each C-shaped RSP at 0°,  $\alpha_3$ , and  $\alpha_6$ , as well as under each J-shaped RSP at 0°,  $\beta_3$ , and  $\beta_6$  (Fig 2). We applied three successive loading and unloading cycles at 100 N/s on each RSP for each condition. This loading rate was relatively fast and ensured that our materials testing machine operated within the safe speed range, even with our most compliant RSPs. Three compressive loading and unloading cycles matched the number of cycles from Brüggeman et al. [8].

To determine the peak GRF magnitude applied on each RSP, we considered the heaviest manufacturer recommended body weight for each prosthetic stiffness category, then multiplied it by 3.0 to replicate the upper limit of peak GRFs typically produced by affected legs while running 3 m/s [16], and by 3.5 to replicate the upper limit of peak GRFs produced by affected legs while running 6 m/s [16]. We compared the effects of testing angle and prosthetic height on stiffness and hysteresis by evaluating prosthetic compression with an applied peak resultant GRF of 3.0 times the largest recommended body weight for each RSP. We minimized shearing forces by using a low-friction roller-system beneath each RSP that allowed anterior and posterior translation while maintaining the angle of the applied force relative to the longitudinal axis (Fig 2) [30]. We set the threshold for force detection at 10 N. We recorded applied force magnitudes and prosthetic displacement measurements at 10 Hz, which, when combined

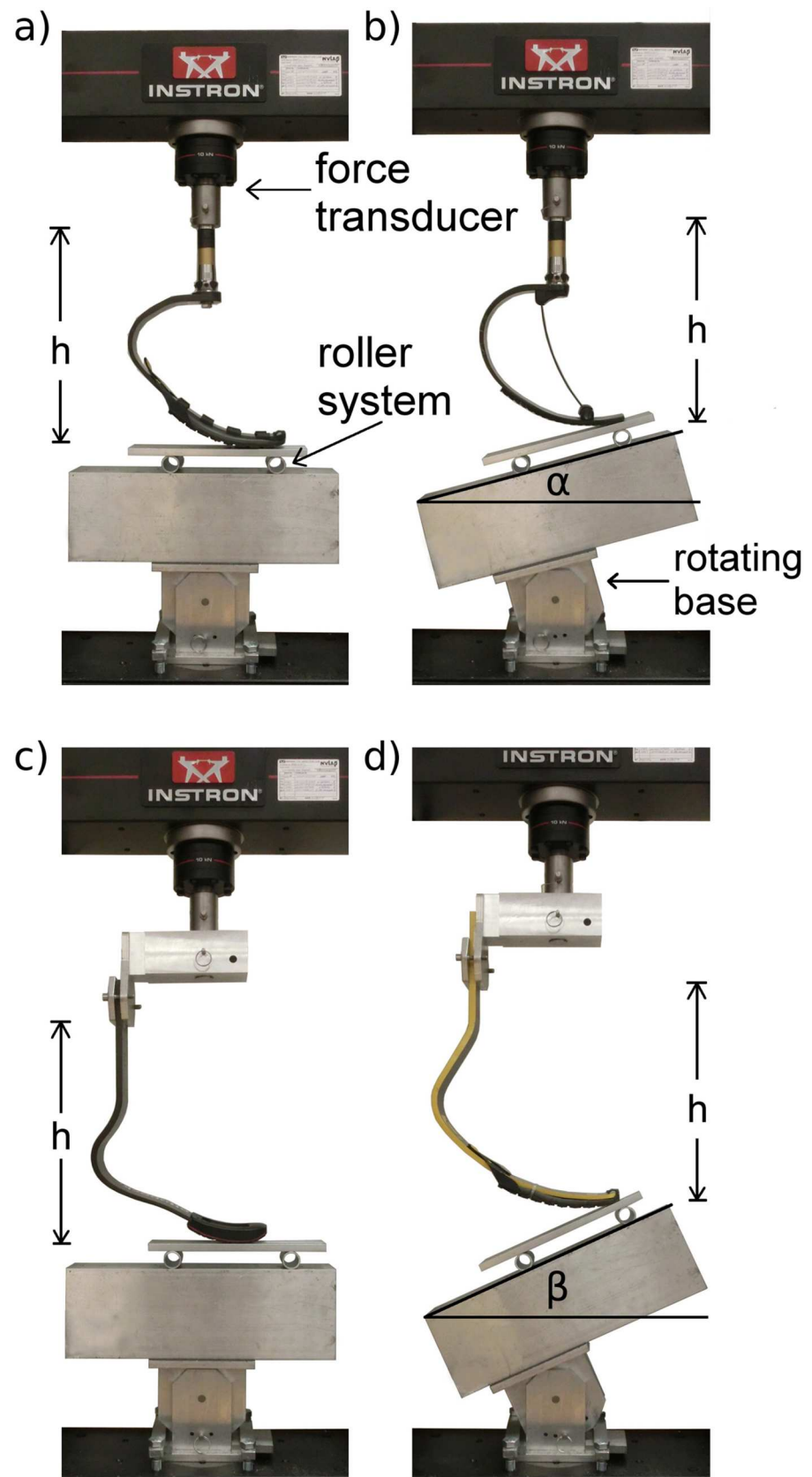


**Fig 2. Material testing setup with each running specific-prosthetic model.** Each running specific-prosthesis (RSP) was tested with the respective manufacturer's rubber sole (Össur Cheetah Xtend prosthesis was equipped with an Össur Flex-Run's sole), using our rotating base, and low-friction roller system. a) An Össur Flex-Run prosthesis (C-shaped) tested at  $0^\circ$ . b) A Freedom Innovations Catapult prosthesis (C-shaped) tested at  $\alpha^\circ$  (3 m/s). c) An Ottobock 1E90 Sprinter prosthesis (J-shaped) tested at neutral ( $0^\circ$ ). d) An Össur Cheetah Xtend prosthesis (J-shaped) tested at  $\beta^\circ$  (6 m/s). h indicates prosthetic height.

doi:10.1371/journal.pone.0168298.g002

with the loading rate (100 N/s), allowed the measurement of force-displacement data from every 10 N of applied force; ~150 to 400 data points per loading cycle.

To determine the effect of prosthetic height on the stiffness of C-shaped RSPs, we tested the Catapult and Flex-Run prostheses at 38.2 cm and 69.7 cm by altering the aluminum pylon height. To determine the effect of height on the stiffness of J-shaped RSPs, we tested the 1E90 Sprinter prostheses at 25.0, 31.5, and 38.0 cm, and the Cheetah Xtend prostheses at 31.5, 38.0, and 41.5 cm. Prosthetic height was measured vertically from the ground to the base of our height adjustment attachment in an unloaded state (Fig 2). We chose to test C-shaped RSPs across the largest possible height range given our components. We tested J-shaped RSPs at heights that spanned the largest possible range while allowing matched height comparisons (31.5 cm and 38.0 cm) between different models.

**Table 1. The manufacturer recommended running-specific prosthesis (RSP) stiffness categories with the corresponding body mass for distance running and sprinting, plus the quantity of RSPs tested.**

| RSP Model                        | Stiffness Category | Body Mass (kg)   |           | Quantity of RSPs |
|----------------------------------|--------------------|------------------|-----------|------------------|
|                                  |                    | Distance Running | Sprinting |                  |
| Össur Flex-Run                   | 3 Low              | 53–56            | N/A       | 1                |
|                                  | 3 High             | 56–59            |           | 1                |
|                                  | 4 Low              | 60–64.5          |           | 1                |
|                                  | 4 High             | 64.5–68          |           | 2                |
|                                  | 5 Low              | 69–73            |           | 1                |
|                                  | 5 High             | 73–77            |           | 2                |
|                                  | 6 Low              | 78–83            |           | 1                |
|                                  | 6 High             | 83–88            |           | 2                |
|                                  | 7 Low              | 89–94.5          |           | 1                |
|                                  | 7 High             | 94.5–100         |           | 2                |
| Freedom Innovations Catapult FX6 | 2                  | 53–59            | N/A       | 2                |
|                                  | 3                  | 60–68            |           | 2                |
|                                  | 4                  | 69–77            |           | 2                |
|                                  | 5                  | 78–88            |           | 2                |
|                                  | 6                  | 89–100           |           | 2                |
|                                  | 7                  | 101–116          |           | 2                |
| Ottobock 1E90 Sprinter           | 1                  | 40–59            | 40–52     | 3                |
|                                  | 2                  | 60–70            | 53–63     | 3                |
|                                  | 3                  | 71–86            | 64–79     | 3                |
|                                  | 4                  | 87–102           | 80–95     | 3                |
|                                  | 5                  | 103–118          | 96–111    | 3                |
| Össur Cheetah Xtend              | 2                  | 53–59            | 53–59     | 2                |
|                                  | 3                  | 60–68            | 60–68     | 2                |
|                                  | 4                  | 69–77            | 69–77     | 3                |
|                                  | 5                  | 78–88            | 78–88     | 3                |
|                                  | 6                  | 89–100           | 89–100    | 3                |
|                                  | 7                  | 101–116          | 101–116   | 2                |

doi:10.1371/journal.pone.0168298.t001

## Analyses

To characterize prosthetic stiffness, we calculated the average coefficients of determination ( $R^2$ ) for linear and curvilinear characterizations of the applied force relative to the vertical displacement for each 3-cycle trial. Next, we averaged  $R^2$  values within and across trials for a given prosthetic model, stiffness category, height, and testing angle combination. Furthermore, we calculated average prosthetic stiffness for each model across stiffness categories using the force-displacement function during simulated running conditions.

For every cycle, we calculated hysteresis as the ratio of energy lost during recoil relative to the energy stored during compression, then expressed it as a percentage:

$$\text{Hysteresis} = \frac{\int_0^H F(h)dh - \int_H^0 F(h)dh}{\int_0^H F(h)dh} \times 100 \quad (2)$$

where  $F$  is the applied force as a function of the change in prosthetic height ( $h$ ) and peak change in prosthetic height ( $H$ ) of the corresponding cycle. Hysteresis was averaged for each 3-cycle trial, and averaged across trials of the same prosthetic model, stiffness category, height, and testing angle. We measured prosthetic stiffness and hysteresis with the respective manufacturers supplied rubber sole. We also measured the stiffness and hysteresis of the highest stiffness category from each model at  $0^\circ$  without the rubber sole.

## Statistical Analyses

We used paired two-tailed t-tests to compare average  $R^2$  values from linear and curvilinear force-displacement functions across prosthetic models and to compare the manufacturer recommended stiffness across prosthetic models for athletes at body masses of 55 kg to 100 kg in 5 kg increments using the average angles and peak applied force magnitudes produced at 3 m/s ( $\alpha_3$  and  $\beta_3$ ) from the C- and J-shaped RSPs, respectively. We also used paired two-tailed t-tests to compare the prescribed stiffness of different prosthetic models for athletes at body masses of 55 kg to 100 kg in 5 kg increments using the average angles and peak applied force magnitudes produced at 6 m/s ( $\alpha_6$  and  $\beta_6$ ) from the C- and J-shaped RSPs, respectively. The recommended stiffness values for J-shaped RSPs were calculated using the tallest mutual height (38 cm).

Moreover, for C-shaped RSPs, we used linear mixed models to compare 1) prosthetic stiffness and 2) hysteresis for each prosthetic model across stiffness categories, testing angles, and interaction effects. For the J-shaped RSPs we included prosthetic height as an independent variable and used two linear mixed models to compare 1) prosthetic stiffness and 2) hysteresis for each prosthetic model across stiffness categories, testing angles, and heights, in addition to their interactions. We performed paired two-tailed t-tests to assess the influence of the prosthetic sole on stiffness and hysteresis. We carried out our statistical analyses using R-studio (Boston, MA, USA) software. Significance was set at  $p < 0.05$ . When applicable, we implemented the Bonferroni correction to account for multiple comparisons.

## Results

### Subject Data

When participants used C-shaped RSPs to run 3 m/s, the average angle of their RSP's longitudinal axis relative to the peak resultant GRF was  $15.1^\circ \pm 4.8^\circ$  and the mean peak resultant GRF was  $2.5 \pm 0.3$  times body weight. At 6 m/s the average angle was  $10.0^\circ \pm 4.2^\circ$  and the peak resultant GRF was  $2.7 \pm 0.3$  times body weight. When participants used a J-shaped RSP to run 3 m/s, the average angle of their RSP's longitudinal axis relative to the peak resultant GRF was  $20.9^\circ$

$\pm 8.9^\circ$  while the average peak resultant GRF was  $2.6 \pm 0.3$  times body weight. At 6 m/s, the average angle was  $24.2^\circ \pm 9.3^\circ$  and the average peak resultant GRF magnitude was  $2.8 \pm 0.3$  times body weight. Since our custom base was constructed to rotate in incremental steps, we used the following values for RSP testing:  $\alpha_3 = 15.0^\circ$ ,  $\alpha_6 = 10.0^\circ$ ,  $\beta_3 = 20.0^\circ$ , and  $\beta_6 = 25.0^\circ$ .

### Prosthetic force-displacement characteristics

Overall, characterizing the slope of the force-displacement curves with a 2<sup>nd</sup> degree polynomial explained 4.4% more of the variance than a linear function using angles indicative of 3 m/s and 6 m/s ( $p < 0.001$ ) (Fig 3). At a testing angle of  $0^\circ$ , a 2<sup>nd</sup> degree polynomial explained 5.0% more of the variance than using a linear function ( $p < 0.001$ ). We did not explore functions beyond a 2<sup>nd</sup> degree polynomial due to its impeccable fit (average  $R^2 = 0.998$ ).

### Prosthetic Prescription

Using the peak resultant GRFs and angles produced at 3 m/s, the actual stiffness of the manufacturer recommended Cheetah Xtend, which is prescribed based on user body mass, was 4% to 15% stiffer than the Flex-Run ( $p < 0.001$ ), 7% to 19% stiffer than the Catapult ( $p < 0.001$ ), and 20% to 28% stiffer than the 1E90 Sprinter ( $p < 0.001$ ) prostheses across matched user body masses (Fig 4). Using the peak resultant GRFs and angles produced at 6 m/s, the manufacturer recommended Cheetah Xtend prostheses were the same stiffness as the Flex-Run ( $p = 0.166$ ), 0% to 22% less stiff than the Catapult ( $p = 0.001$ ), and 3% to 21% stiffer than the 1E90 Sprinter ( $p < 0.001$ ) prostheses at matched user body masses (Fig 4). The Flex-Run and Catapult prostheses are not specifically recommended for fast running/sprinting; therefore we used manufacturer recommended stiffness categories for distance running at 6 m/s.

Prosthetic stiffness depends on peak GRF magnitude; hence we calculated the average 2<sup>nd</sup> order polynomial equations for each prosthetic model and stiffness category (S1-S4) so that prosthetists can predict an athlete's prosthetic stiffness from the amount of force they apply on the ground and/or prosthetic compression. For those unable to quantify force magnitudes or compression, and because of the relatively linear force-displacement relationships (average  $R^2 = 0.956$ ), we also report average linear stiffness values (Table 2).

### Hysteresis

The percentage of mechanical energy lost per cycle for C-shaped RSPs across conditions averaged 5.14% (SD: 0.70%). For every  $1^\circ$  increase in testing angle, the hysteresis magnitude decreased 0.04% ( $p < 0.001$ ). The average hysteresis for J-shaped RSPs across conditions was 4.28% (SD: 0.65%), which was lower than that of the C-shaped RSPs ( $p < 0.001$ ). Furthermore, testing angle affected the hysteresis of J-shaped RSPs ( $p < 0.001$ ), while height had no effect ( $p = 0.215$ ). For every  $1^\circ$  increase in testing angle, the hysteresis of the 1E90 Sprinter and Cheetah Xtend prostheses decreased 0.01% and 0.08%, respectively ( $p < 0.001$ ). Additionally, removing the rubber soles from C- and J-shaped RSPs reduced the hysteresis magnitudes by 42% ( $p < 0.001$ ).

### Effect of angle and height on prosthetic stiffness

While controlling for prosthetic height, every  $1^\circ$  increase in testing angle decreased the stiffness of the Flex-Run and Catapult prostheses by 0.41 kN/m ( $p < 0.001$ ) and 0.79 kN/m ( $p < 0.001$ ), respectively (Fig 3). Every  $1^\circ$  increase in testing angle decreased the stiffness of the 1E90 Sprinter and Cheetah Xtend prostheses by 0.45 kN/m ( $p < 0.001$ ) and 0.76 kN/m ( $p < 0.001$ ), respectively. Moreover, at a fixed testing angle, every 1 cm increase in height decreased the stiffness of both J-shaped RSPs by 0.27 kN/m ( $p < 0.001$ ). Despite a drastic pylon height difference

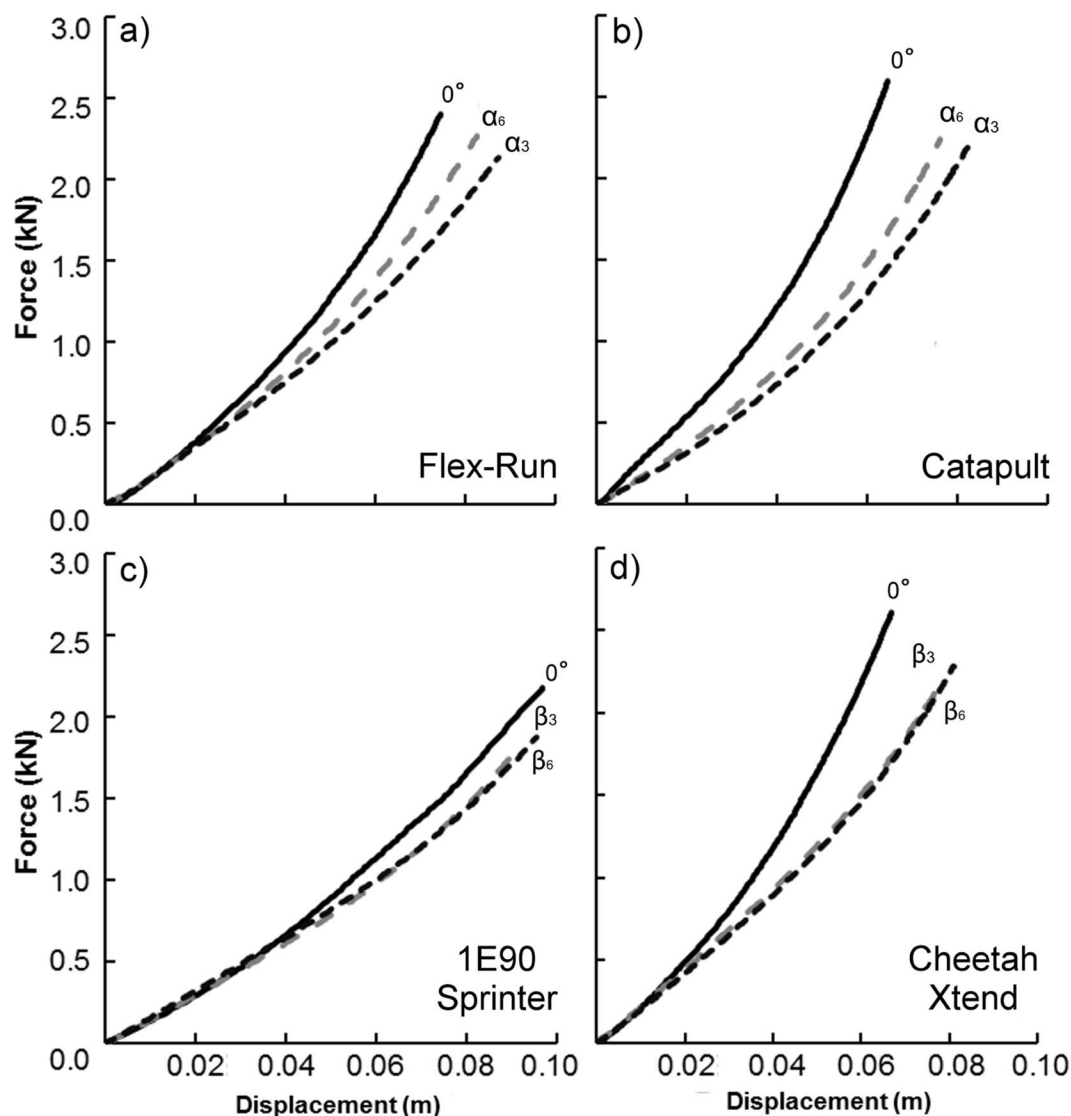


**Fig 3. Representative force-displacement profiles for running-specific prosthetic models at each testing angle.** Each running-specific prosthesis (RSP) is the manufacturer recommended stiffness category for a 70 kg distance runner.  $\alpha_3$  and  $\beta_3$  indicate the measured angle between the RSP and peak resultant ground reaction force (GRF) vector while running 3 m/s using the C-shaped RSPs (Flex-Run and Catapult) and J-shaped RSPs (1E90 Sprinter and Cheetah Xtend), respectively.  $\alpha_6$  and  $\beta_6$  indicate the measured angles between the RSP and peak resultant GRF vector while running 6 m/s using the C-shaped RSPs and J-shaped RSPs, respectively. a) The Flex-Run prosthesis at testing angles of  $0^\circ$ ,  $\alpha_3$ , and  $\alpha_6$ , b) the Catapult prosthesis at testing angles of  $0^\circ$ ,  $\alpha_3$ , and  $\alpha_6$ , c) the 1E90 Sprinter prosthesis at testing angles of  $0^\circ$ ,  $\beta_3$ , and  $\beta_6$ , and d) the Cheetah Xtend prosthesis at testing angles of  $0^\circ$ ,  $\beta_3$ , and  $\beta_6$ .

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(31.5 cm), preliminary testing revealed no effect of height on the stiffness of C-shaped RSPs; therefore we did not further test the effect of height across C-shaped RSPs. Furthermore, removing the rubber soles did not affect prosthetic stiffness across models ( $p = 0.151$ ).

## Discussion

Despite well-characterizing the force-displacement relationships of the RSPs (average  $R^2 = 0.956$ ), a linear function did not fit quite as well as a 2<sup>nd</sup> degree polynomial function

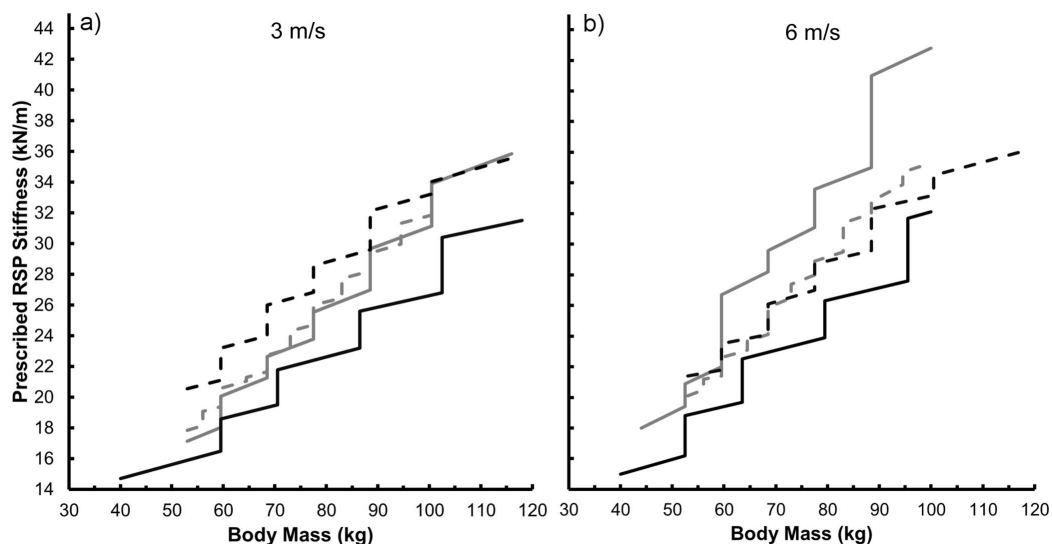


**Fig 4. Prescribed prosthetic stiffness.** The average stiffness (kN/m) of each running-specific prosthesis (RSP) as a function of the respective manufacturer's recommended user body mass (kg) at running speeds of 3 m/s (a), and 6 m/s (b). The stiffness of each RSP was calculated using peak applied force magnitudes that simulated running 3 m/s ( $\alpha_3$  and  $\beta_3$ ) and 6 m/s ( $\alpha_6$  and  $\beta_6$ ). We then calculated displacement using the mean curvilinear force-displacement profiles with the appropriate applied force magnitudes. See S1–S4 Tables.

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( $p < 0.001$ ), leading us to partially reject our initial hypothesis. Contrary to the notion that prosthetic stiffness is invariant during running [8,16–18], our data suggest that as athletes exert greater forces on the ground and/or adjust the angle between the peak resultant GRF and their RSP during stance, prosthetic stiffness is altered. For example, a 70 kg athlete that produces peak resultant GRFs of 2.2, 2.6, 3.0, 3.4 times body weight with their affected leg using a manufacturer recommended Cheetah Xtend prosthesis (height: 38 cm; angle:  $25.0^\circ$ ) would exhibit stiffness values of 25.1, 26.1, 27.1, and 28.1 kN/m, respectively. Yet, if the 70 kg athlete increased the angle of their RSP with respect to the resultant GRF from  $15^\circ$  to  $30^\circ$  in  $5^\circ$  increments, the aforementioned prosthetic stiffness values would change to 32.7, 29.9, 27.1, 24.3 kN/m. It is possible that the inverse relationship between affected leg stiffness and running

**Table 2. The manufacturer recommended average prosthetic stiffness across models based on running 3 m/s and 6 m/s.** All values include the rubber sole that comes with the prosthetic model, with the exception of the Össur Cheetah Xtend, which was equipped with the Össur Flex-Run's rubber sole.

| Users Mass (kg) | 3 m/s           |                 |                      |                      | 6 m/s           |                 |                      |                      |
|-----------------|-----------------|-----------------|----------------------|----------------------|-----------------|-----------------|----------------------|----------------------|
|                 | Flex-Run (kN/m) | Catapult (kN/m) | 1E90 Sprinter (kN/m) | Cheetah Xtend (kN/m) | Flex-Run (kN/m) | Catapult (kN/m) | 1E90 Sprinter (kN/m) | Cheetah Xtend (kN/m) |
| 55              | 18.0            | 17.4            | 16.2                 | 20.7                 | 20.4            | 20.4            | 19.0                 | 21.5                 |
| 60              | 20.6            | 20.1            | 18.6                 | 23.2                 | 22.6            | 25.8            | 19.5                 | 23.5                 |
| 65              | 22.1            | 20.8            | 19.1                 | 23.7                 | 23.7            | 27.6            | 22.7                 | 23.9                 |
| 70              | 22.9            | 22.8            | 21.8                 | 26.1                 | 26.1            | 29.9            | 23.1                 | 26.4                 |
| 75              | 23.7            | 23.5            | 22.2                 | 26.6                 | 27.7            | 30.7            | 23.5                 | 26.8                 |
| 80              | 26.2            | 25.9            | 22.7                 | 28.8                 | 29.2            | 33.7            | 26.4                 | 28.9                 |
| 85              | 26.1            | 26.5            | 23.2                 | 29.3                 | 31.3            | 34.5            | 26.8                 | 29.4                 |
| 90              | 29.5            | 29.9            | 25.9                 | 32.3                 | 33.4            | 41.2            | 27.2                 | 32.4                 |
| 95              | 31.4            | 30.5            | 26.3                 | 32.7                 | 34.7            | 42.0            | 27.6                 | 32.8                 |
| 100             | 31.8            | 31.1            | 26.7                 | 33.2                 | 35.3            | 42.8            | 32.1                 | 33.1                 |

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speed found in McGowan et al. [16] can be attributed to decreased prosthetic stiffness via increased angles between the resultant GRF vectors and RSPs at faster speeds.

Overall, mechanically testing RSPs at 0° overestimates prosthetic stiffness (linear) by 10% to 39% compared to using angles utilized by athletes with transtibial amputations while running at 3 m/s and 6 m/s. Previous studies have tested the stiffness of RSPs at 0° [8], and 30° [19]. We compared our methodology to that of Brüggeman et al. [8] by acquiring the same prosthetic model (Össur Cheetah) as the previous study, replicating their protocol (applied force: 1500 N, testing angle: 0°, loading velocity: 1 m/min), and then using our method (applied force: 2724 N, testing angle: 25°, loading velocity: 100 N/s) to determine stiffness. Brüggeman et al.'s protocol resulted in a prosthetic stiffness (linear) of 34.2 kN/m, whereas our protocol resulted in a linear stiffness of 29.2 kN/m. These discrepancies suggest that prosthetic stiffness testing procedures should be standardized.

We reject our second hypothesis; manufacturer recommended prosthetic stiffness varies across models for a given user body mass and activity. Additionally, we compared manufacturer recommended prosthetic stiffness during running at 6 m/s versus at 3 m/s. At a given body mass (prosthetic height of 38 cm), the manufacturer recommended 1E90 Sprinter prostheses were 11% stiffer at 6 m/s compared to 3 m/s across a 45 kg span in user body mass ( $p = 0.003$ ). Also, the recommended Catapult prosthetic stiffness increased 32% due to a greater recommended prosthetic stiffness category and reduced angle between the RSP and peak resultant GRF (Fig 4). Conversely, the Cheetah Xtend prostheses are recommended at the same stiffness categories for 3 m/s and 6 m/s [24], and thus the stiffness values varied by <1% (Bonferroni corrected  $p$ -value:  $p = 0.080$ ). Prosthetic stiffness requirements may be different for running at various speeds due to the different mechanical demands of the respective tasks. Future studies are needed to assess the effects of prosthetic stiffness on distance running and sprinting performance.

Since testing angle affected hysteresis, we also reject our third hypothesis stating that prosthetic hysteresis would be invariant across testing conditions. Intriguingly, RSPs dissipate less energy when their proximal end is rotated forward with respect to the applied force. Future studies are needed to examine prosthetic designs and decipher why RSPs display less hysteresis when rotated forward. Due to the importance of mechanical energy return on running and sprinting performance [4,5], the designs of future RSPs should be developed to mitigate mechanical energy dissipation.

Moreover, prosthetic hysteresis was 42% lower when we removed the rubber soles, indicating that the rubber soles were responsible for almost half of the dissipated energy. Athletes with leg amputations should use soles with minimal damping to maximize the mechanical energy return of RSPs. In addition to the sole, energy dissipation probably occurs at the residual limb/socket interface. To our knowledge, no study has quantified the mechanical behavior of the residual limb and socket interface while running. Improving socket design by enhancing the connection between athletes and their RSPs may allow better utilization of the returned mechanical energy and potentially improve running performance.

Pylon height does not affect the stiffness of C-shaped RSPs; therefore, we reject our final hypothesis. The aluminum pylon of C-shaped RSPs has an annular section (i.e. an empty cylinder) and appears less prone to bending due to the perpendicular components of the applied compression forces, and due to a higher area moment of inertia [31] compared to the rectangular section of J-shaped RSPs. Increasing the overall length of the aluminum pylon technically reduces its overall stiffness, but the lengths used in our measurements were not enough to elicit a measurable difference. The height of RSPs needs to be within a relatively narrow range for athletes with unilateral amputations due to their unaffected leg length. Therefore prosthetic stiffness adjustments would primarily be accomplished by changing stiffness category or

sagittal plane angle. On the other hand, athletes with bilateral amputations can consider a wide range of heights and stiffness categories to achieve a specified prosthetic stiffness; however, height and stiffness may affect running performance in different ways. In addition to stiffness, the effects of prosthetic height and alignment on performance warrant future research.

We assumed that the C-shaped RSPs were perpendicular to the respective pylons. Yet, the sagittal plane RSP-pylon alignment may have been slightly altered due to individual preference, thus our reported angles between the C-shaped RSPs and resultant GRF vectors may have been over/underestimated by a few degrees. We collected prosthetic angles and peak resultant GRFs from a cohort of exceptional athletes with unilateral transtibial amputations at 3 m/s and 6 m/s. Conceivably, less athletic individuals with amputations, or athletes with different amputation levels may not utilize the same prosthetic angles and/or generate the same resultant GRFs compared to those exhibited by our participants, and consequently prosthetic stiffness may differ. For example, athletes with transfemoral amputations with pylons connecting their RSPs to their sockets can use our reported values at 0°, as it is a fair approximation of their RSP-peak GRF angle to determine the prosthetic stiffness and hysteresis.

Our methodology does not account for the rotation of the RSP with respect to the resultant GRF throughout ground contact. It may be that RSPs are stiffer at initial and terminal ground contact than at mid-stance due to a smaller angle between the RSP and resultant GRF vector. On the other hand, as applied force accrues RSPs become stiffer, implying that RSPs are stiffest at mid-stance. The influence of angle and force may counteract each other, exhibiting a constant prosthetic stiffness throughout stance; perhaps a deliberate design choice of prosthetic manufacturers. Future studies are warranted to include a rotational component to the mechanical stiffness testing of RSPs. Furthermore, we tested our RSPs with a loading rate (100 N/s) that is much lower than that recorded during running (over 4000 N/s [16,18]). However, our low loading rate (100 N/s) enabled us to record force-displacement data from every 10 N of applied force, thus presenting ~150 to 400 data points per loading cycle. When athletes with an amputation run 6 m/s, they have a ground contact time of ~0.2 seconds [18,25]. If ground reaction forces were recorded at 2000 Hz, then 200 data points would have been collected from initial ground contact to mid-stance/peak GRF, which coincides with our material testing machines sampling versus loading rate data. Nevertheless, it is ideal for prosthetic testing to mimic the loading/unloading rates of those recorded during running; unfortunately these rates are beyond the capability of our equipment.

## Conclusions

We assessed prosthetic stiffness and hysteresis across a wide range of models, stiffness categories, and heights, at forces and angles that simulate those exhibited by athletes with transtibial amputations running at 3 m/s and 6 m/s. We found that the force-displacement profiles of RSPs are curvilinear, indicating that prosthetic stiffness varies with the magnitude of applied force. Yet, a linear force-displacement characterization is strongly predictive. We also found that manufacturer recommended prosthetic stiffness varies between models, and that the height of J-shaped RSPs is inversely related to stiffness. Moreover, we provide evidence that prosthetic stiffness is much greater at 0° than at angles representative of those that occur during running.

When athletes with leg amputations change prosthetic models, height, and/or sagittal plane alignment, prosthetic stiffness also changes; therefore variations in comfort, performance, etc. may be indirectly due to altered stiffness. We propose that prosthetic stiffness should be assessed under conditions that simulate the demands of the respective activity, and that manufacturers should provide the stiffness values of each RSP at specific heights. Until then, our

study provides reference for the stiffness values of various prosthetic models across multiple stiffness categories and heights, and provides a foundation for future research to understand the potential effects of prosthetic stiffness on performance during distance running and sprinting.

## Supporting Information

**S1 Table. The stiffness and hysteresis characteristics for Össur Flex-Run prostheses at each testing condition.** The equations indicate prosthetic displacement in meters (h) used to calculate the applied force in kN. Stiffness equals applied force divided by displacement. a and b are constants. All prostheses were tested with the manufacturer supplied sole, with the exception of stiffness category 7 High No Sole.  
(DOCX)

**S2 Table. The stiffness and hysteresis characteristics for Freedom Innovations Catapult FX6 prostheses at each testing condition.** The equations indicate prosthetic displacement in meters (h) used to calculate the applied force in kN. Stiffness equals applied force divided by displacement. a and b are constants. All prostheses were tested with the manufacturer supplied sole, with the exception of stiffness category 7 No Sole.  
(DOCX)

**S3 Table. The stiffness and hysteresis characteristics for Ottobock 1E90 Sprinter prostheses at each testing condition.** The equations indicate prosthetic displacement in meters (h) used to calculate the applied force in kN. Stiffness equals applied force divided by displacement. a and b are constants. All prostheses were tested with the manufacturer supplied sole, with the exception of stiffness category 5 No Sole.  
(DOCX)

**S4 Table. The stiffness and hysteresis characteristics for the Össur Cheetah Xtend prostheses at each testing condition.** The equations indicate prosthetic displacement in meters (h) used to calculate the applied force in kN. Stiffness equals applied force divided by displacement. a and b are constants. All RSPs were tested with the supplied sole from the Össur Flex-Run prostheses, with the exception of stiffness category 7 No Sole.  
(DOCX)

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**Funding acquisition:** AMG.

**Investigation:** ONB PT AMG.

**Methodology:** ONB PT AMG.

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**Supervision:** AMG.

**Validation:** ONB PT AMG.

**Visualization:** ONB PT AMG.

**Writing – original draft:** ONB PT AMG.

**Writing – review & editing:** ONB PT AMG.

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## RESEARCH ARTICLE | *Case Studies in Physiology*

# The biomechanics of the fastest sprinter with a unilateral transtibial amputation

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**Beck ON, Grabowski AM.** The biomechanics of the fastest sprinter with a unilateral transtibial amputation. *J Appl Physiol* 124: 641–645, 2018. First published October 19, 2017; doi:10.1152/jappphysiol.00737.2017.—People have debated whether athletes with transtibial amputations should compete with nonamputees in track events despite insufficient information regarding how the use of running-specific prostheses (RSPs) affect athletic performance. Thus, we sought to quantify the spatiotemporal variables, ground reaction forces, and spring-mass mechanics of the fastest athlete with a unilateral transtibial amputation using an RSP to reveal how he adapts his biomechanics to achieve elite running speeds. Accordingly, we measured ground reaction forces during treadmill running trials spanning 2.87 to 11.55 m/s of the current male International Paralympic Committee T44 100- and 200-m world record holder. To achieve faster running speeds, the present study's athlete increased his affected leg (AL) step lengths ( $P < 0.001$ ) through longer contact lengths ( $P < 0.001$ ) and his unaffected leg (UL) step lengths ( $P < 0.001$ ) through longer contact lengths ( $P < 0.001$ ) and greater stance average vertical ground reaction forces ( $P < 0.001$ ). At faster running speeds, step time decreased for both legs ( $P < 0.001$ ) through shorter ground contact and aerial times ( $P < 0.001$ ). Unlike athletes with unilateral transtibial amputations, this athlete maintained constant AL and UL stiffness across running speeds ( $P \geq 0.569$ ). Across speeds, AL step lengths were 8% longer ( $P < 0.001$ ) despite 16% lower AL stance average vertical ground reaction forces compared with the UL ( $P < 0.001$ ). The present study's athlete exhibited biomechanics that differed from those of athletes with bilateral and without transtibial amputations. Overall, we present the biomechanics of the fastest athlete with a unilateral transtibial amputation, providing insight into the functional abilities of athletes with transtibial amputations using running-specific prostheses.

**NEW & NOTEWORTHY** The present study's athlete achieved the fastest treadmill running trial ever attained by an individual with a leg amputation (11.55 m/s). From 2.87 to 11.55 m/s, the present study's athlete maintained constant affected and unaffected leg stiffness, which is atypical for athletes with unilateral transtibial amputations. Furthermore, the asymmetric vertical ground reaction forces of athletes with unilateral transtibial amputations during running may be the result of leg length discrepancies.

amputee; force; paralympic; prosthesis; sprint

## INTRODUCTION

The fastest humans can achieve running speeds  $>12$  m/s during track competitions (18). Running speed equals the product of stride length and stride frequency, where one stride comprises two steps. Humans increase step length by furthering the horizontal distance traveled by their center of mass (CoM) during ground contact (contact length) and/or by applying a greater average vertical force on the ground relative to body weight (23, 24). Step frequency is improved by decreasing step time, which is the sum of ground contact time and subsequent aerial time (23, 24).

The running speed of athletes with leg amputations is constrained by the same spatiotemporal and vertical ground reaction force (GRF) variables as nonamputees (22). During running, athletes with leg amputations use passive-elastic carbon-fiber running-specific prostheses (RSPs). These devices attach in-series to carbon-fiber sockets that encompass the residual limbs and facilitate the fundamental spring-like behavior of level-ground running (3–5, 19). Unlike biological legs, RSPs cannot generate mechanical power *de novo* or adjust stiffness neurally during running (1). Also, the overall affected leg stiffness of athletes with unilateral transtibial amputations is inversely related to running speed, whereas their overall unaffected leg stiffness is independent of running speed (19). Despite differences between purely biological and RSP incorporated legs, RSPs have enabled many athletes with leg amputations to compete with nonamputees in track races ranging from regional competitions to the Olympic Games.

The running performances of extraordinary athletes with transtibial amputations have been controversial because of the use of RSPs, rather than purely biological legs (14, 22). However, in spite of the ongoing conversation regarding whether athletes with transtibial amputations should compete with nonamputees in running events (17, 21), the running biomechanics of the fastest athlete with a unilateral transtibial amputation using an RSP are unknown. Thus, to uncover the capabilities of athletes with unilateral transtibial amputations using RSPs, we sought to establish how the fastest athlete with a unilateral transtibial amputation using an RSP modulates spatiotemporal variables, GRFs, and spring-mass mechanics across a wide range of running speeds, including top speed.

## METHODS

One male athlete with a unilateral transtibial amputation participated [age: 23 yr, height: 1.90 m, mass: 84.5 kg, unaffected leg (UL)

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length from the greater trochanter to the floor during standing: 1.03 m, affected leg (AL) length from the greater trochanter to the distal end of the unloaded RSP: 1.09 m, cause of amputation: trauma]. We tested this athlete during the preseason of his competition cycle that concluded with two International Paralympic Committee male T44 classification (25) world records: 10.61 s for 100 m and 21.27 s for 200 m (26). Before participation, this athlete gave informed written consent according to the protocol approved by the Colorado Multiple Institutional Review Board and the United States Army Medical Research and Materiel Command Office of Research Protection, Human Research Protection Office.

**Protocol.** Following a treadmill running warm-up, the athlete performed a set of treadmill running trials (Treadmetrix, Park City, UT) using a stiffness category 7 Össur Cheetah Xtreme RSP (Össur, Reykjavík, Iceland). The running trials were performed in the following order: 2.87, 3.84, 4.60, 5.62, 6.51, 7.50, 8.35, 9.21, 10.14, 10.48, and 11.55 m/s. Each trial began with the athlete standing on the static treadmill belt. Next, he and the treadmill belt accelerated until belt speed plateaued; at that point, we began counting his steps. For each trial, the athlete maintained forward position on the treadmill while taking 18 consecutive steps (14, 19, 22, 24). Ad libitum rest preceded each trial.

**Data analysis.** Athletes with unilateral transtibial amputations exhibit asymmetric spatiotemporal, GRF, and spring-mass model variables between legs while running (3, 14, 19, 20); accordingly, we quantified the respective variables from each leg separately. We determined running speed ( $v$ ) as treadmill belt speed. Biomechanically, running speed ( $v$ ) is the product of step length ( $L_{\text{step}}$ ) and step frequency ( $\text{Freq}_{\text{step}}$ ).

$$v = (\text{AL } L_{\text{step}} \times \text{AL } \text{Freq}_{\text{step}} + \text{UL } L_{\text{step}} \times \text{UL } \text{Freq}_{\text{step}}) / 2 \quad (1)$$

Steps lengthen by increasing contact length ( $L_c$ ) and/or stance average vertical GRF ( $F_{\text{avg}}$ ) relative to body weight (BW) including running gear (23, 24).

$$L_{\text{step}} = L_c \times F_{\text{avg}} / \text{BW} \quad (2)$$

We calculated step frequency as the reciprocal of step time ( $t_{\text{step}}$ ), which equals the sum of the ground contact time ( $t_c$ ) and subsequent aerial time ( $t_a$ ) (23, 24).

$$\text{Freq}_{\text{step}} = \frac{1}{t_{\text{step}}} = \frac{1}{t_c + t_a} \quad (3)$$

For our analyses, we calculated  $L_{\text{step}}$  as  $t_{\text{step}}$  multiplied by  $v$  (treadmill belt speed).

We calculated overall leg stiffness ( $k_{\text{leg}}$ ) as peak vertical GRF ( $F_{\text{peak}}$ ) divided by peak leg spring compression ( $\Delta L$ ) during ground contact in accordance with Farley et al. (12).

$$k_{\text{leg}} = \frac{F_{\text{peak}}}{\Delta L} \quad (4)$$

We calculated peak leg spring compression ( $\Delta L$ ) using the initial AL and UL lengths ( $L_0$ ), theta ( $\theta$ ), treadmill speed ( $v$ ), and ground contact time ( $t_c$ ).

$$\theta = \sin^{-1} \left( \frac{vt_c}{2L_0} \right) \quad (5)$$

Next, we determined peak leg spring compression ( $\Delta L$ ) using peak vertical displacement of the CoM during ground contact ( $\Delta y$ ), calculated by twice integrating the vertical acceleration of the CoM with respect to time (8).

$$\Delta L = \Delta y + L_0(1 - \cos\theta) \quad (6)$$

**Data collection.** We measured vertical and horizontal GRFs (1,000 Hz) throughout the duration of each trial, filtered them using a 4th order low-pass Butterworth filter (20-Hz cutoff), and then used the

filtered data and a 40 N vertical GRF threshold to calculate the variables in Eqs. 1 through 6 with a custom MATLAB script (Mathworks, Natick, MA).

**Statistical analyses.** We performed linear regressions for each biomechanical variable from Eqs. 1 to 6 across running speeds. We used paired two-tailed  $t$ -tests to assess the influence of the AL vs. UL on each biomechanical variable across running speeds. We set the level of significance at  $P = 0.05$  and performed statistical analyses using R-studio (Boston, MA).

## RESULTS

Some trials contained steps where the treadmill and athlete were still accelerating to the target speed. Thus, after we removed all acceleration phase running steps, some trials contained <18 consecutive steps. Nonetheless, all trials comprised  $\geq 6$  consecutive steps at a constant running speed (2). In addition, we measured a top speed of 11.55 m/s, which to our knowledge is the fastest treadmill running trial ever recorded for a human with a leg amputation.

From 2.87 to 11.55 m/s, AL and UL  $t_c$  decreased 55 and 51%, respectively ( $P < 0.001$ ), and AL and UL  $t_a$  decreased 39 and 41%, respectively ( $P < 0.001$ ) (Fig. 1). This led to a 47 and 46% decreased AL and UL  $t_{\text{step}}$  ( $P < 0.001$ ) and a 107 to 108% increased AL and UL  $L_{\text{step}}$ , respectively ( $P < 0.001$ ) (Fig. 2). Additionally, from 2.87 to 11.55 m/s, AL  $L_c$  increased 82% (AL  $L_c = 0.055 \text{ speed} + 0.478$ ;  $R^2 = 0.93$ ;  $P < 0.001$ ), UL  $L_c$  increased 96% (UL  $L_c = 0.052 \text{ speed} + 0.480$ ;  $R^2 =$

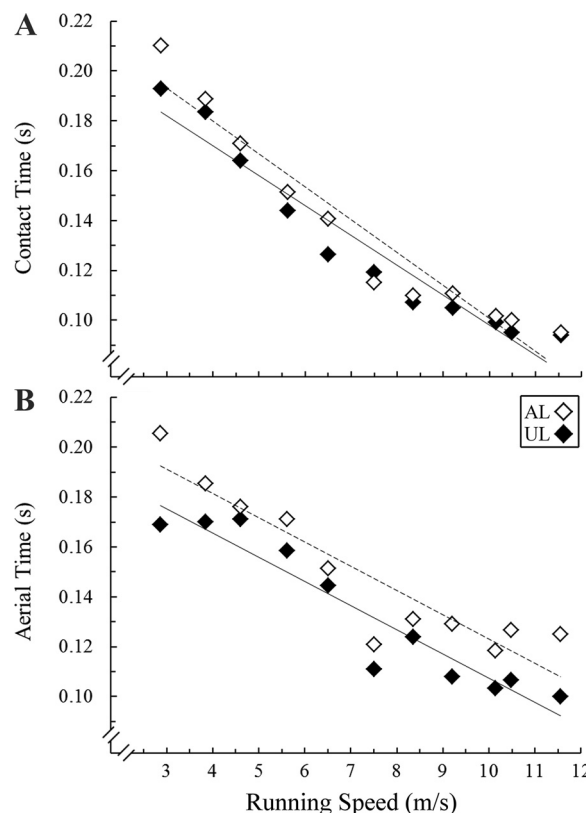


Fig. 1. Ground contact time ( $t_c$ , A) and aerial time ( $t_a$ , B) for the AL and UL across running speeds ( $v$ ). Broken lines, AL regression lines; solid lines, UL regression lines. The following are the respective regression equations: AL  $t_c = -0.013v + 0.233$ ;  $R^2 = 0.93$ ;  $P < 0.001$ . UL  $t_c = -0.012v + 0.218$ ;  $R^2 = 0.93$ ;  $P < 0.001$ . AL  $t_a = -0.010v + 0.220$ ;  $R^2 = 0.85$ ;  $P < 0.001$ . UL  $t_a = -0.010v + 0.205$ ;  $R^2 = 0.90$ ;  $P < 0.001$ .

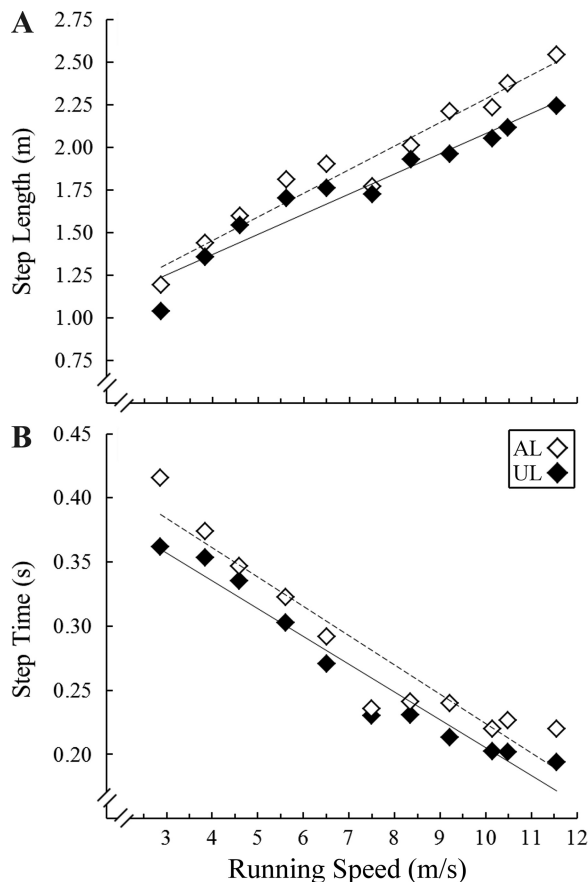


Fig. 2. Step length ( $L_{\text{step}}$ , A) and step time ( $t_{\text{step}}$ , B) for the affected leg (AL) and unaffected leg (UL) over the range of running speeds ( $v$ ). Broken lines, AL regression lines; solid lines, UL regression lines. The following are the respective regression equations: AL  $L_{\text{step}} = 0.14v + 0.90$ ;  $R^2 = 0.95$ ;  $P < 0.001$ . UL  $L_{\text{step}} = 0.12v + 0.90$ ;  $R^2 = 0.93$ ;  $P < 0.001$ . AL  $t_{\text{step}} = -0.023v + 0.453$ ,  $R^2 = 0.90$ ;  $P < 0.001$ . UL  $t_{\text{step}} = -0.022v + 0.423$ ;  $R^2 = 0.95$ ;  $P < 0.001$ .

0.95;  $P < 0.001$ ), and UL  $F_{\text{avg}}$  increased 10% ( $P = 0.001$ ) (Fig. 3 and Table 1). Over the speed range, AL peak braking GRF increased 230% ( $y = -0.025x + 0.014$ ;  $R^2 = 0.90$ ;  $P < 0.001$ ), UL peak braking GRF increased 466% ( $y = -0.082x - 0.021$ ;

$R^2 = 0.83$ ;  $P < 0.001$ ), and AL peak propulsive GRF increased 183% ( $y = 0.044x + 0.166$ ;  $R^2 = 0.82$ ;  $P < 0.001$ ) (Table 1). Running speed did not affect AL  $F_{\text{avg}}$  ( $P = 0.676$ ) (Fig. 3 and Table 1) or UL peak propulsive GRF ( $P = 0.943$ ) (Table 1).

From 2.87 to 11.55 m/s, AL peak vertical GRF increased 17% ( $y = 0.05x + 2.68$ ;  $R^2 = 0.60$ ;  $P = 0.005$ ) and UL peak vertical GRF increased 16% ( $y = 0.10x + 3.11$ ;  $R^2 = 0.79$ ;  $P < 0.001$ ) (Table 1). Across running speeds, peak AL ( $y = -0.006x + 0.081$ ;  $R^2 = 0.90$ ;  $P < 0.001$ ) and UL ( $y = -0.007x + 0.091$ ;  $R^2 = 0.89$ ;  $P < 0.001$ )  $\Delta y$  decreased 76 and 69%, respectively, due in part to a 110% increased AL  $\theta$  ( $y = 0.027x + 0.217$ ;  $R^2 = 0.94$ ;  $P < 0.001$ ) and 96% increased UL  $\theta$  ( $y = 0.026x + 0.239$ ;  $R^2 = 0.91$ ;  $P < 0.001$ ). Furthermore, from 2.87 to 11.55 m/s, AL ( $y = 0.003x + 0.107$ ;  $R^2 = 0.42$ ;  $P = 0.030$ ) and UL ( $y = 0.004x + 0.116$ ;  $R^2 = 0.65$ ;  $P = 0.003$ )  $\Delta L$  increased 28 and 38%, respectively.  $k_{\text{AL}}$  ( $P = 0.569$ ) and  $k_{\text{UL}}$  ( $P = 0.941$ ) were independent of running speed (Table 1). Moreover, the only variables that were similar between the AL and UL across running speeds were peak propulsive GRF ( $P = 0.345$ ) and  $\theta$  ( $P = 0.224$ ).

## DISCUSSION

The purpose of this case study was to quantify the spatio-temporal, GRF, and spring-mass model parameters of the fastest athlete with a unilateral transtibial amputation across running speeds. From 2.87 to 11.55 m/s, this athlete increased his AL and UL step lengths from 1.19 to 2.54 m and 1.03 to 2.24 m, respectively (Fig. 2). The longer AL steps at each speed coincide with previous research suggesting that athletes with unilateral transtibial amputations exhibit similar or longer steps with their AL compared with their UL (14, 15). Also, at similar speeds, the present study's athlete exhibited AL and UL step lengths that were both within 1SD of those elicited by six athletes with unilateral transtibial amputations at their top running speeds ( $8.75 \pm 0.97$  m/s) (14). Additionally, an accomplished athlete with bilateral transtibial amputations exhibited mean step lengths of 2.03 m at 10.0 m/s (22), which is similar to the mean UL step length (2.05 m) and shorter than the mean AL step length (2.23 m) of the present study's athlete at 10.14 m/s. For further comparison, nonamputees yield mean

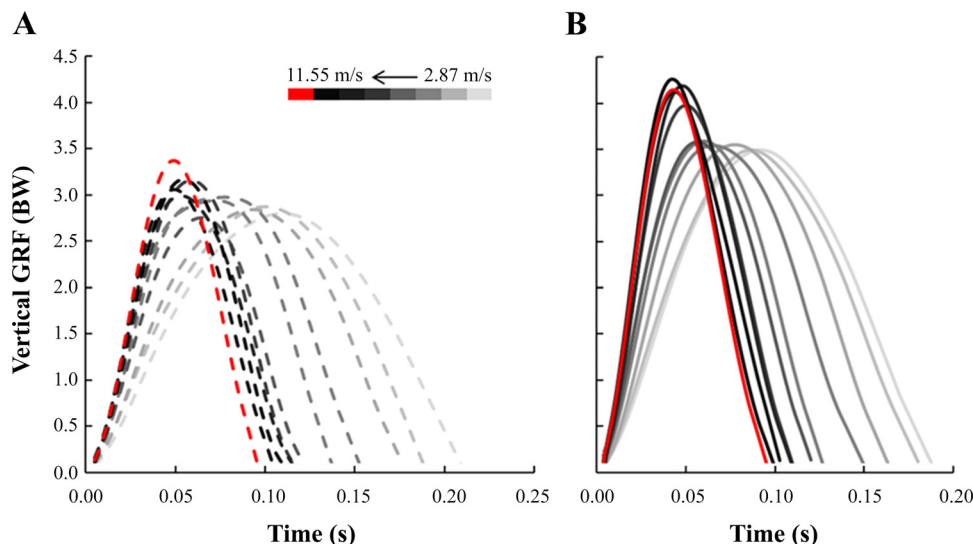


Fig. 3. Mean vertical ground reaction force (vGRF) traces from the AL (broken lines, A) and UL (solid lines, B) across running speeds (2.87–11.55 m/s). Light to dark vGRF lines indicate slower to faster running trials, with the fastest running trial in red. AL average vertical GRF ( $F_{\text{avg}}$ ) was not statistically different across running speed ( $P = 0.676$ ). The following is the regression equation: UL  $F_{\text{avg}} = 0.03v + 1.88$ ;  $R^2 = 0.72$ ;  $P = 0.001$ .

Table 1. Mean elicited vGRFs and hGRFs across running speeds for the UL and AL

| Running Speed, m/s | Peak vGRF |      | Stance Avg vGRF |      | Peak Braking hGRF |      | Peak Propulsive hGRF |      | Leg Stiffness, kN/m |      |
|--------------------|-----------|------|-----------------|------|-------------------|------|----------------------|------|---------------------|------|
|                    | UL        | AL   | UL              | AL   | UL                | AL   | UL                   | AL   | UL                  | AL   |
| 2.87               | 3.52      | 2.82 | 1.98            | 1.72 | 0.14              | 0.09 | 0.39                 | 0.25 | 24.0                | 19.9 |
| 3.84               | 3.53      | 2.85 | 1.96            | 1.76 | 0.27              | 0.08 | 0.43                 | 0.36 | 21.0                | 18.5 |
| 4.60               | 3.62      | 2.94 | 2.07            | 1.81 | 0.38              | 0.10 | 0.48                 | 0.42 | 20.6                | 17.4 |
| 5.62               | 3.61      | 3.09 | 2.07            | 1.92 | 0.53              | 0.11 | 0.49                 | 0.47 | 21.1                | 18.1 |
| 6.51               | 3.56      | 3.06 | 2.10            | 1.89 | 0.56              | 0.15 | 0.50                 | 0.47 | 21.6                | 17.0 |
| 7.50               | 3.56      | 2.81 | 2.03            | 1.64 | 0.86              | 0.18 | 0.50                 | 0.36 | 20.1                | 19.0 |
| 8.35               | 3.98      | 3.22 | 2.21            | 1.80 | 0.81              | 0.17 | 0.37                 | 0.46 | 22.0                | 19.5 |
| 9.21               | 4.22      | 3.04 | 2.29            | 1.67 | 0.86              | 0.23 | 0.41                 | 0.59 | 20.1                | 14.8 |
| 10.14              | 4.14      | 3.07 | 2.27            | 1.73 | 0.80              | 0.21 | 0.44                 | 0.62 | 22.7                | 18.2 |
| 10.48              | 4.27      | 3.29 | 2.25            | 1.83 | 0.83              | 0.30 | 0.43                 | 0.65 | 23.4                | 18.4 |
| 11.55              | 4.18      | 3.39 | 2.17            | 1.76 | 0.82              | 0.28 | 0.46                 | 0.70 | 21.2                | 18.6 |

vGRF, vertical ground reaction forces; hGRF, horizontal ground reaction forces; UL, unaffected leg; AL, affected leg. All forces are presented in units of body weight. UL and AL peak vGRF ( $P \leq 0.005$ ), UL stance average (Avg) vGRF ( $P < 0.001$ ), AL and UL peak braking hGRF ( $P < 0.001$ ), and AL peak propulsive hGRF ( $P < 0.001$ ) correlated with running speed. AL stance Avg vGRF ( $P = 0.676$ ) and UL peak propulsive hGRF ( $P = 0.943$ ) were independent of running speed.

( $\pm$ SD) step lengths of 2.04 m at  $9.20 \pm 0.59$  m/s (23), 2.11 m at  $9.25 \pm 0.37$  m/s (24), and 2.37 m at  $10.0 \pm 0.0$  m/s (22). Therefore, athletes with unilateral, bilateral, and without transtibial amputations achieve fast running speeds using different spatiotemporal variable magnitudes.

Stance average vertical GRF relative to body weight, a key determinant of step length, generally increases with faster running speeds (2, 10, 23, 24). However, this study and others have presented representative data showing that at certain speed increments, athletes with and without amputations naturally increase running speed (e.g., 6.51–7.50 m/s; Fig. 2) by decreasing their stance average vertical GRFs and considerably reducing their step times (2, 10) (Fig. 3). Thus, at these speed increments, athletes run faster by using shorter step lengths and much briefer step durations than those of the preceding slower speed. This can happen because running speed is determined from the combination of contact length, stance average vertical GRF relative to body weight, and step time (23).

The present study's athlete's AL stance average vertical GRFs and AL step lengths were lower and longer than those of his UL at each speed, respectively. Even though he exhibited longer AL contact lengths, based on Eq. 2 we would predict this athlete to exhibit shorter, not longer, AL vs. UL step lengths. Perhaps this phenomenon is related to the athlete's leg length discrepancy (the AL was 6 cm taller than the UL). For instance, AL CoM height was  $5.9 \pm 1.3$  cm taller at initial ground contact compared with UL height across speeds (paired 2-tailed  $t$ -test;  $P < 0.001$ ). Conceivably, his AL stance average vertical GRFs were lower and AL step lengths were longer than those of his UL because of the net lowering of the CoM through the AL step and the net raising of the CoM through the UL step. This notion is supported by the longer aerial times following the AL vs. UL steps (14) (Fig. 1) and by our previous study (3), which found that decreased prosthetic height elicited more symmetric stance average vertical GRFs during running at 2.5 and 3.0 m/s for athletes with unilateral transtibial amputations.

The results of the present study indicate that athletes with unilateral transtibial amputations can achieve elite top speeds (i.e.,  $>10$  m/s) while eliciting different spatiotemporal, GRF, and spring-mass model characteristics than those of athletes with bilateral and without transtibial amputations. The present

study's dataset may be implemented in future studies that compare the sprinting abilities of athletes with unilateral transtibial amputations with those of athletes with different amputation statuses. Furthermore, this investigation may be used for the development of future RSP and socket designs by providing insight into the demands placed on these devices during running. Typically,  $k_{AL}$  of athletes with transtibial amputations decreases with faster running speeds (2, 19), which contrasts the results of the present study's athlete who maintained constant  $k_{AL}$  across running speeds. Perhaps, athletes with unilateral transtibial amputations need to maintain and not decrease  $k_{AL}$  to achieve faster top speeds. Athletes with transtibial amputations may be able to maintain constant  $k_{AL}$  by using different RSP configurations (1) or altering RSP/leg segment geometry during running (13). Additionally, the present study's athlete exhibited more asymmetric spatiotemporal variables and GRFs than those of nonamputees at matched running speeds. For example, at  $9.5 \pm 0.42$  m/s, nonamputees exhibit average step length and stance average vertical GRF asymmetries of  $1.7 \pm 3.2$  and  $2.0 \pm 4.5\%$  ( $\pm$ SD), respectively (16), whereas at 9.21 m/s, the present study's athlete exhibited step length and stance average vertical GRF asymmetries of 11.9 and 31.4%, respectively. Currently, it is unknown whether biomechanical asymmetries limit the top speed of athletes with unilateral transtibial amputations. Moreover, although treadmill and overground running are biomechanically similar (9), athletes only need to overcome minimal air resistance during treadmill running because of arm and leg swing (11). Hence, athletes can theoretically attain faster running speeds on a treadmill than overground.

**Conclusions.** We present spatiotemporal, GRF, and spring-mass model variables of the fastest athlete with a unilateral transtibial amputation while running at 2.87–11.55 m/s. In general, his AL spatiotemporal variables coincide with those of nonamputee sprinters, whereas his AL stance average vertical GRFs better match those from of an athlete with bilateral transtibial amputations. In contrast, the UL spatiotemporal variables of the athlete in the present study coincide with those elicited by an athlete with bilateral transtibial amputations, whereas the present study's athlete's UL stance average vertical GRFs better match those exhibited by nonamputees. Fur-

thermore, the present study's athlete maintained constant  $k_{leg}$  in both legs across running speeds, which is like that of nonamputees and dissimilar to that of athletes with transtibial amputations. In addition to these comparisons, this study provides insight regarding how the fastest athlete with a unilateral transtibial amputation using an RSP adapts his biomechanics to achieve elite running speeds.

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## DISCLOSURES

No conflicts of interest, financial or otherwise, are declared by the authors.

## AUTHOR CONTRIBUTIONS

O.N.B. and A.M.G. conceived and designed research; O.N.B. and A.M.G. performed experiments; O.N.B. and A.M.G. analyzed data; O.N.B. and A.M.G. interpreted results of experiments; O.N.B. and A.M.G. prepared figures; O.N.B. and A.M.G. drafted manuscript; O.N.B. and A.M.G. edited and revised manuscript; O.N.B. and A.M.G. approved final version of manuscript.

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## Short communication

## A mathematical analysis to address the 6 degree-of-freedom segmental power imbalance

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## ABSTRACT

Segmental power is used in human movement analyses to indicate the source and net rate of energy transfer between the rigid bodies of biomechanical models. Segmental power calculations are performed using segment endpoint dynamics (kinetic method). A theoretically equivalent method is to measure the rate of change in a segment's mechanical energy state (kinematic method). However, these two methods have not produced experimentally equivalent results for segments proximal to the foot, with the difference in methods deemed the "power imbalance." In a 6 degree-of-freedom model, segments move independently, resulting in relative segment endpoint displacement and non-equivalent segment endpoint velocities at a joint. In the kinetic method, a segment's distal end translational velocity may be defined either at the anatomical end of the segment or at the location of the joint center (defined here as the proximal end of the adjacent distal segment). Our mathematical derivations revealed the power imbalance between the kinetic method using the anatomical definition and the kinematic method can be explained by power due to relative segment endpoint displacement. In this study, we tested this analytical prediction through experimental gait data from nine healthy subjects walking at a typical speed. The average absolute segmental power imbalance was reduced from 0.023 to 0.046 W/kg using the anatomical definition to  $\leq 0.001$  W/kg using the joint center definition in the kinetic method (95.56–98.39% reduction). Power due to relative segment endpoint displacement in segmental power analyses is substantial and should be considered in analyzing energetic flow into and between segments.

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## 1. Introduction

A segmental power analysis is a useful biomechanical tool (Caldwell and Forrester, 1992), which has been used in analyzing human movement to indicate the source and net rate of energy transfer (flow) between the rigid bodies of biomechanical models (Aleshinsky, 1986; Robertson and Winter, 1980; van Ingen Schenau and Cavanagh, 1999). Segmental power calculations utilize segment endpoint dynamics (kinetic method), but a theoretically equivalent method is to measure changes in the segment's

energy state (kinematic method) (Zajac et al., 2002). Several researchers have used independent measures of segmental power to explain how power flow between segments relates to changes in the energy state of the segments in activities like walking (Aleshinsky, 1986; Caldwell and Forrester, 1992; Robertson and Winter, 1980; Zelik et al., 2015), pedaling (Kautz et al., 1994; Kautz and Neptune, 2002), running (Caldwell and Forrester, 1992), wheelchair propulsion (Guo et al., 2003), lifting (De Looze et al., 1992), and various endurance sports (van Ingen Schenau and Cavanagh, 1999). Researchers have also used this mathematical equivalence to assess the accuracy of specific models (McGibbon and Krebs, 1998) based on how closely powers calculated using the kinetic method match with those using the kinematic method. Several investigators theorized the kinematic

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## Nomenclature

|                     |                                                                                                                          |                      |                                                                                                           |
|---------------------|--------------------------------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------|
| $m_m$               | segment mass                                                                                                             | $\vec{r}_{m/m-1}$    | relative displacement vector between the distal end of segment $m$ and proximal end of segment $m-1$      |
| $\vec{a}_m$         | segment center of mass acceleration                                                                                      | $\vec{v}_{d-AR,m}$   | distal segment translational velocity from the anatomically relevant definition of $\vec{r}_{d-AR,m}$     |
| $\vec{g}$           | gravity                                                                                                                  | $\vec{v}_{d-JC,m}$   | distal segment translational velocity from the joint center definition of $\vec{r}_{d-JC,m}$              |
| $\vec{F}_{grf}$     | ground reaction force                                                                                                    | $\vec{v}_{m/m-1}$    | relative displacement velocity associated with $\vec{r}_{m/m-1}$                                          |
| $\vec{F}_{p,m}$     | proximal joint intersegmental force                                                                                      | $\vec{v}_m$          | segment center of mass velocity                                                                           |
| $\vec{F}_{d,m}$     | distal joint intersegmental force                                                                                        | $P_{AR,m}$           | segmental power using the anatomically relevant definition of $\vec{v}_{d-AR,m}$ using the kinetic method |
| $\vec{M}_{p,m}$     | proximal net joint moment                                                                                                | $P_{JC,m}$           | segmental power using the joint center definition of $\vec{v}_{d-JC,m}$ using the kinetic method          |
| $\vec{M}_{d,m}$     | distal net joint moment                                                                                                  | $\frac{d}{dt}E_m$    | segment rate of energy change using the kinematic method                                                  |
| $I_m$               | segment moment of inertia                                                                                                | $PI_{AR,m}$          | power imbalance between $\frac{d}{dt}E_m$ and $P_{AR,m}$                                                  |
| $\vec{\alpha}_m$    | segment angular acceleration                                                                                             | $PI_{JC,m}$          | power imbalance between $\frac{d}{dt}E_m$ and $P_{JC,m}$                                                  |
| $\vec{\omega}_m$    | segment angular velocity                                                                                                 | $P_{m/m-1}$          | relative displacement power term between adjacent segments $m$ and $m-1$                                  |
| $\vec{\tau}_{free}$ | free moment                                                                                                              | $ PI_{AR,m} _{mean}$ | mean absolute value of the $PI_{AR,m}$                                                                    |
| $\vec{r}_{COM,n/m}$ | position vector from proximal segment $m$ to the center of mass of segment $n$                                           | $ P_{m/m-1} _{mean}$ | mean absolute value of the relative displacement power term                                               |
| $\vec{r}_{COP,m}$   | position vector from the proximal segment $m$ to the center of pressure                                                  |                      |                                                                                                           |
| $\vec{v}_{p,m}$     | proximal segment velocity                                                                                                |                      |                                                                                                           |
| $\vec{r}_{p,m}$     | position vector from the center of mass to the proximal segment end                                                      |                      |                                                                                                           |
| $\vec{r}_{d-AR,m}$  | position vector from the center of mass to the anatomically relevant distal segment end                                  |                      |                                                                                                           |
| $\vec{r}_{d-JC,m}$  | position vector from the center of mass to the joint center (defined as the proximal end of the adjacent distal segment) |                      |                                                                                                           |

method is more accurate as it is based only on motion and anthropometric estimates (Caldwell and Forrester, 1992; Robertson and Winter, 1980).

The models and corresponding model assumptions used to analyze segmental power flow influence how results may be interpreted. A pin-joint model, which fixes segment ends at a coincident point, has been used for two- (i.e. sagittal plane) or three-dimensional gait analyses (De Looze et al., 1992; McGibbon and Krebs, 1998; Robertson and Winter, 1980). However, use of the pin-joint model may require segment lengths and inertial alignment (e.g. segment center of mass position) to change due to a shared joint center with adjacent segments, thus violating rigid body assumptions. Conversely, a 6 degree-of-freedom (6 DOF) model for three-dimensional gait analyses fixes segment characteristics, which can lead to relative displacement between adjacent segment ends, and thus non-equivalent segment endpoint velocities at a joint (Buczek et al., 1994; McGibbon and Krebs, 1998). While both models have limitations, the translational power resulting from the intersegmental joint force and the segment endpoint velocities in a 6 DOF model is valuable to include for a complete mechanical energy analysis of human gait (Buczek et al., 1994; Geil et al., 2000; Zelik et al., 2015).

Independent of chosen model, the kinetic and kinematic methods typically do not provide experimentally equivalent results, leading to a “power imbalance” (PI) (McGibbon and Krebs, 1998). Using a three-dimensional analysis, McGibbon and Krebs reported using the pin-joint model resulted in a mean absolute PI over stance ranging from 9.9–25.6 W for the shank and 6.8–23.4 W for the thigh. The mean absolute PI was reduced when segment lengths were fixed and radial velocities of the distal and proximal ends of the segment relative to the segment's center of mass were accounted for (1.1–5.0 W and 0.7–4.1 W for the shank and thigh, respectively). However, while fixed segment lengths reduced the PI within a segment, there was a large power discrepancy between segment ends across a joint (e.g. 10.7–37.8 W at the knee), which was considered an “energy well” (McGibbon and Krebs, 1998).

Thus, identifying the source of the PI is important for effectively characterizing energetic measures in the study of human movement. To date, the foot is the only segment whose PI was computationally accounted for by the inclusion of a calculation for distal foot segmental power (Siegel et al., 1996).

The purpose of this study was to determine the source of PI by conducting a mathematical analysis to equate the kinematic and kinetic methods for a 6 DOF model. We theorized accounting for power due to relative displacement between the distal end of a segment and the joint center in the kinetic model (relative displacement power) would reduce the PI. We then experimentally characterized the PI with and without accounting for the relative displacement power.

## 2. Computational development

Using Newton-Euler formulas (Sieglar and Liu, 1997) in inverse dynamics calculations (Robertson et al., 2013), the general form for the proximal joint intersegmental force ( $\vec{F}_{p,m}$ ) for any segment  $m$ , linked by  $n$  number of segments, is given by Eq. (1) where  $m_m$ ,  $\vec{a}_m$ ,  $\vec{g}$ , and  $\vec{F}_{grf}$  represent the segment mass, segment center of mass acceleration, gravity (9.81 m/s<sup>2</sup>), and ground reaction force, respectively. Similarly, the proximal net joint moment ( $\vec{M}_{p,m}$ ) is given by Eq. (2) where  $I_m$ ,  $\vec{\alpha}_m$ ,  $\vec{\omega}_m$ , and  $\vec{\tau}_{free}$  represent the moment of inertia, angular acceleration, angular velocity, and free moment, respectively. The  $\vec{r}_{COM,n/m}$  and  $\vec{r}_{COP,m}$  are vectors from the proximal end of the  $m^{\text{th}}$  segment end to the center of mass of the  $n^{\text{th}}$  segment and to the center of pressure, respectively (Fig. 1).

$$\vec{F}_{p,m} = \left[ \sum_{n=1}^m (m_n \vec{a}_n - m_n \vec{g}) \right] - \vec{F}_{grf} \quad (1)$$

$$\vec{M}_{p,m} = \left[ \sum_{n=1}^m (I_n \vec{\alpha}_n + \vec{\omega}_n \times I_n \vec{\omega}_n + \vec{r}_{COM,n/m} \times (m_n \vec{a}_n - m_n \vec{g})) \right] - \vec{\tau}_{free} - \vec{r}_{COP,m} \times \vec{F}_{grf} \quad (2)$$

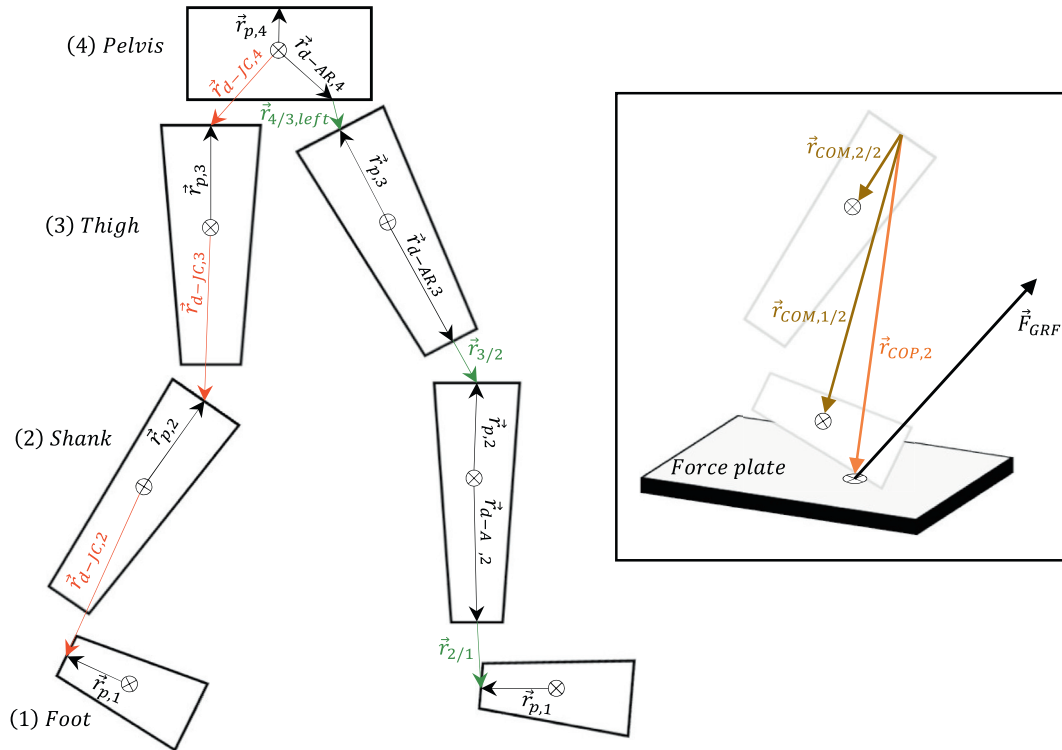


**Fig. 1.** Visual representation of vectors used in inverse dynamics calculations for a 6 DOF multi-segment model. Here, segment  $m$  is numbered 1, 2, 3, and 4 which can represent the foot, shank, thigh, and pelvis, respectively. The model shows position vectors from a segment center of mass to the proximal segment end ( $\vec{r}_{p,m}$ ) as well as to the distal segment end using the anatomically relevant (AR) definition ( $\vec{r}_{d-AR,m}$ ) or the joint center (JC) definition ( $\vec{r}_{d-JC,m}$ ). The displacement vector ( $\vec{r}_{m/m-1}$ ) is defined from the AR distal end of the proximal segment  $m$  relative to the proximal end of the distal segment  $m-1$  (i.e. joint center). Note that all segments are modelled equally, and representations being different on the two limbs are for clarity only. For the pelvis, the displacement vector is from the right or left hip joint center in the pelvis coordinate system (as defined by the static model pose) to the proximal end of the respective thigh. Inset shows notation for the position vectors  $\vec{r}_{COM,n/m}$  and  $\vec{r}_{COP,m}$  from the proximal segment end to the center of mass of the  $n^{\text{th}}$  segment (where  $n$  is less than or equal to  $m$ ) and to the center of pressure, respectively.

The proximal segment translational velocity is given by Eq. (3) where  $\vec{r}_{p,m}$  is the vector from the center of mass to the proximal (p) end of the segment, and the segment velocity is represented by  $\vec{v}_m$ .

$$\vec{v}_{p,m} = \vec{v}_m + \vec{\omega}_m \times \vec{r}_{p,m} \quad (3)$$

In an anatomically relevant (AR) definition, distal translational velocity is given by Eq. (4) where  $\vec{r}_{d-AR,m}$  is the vector from the center of mass to the distal (d) end of the segment.

$$\vec{v}_{d-AR,m} = \vec{v}_m + \vec{\omega}_m \times \vec{r}_{d-AR,m} \quad (4)$$

However, the AR definition of distal velocity is not always coincident with the point of force application (i.e. the joint center), which is defined here as the proximal end of the adjacent distal segment (Fig. 1). Therefore, there exists a displacement vector ( $\vec{r}_{m/m-1}$ ) between the distal end of segment  $m$  and proximal end of segment  $m-1$  with a velocity given by Eq. (5).

$$\vec{v}_{m/m-1} = \vec{\omega}_m \times \vec{r}_{m/m-1} \quad (5)$$

In a joint center (JC) definition, distal translational velocity is given by Eq. (6) where  $\vec{r}_{d-JC,m}$  is the vector from the center of mass to the joint center. This vector is equivalent to the sum of  $\vec{r}_{d-AR,m}$  and  $\vec{r}_{m/m-1}$  (Fig. 1).

$$\begin{aligned} \vec{v}_{d-JC,m} &= \vec{v}_m + \vec{\omega}_m \times \vec{r}_{d-JC,m} \\ &= \vec{v}_m + \vec{\omega}_m \times (\vec{r}_{d-AR,m} + \vec{r}_{m/m-1}) \end{aligned} \quad (6)$$

Segmental power using the kinetic method can be calculated using the AR definition ( $P_{AR,m}$ ) in Eq. (7), where distal joint intersegmental force and net joint moment are represented by  $\vec{F}_{d,m}$  and

$\vec{M}_{d,m}$ , respectively. The pelvis segment ( $m = 4$ ) is calculated using proximal powers as well as left and right  $\vec{F}_{d,4}$  and  $\vec{M}_{d,4}$ . The  $\vec{r}_{d-AR,4}$  is from the center of mass to the left or right hip joint center positions in the pelvis coordinate system (as defined in the static model pose).

$$P_{AR,m} = \vec{M}_{p,m} \cdot \vec{\omega}_m + \vec{M}_{d,m} \cdot \vec{\omega}_m + \vec{F}_{p,m} \cdot \vec{v}_{p,m} + \vec{F}_{d,m} \cdot \vec{v}_{d-AR,m} \quad (7)$$

Segmental power calculated using the JC definition ( $P_{JC,m}$ ) can be represented using Eqs. (6) and (7) as shown in Eq. (8a). The power due to the displacement between segment ends of adjacent segments, or relative displacement power ( $P_{m/m-1}$ ), is shown in Eq. (8b).

$$\begin{aligned} P_{JC,m} &= \vec{M}_{p,m} \cdot \vec{\omega}_m + \vec{M}_{d,m} \cdot \vec{\omega}_m + \vec{F}_{p,m} \cdot \vec{v}_{p,m} + \vec{F}_{d,m} \cdot \vec{v}_{d-JC,m} \\ &= P_{AR,m} + P_{m/m-1} \end{aligned} \quad (8a)$$

where

$$P_{m/m-1} = \vec{F}_{d,m} \cdot \vec{v}_{m/m-1} \quad (8b)$$

Eqs. 1–3 and 6 can be substituted into Eq. (8a) to achieve Eq. (9) (see Appendix for complete details).

$$\begin{aligned} P_{JC,m} &= \vec{M}_{p,m} \cdot \vec{\omega}_m + \vec{M}_{d,m} \cdot \vec{\omega}_m + \vec{F}_{p,m} \cdot \vec{v}_{p,m} + \vec{F}_{d,m} \cdot \vec{v}_{d-JC,m} \\ &= (I_m \vec{\alpha}_m + \vec{\omega}_m \times I_m \vec{\omega}_m) \cdot \vec{\omega}_m + (m_m \vec{a}_m - m_m \vec{g}) \cdot \vec{v}_m \\ &\quad - (\vec{r}_{COP,m} \times \vec{F}_{grf}) \cdot \vec{\omega}_m + (\vec{r}_{COP,m-1} \times \vec{F}_{grf}) \cdot \vec{\omega}_m - \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{p,m}) \\ &\quad + \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{d-AR,m}) + \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{m/m-1}) \end{aligned} \quad (9)$$

The rate of energy change ( $\frac{d}{dt}E_m$ ) using the kinematic method is calculated in Eq. (10), which sums the rotational kinetic, translational kinetic, and gravitational potential segmental energy. Note  $\frac{d}{dt}E_m$  is computationally equivalent to  $P_{JC,m}$  from Eq. (9) because the vector  $-\vec{r}_{COP,m}$  will cancel with the summed vectors  $-\vec{r}_{p,m}$ ,  $\vec{r}_{d-AR,m}$ ,  $\vec{r}_{m/m-1}$  and,  $\vec{r}_{COP,m-1}$  using the properties of cross and dot products.

$$\frac{d}{dt}E_m = (I_m \vec{\alpha}_m + \vec{\omega}_m \times I_m \vec{\omega}_m) \cdot \vec{\omega}_m + m_m \vec{a}_m \cdot \vec{v}_m - m_m \vec{g} \cdot \vec{v}_m \quad (10)$$

### 3. Experimental method

Experimental data were derived from a coded database of nine healthy subjects ( $34 \pm 10$  years,  $1.69 \pm 0.10$  m,  $75.6 \pm 16.2$  kg), consented under an IRB approved protocol, walking with standard shoes on an instrumented treadmill (Bertec Corp., Columbus, OH). Kinematic data were collected using a seven-camera motion capture system (Motion Analysis, Santa Rosa, CA). Motion capture and force data were sampled at 240 Hz and 1200 Hz and low-pass filtered at 6 Hz and 25 Hz, respectively, and analyzed in Visual3D software (C-Motion, Inc. Germantown, MD). Reflective markers were placed on subjects using a modification to a previously

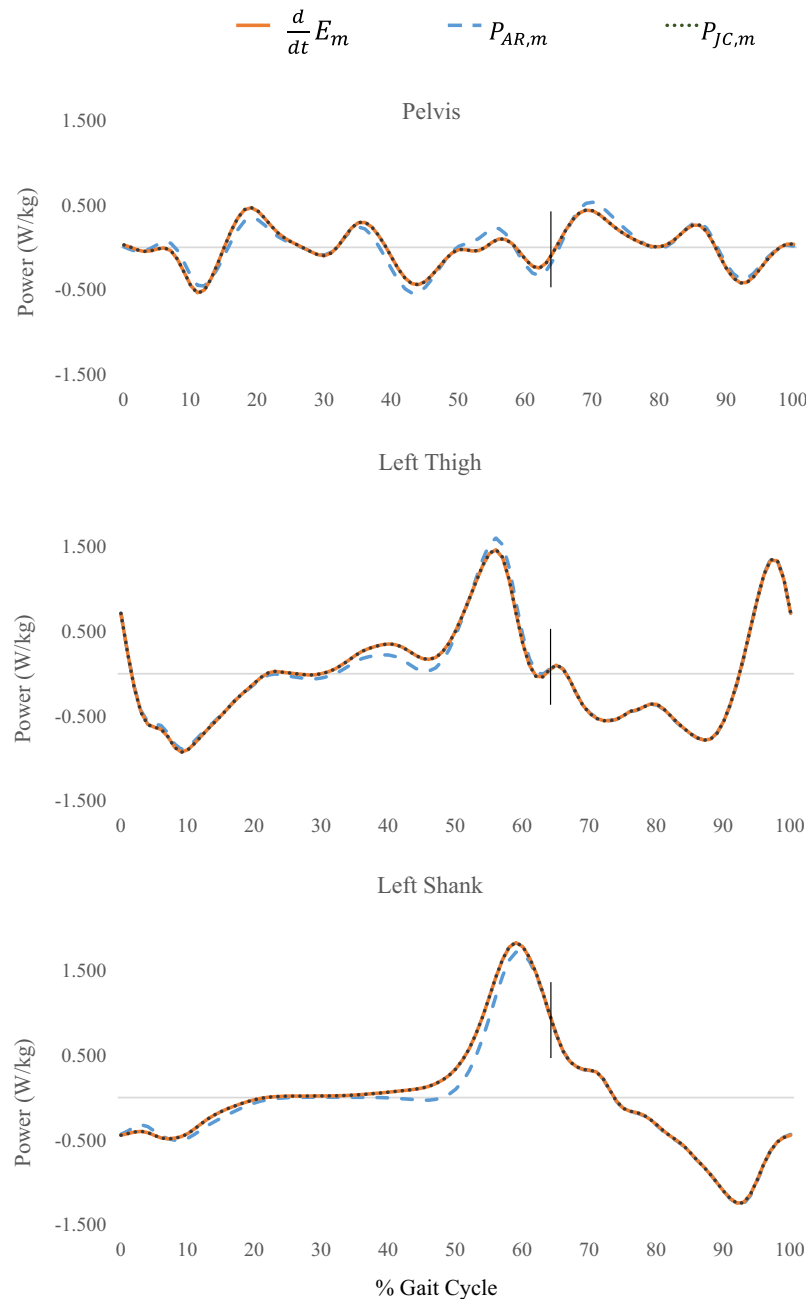


**Fig. 2.** A noticeable power imbalance exists between segmental power using the anatomically relevant kinetic method ( $P_{AR,m}$ ) and the rate of energy change using the kinematic method ( $\frac{d}{dt}E_m$ ) over 100% of the gait cycle for a representative subject (where  $m$  represents the pelvis, left thigh, or left shank). The power imbalance is reduced between the segmental power using the joint center kinetic method ( $P_{JC,m}$ ) and  $\frac{d}{dt}E_m$ . The power imbalance during swing phase (indicated to the right of the vertical black line at 64.3%) is much smaller than in stance phase due in part to the relatively small power during this phase where there is no ground reaction force.

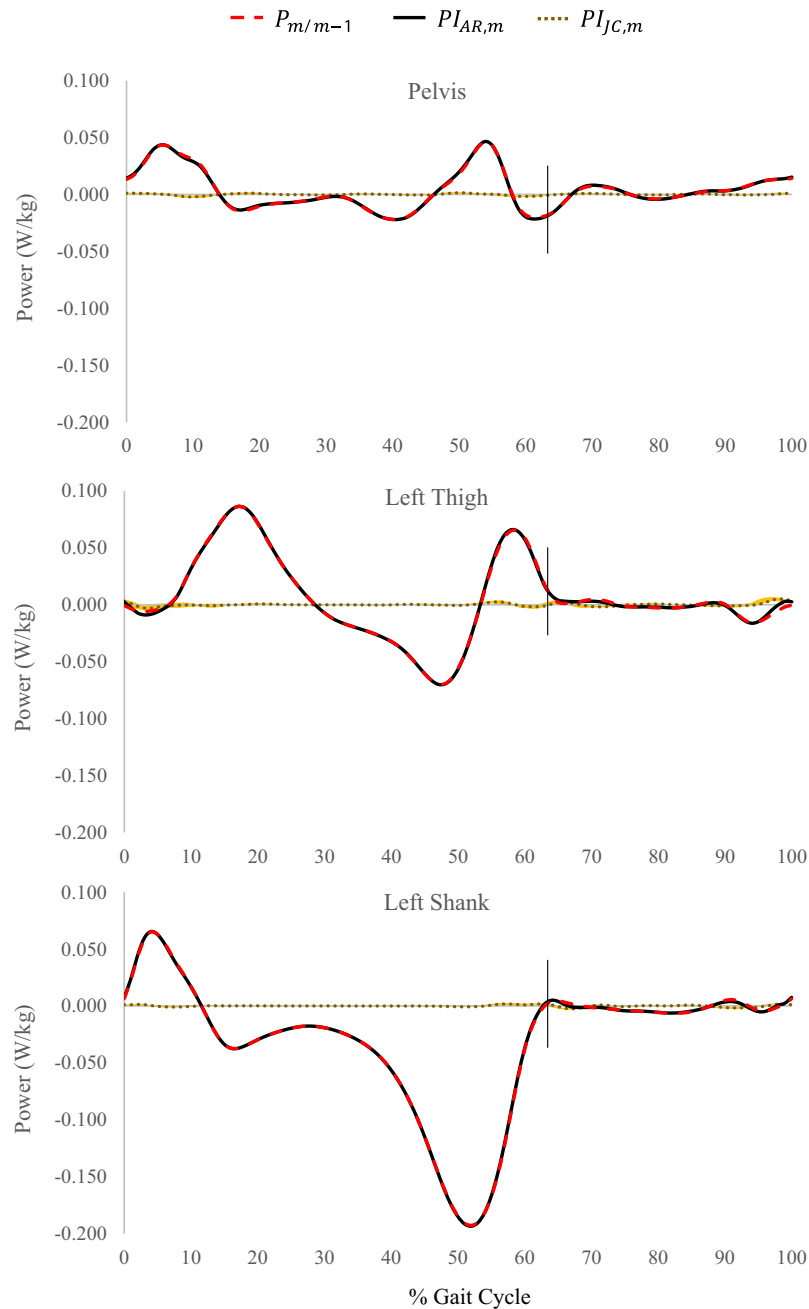


**Fig. 3.** Average power imbalance between the segmental rate of energy change and the anatomically relevant kinetic method ( $P_{I_{AR,m}}$ ) is almost completely explained by the average power due to the relative segment endpoint displacement ( $P_{m/m-1}$ ), as seen graphed over 100% of the gait cycle (where  $m$  represents the pelvis, left thigh, or left shank). Average ( $\pm 1$  standard deviation in yellow) power imbalance between the segmental rate of energy change and the joint center kinetic method ( $P_{I_{JC,m}}$ ) is relatively small in comparison to  $P_{I_{AR,m}}$ . The range of  $P_{m/m-1}$  is smaller in swing phase (indicated to the right of the vertical black line at 63%) than in stance for all three segments, and largest in the left shank compared to the thigh and pelvis over stance phase. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

reported marker configuration (Holden et al., 1997). Subjects walked at a height-scaled speed of 0.8 statures/s (approximately 1.4 m/s).

A minimum of 10 strides for the pelvis, left thigh, and left shank were analyzed. In the AR definition, the distal end of a segment was defined in the static model pose and tracked using marker clusters. In the JC definition, the location of the joint center, was determined on a frame-by-frame basis. All power terms were averaged across all subjects and scaled by body mass. Pelvis segmental power was the sum of powers at the left and right hip as well as the proximal pelvis. For each subject, the PI was calculated as the difference between the kinematic method and the kinetic method using the

AR definition ( $P_{I_{AR,m}}$ ) or the JC definition ( $P_{I_{JC,m}}$ ) on a frame-by-frame basis across the gait cycle. Maximum and minimum PI were calculated along with the mean PI over the gait cycle for each subject and overall. Mean absolute PI was defined by the absolute value of the PI frame-by-frame averaged across the gait cycle. Mean absolute relative displacement power for the left and right hips are quantified in Supplementary Table 1.

#### 4. Results

The experimental segmental powers (Fig. 2) and PI (Figs. 3 and 4) revealed  $P_{m/m-1}$  accounted for nearly all  $P_{I_{AR,m}}$ . The average

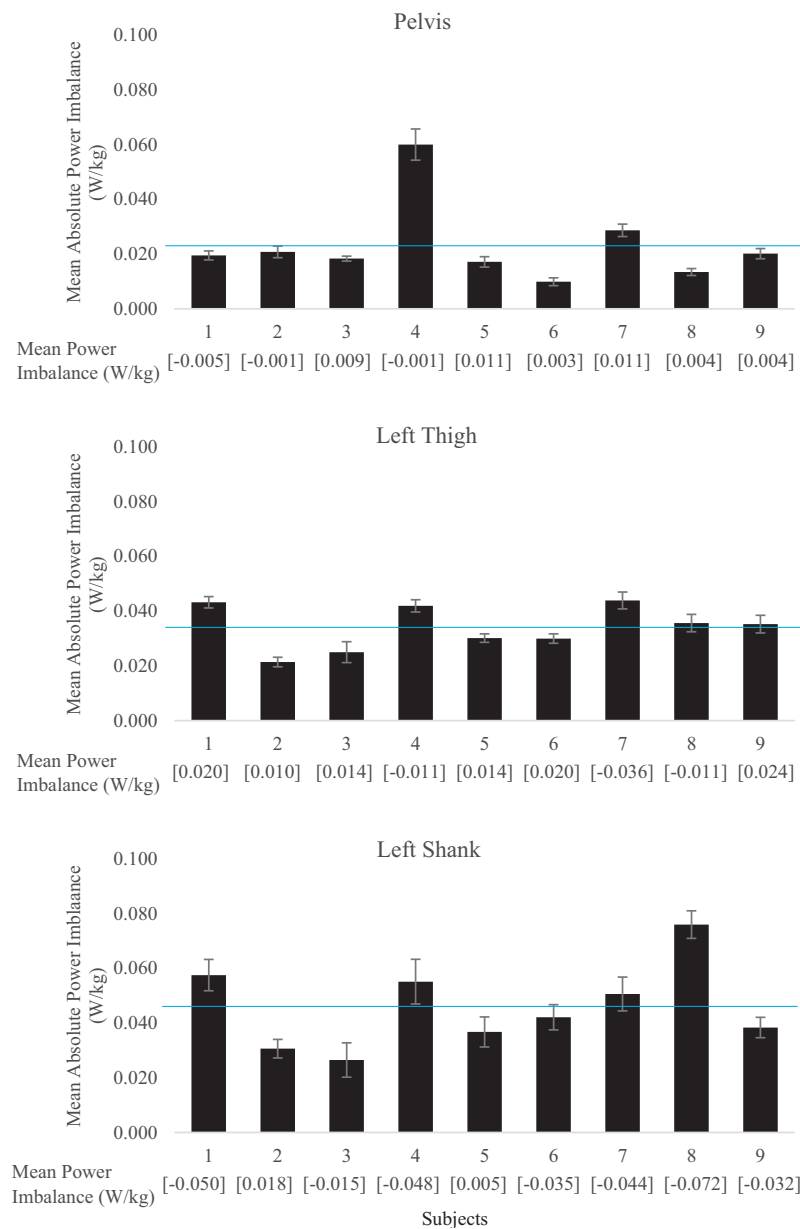


**Fig. 4.** The mean ( $\pm 1$  standard deviation error bars) absolute power imbalance between the segmental rate of energy change and the anatomically relevant kinetic method ( $|PI_{AR,m}|_{\text{mean}}$ ) averaged across a minimum of 10 gait cycles for each subject shows the inter-subject variability. Overall  $|PI_{AR,m}|_{\text{mean}}$  across all subjects (indicated by the blue horizontal line) was  $0.046 \pm 0.015$  W/kg,  $0.034 \pm 0.008$  W/kg, and  $0.023 \pm 0.015$  W/kg for the shank, thigh, and pelvis, respectively. The mean  $PI_{AR,m}$  (bracketed numbers under subject data) further highlight the inter-subject variability, revealing no clear pattern in sign or magnitude of mean power imbalance across subjects. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

absolute segmental PI was reduced from  $0.046 \pm 0.015$  W/kg,  $0.034 \pm 0.008$  W/kg, and  $0.023 \pm 0.015$  W/kg for the shank, thigh and pelvis, respectively, using the anatomical definition to  $\leq 0.001 \pm 0.000$  W/kg using the joint center definition in the kinetic method. For context, the percent difference between these two measures was 98.4%, 95.7%, and 95.6% for the shank, thigh, and pelvis, respectively.

## 5. Discussion

The mathematical analysis presented explains how the segmental PI between segmental power and rate of energy change is influenced by the definition of the distal translational velocity term. An AR definition of the distal translational velocity ignores the relative displacement of segment ends at a joint, resulting in a PI. A JC def-

inition includes a relative displacement power ( $P_{m/m-1}$ ) to accurately equate segmental power and rate of energy change mathematically.

The  $P_{m/m-1}$  term computationally accounts for the  $PI_{AR,m}$ . The addition of the displacement vector  $\vec{r}_{m/m-1}$  represents the magnitude of separation at the joint. The cross product of  $\vec{\omega}_m$  and  $\vec{r}_{m/m-1}$  is a result of relative motion physics (similar in concept to the previously derived distal foot velocity (Siegel et al., 1996)) which represents the relative translational velocity due to the separation of segment ends of the joint. While  $P_{m/m-1}$  is included in the  $m^{\text{th}}$  segment because of our joint center definition, it is a result of imperfect modeling of the instantaneous joint center using marker based motion capture techniques.

Figs. 3 and 4 show the magnitude of  $P_{m/m-1}$  – previously referred to as an “energy well” (McGibbon and Krebs, 1998) –

is substantial. Interestingly, the pelvis had the lowest mean absolute PI. [Supplementary Table 1](#) supports the possibility that relative displacement power at the left and right hips negate each other at parts of the gait cycle. 6 DOF joint power calculations use the JC definition of distal translational velocity (Eq. (6)), which inherently include the  $P_{m/m-1}$  as originally intended when presented by Buczek and colleagues (Buczek et al., 1994). For explicit clarity, the 6 DOF joint powers include a change in velocity vector ( $\Delta v_{joint}$ ) which denotes the difference in segment end velocities at the coincident location of the joint center (Buczek et al., 1994).

Irrespective of whether  $\vec{r}_{m/m-1}$  is due to measurement artefact or physiological separation between segment ends at a joint, the translational velocity terms are a necessary inclusion for joint power calculations using 6 DOF models. If the source of  $\vec{r}_{m/m-1}$  is due to measurement artefact (e.g. soft tissue movement), then  $\vec{r}_{m/m-1}$  will affect segmental angular velocities used to calculate rotational powers. Thus, the true joint power is not better estimated by rotational terms alone. In fact, the results show  $P_{m/m-1}$  would be equivalent to the  $PI_{AR,m}$  if the primary source of error was joint displacement artefact. Furthermore, if  $\vec{r}_{m/m-1}$  is physiological (rather than artefactual), then the same conclusion is reached – translational velocity terms in 6 DOF joint power calculations should not be disregarded.

Although the JC definition for the kinetic method theoretically equates the kinetic and kinematic methods, there remains a small ( $\leq 0.001$  W/kg) average absolute experimental PI. All measures derived from motion and force data are estimates that contribute to errors not shared equally between the kinetic and kinematic methods. Regarding the tracking of motion data, errors may arise from accessory motion of skin-mounted markers due to soft tissue movement making segment endpoints inaccurate (violating rigid body assumptions) and missing axes of rotation (McGibbon and Krebs, 1998; van Ingen Schenau and Cavanagh, 1999; Zajac et al., 2002; Zelik et al., 2015). Regarding the measurement of force data, errors may arise from locating the center of pressure or from estimating the inertial properties of the segments. Furthermore, there may be numerical processing errors due to filtering of motion and force data. Noise in kinematic data due to a series of differentiations or estimates of segment position using least square calculations of retroreflective marker locations may all be factors for why a PI may be detected experimentally.

A limitation of the 6 DOF model is that traditional motion capture systems cannot precisely measure instantaneous joint translations from surface markers, which would be necessary to fully interpret  $P_{m/m-1}$ . Note that positive or negative powers at segment ends using the kinetic method produce computationally equivalent segmental energy values based on an assumed uniarticular muscle model to models using biarticular muscles. However, the net power does not identify the source of power generated or absorbed by uni- or biarticular muscles (Kautz et al., 1994; Prilutsky and Zatsiorsky, 1994; van Ingen Schenau and Cavanagh, 1999).

This study shows (1) the relative displacement power ( $P_{m/m-1}$ ) mathematically accounts for the PI between the AR kinetic method and the kinematic method, and (2) the magnitude of  $P_{m/m-1}$  is substantial. When tracking power and energy flow between the segments, it is important that the definition of the distal translational velocity is explicitly clear. In conclusion,  $P_{m/m-1}$  must be included for the kinetic and kinematic analyses of segmental power to agree. These results support using both rotational and translational power terms to calculate joint powers for 6 DOF models.

## Conflict of interest

The authors have no financial or personal relationships with individuals or organizations that inappropriately influenced this work. All authors have no conflicts of interest to disclose.

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## Appendix A.

Eq. (8a) in the text can be parsed into two components based on the powers calculated from joint intersegmental forces proximally (Ia) and distally (Ib).

$$\begin{aligned} \text{Ia. } \vec{F}_{p,m} \cdot \vec{v}_{p,m} &= \left( \left[ \sum_{n=1}^m (m_n \vec{a}_n - m_n \vec{g}) \right] - \vec{F}_{grf} \right) \cdot (\vec{v}_m + \vec{\omega}_m \times \vec{r}_{p,m}) \\ &= \left[ \sum_{n=1}^m (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot \vec{v}_m - \vec{F}_{grf} \cdot \vec{v}_m \\ &\quad + \left[ \sum_{n=1}^m (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot (\vec{\omega}_m \times \vec{r}_{p,m}) - \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{p,m}) \end{aligned}$$

$$\begin{aligned} \text{Ib. } \vec{F}_{d,m} \cdot \vec{v}_{d-JC,m} &= - \left( \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] - \vec{F}_{grf} \right) \\ &\quad \cdot (\vec{v}_m + \vec{\omega}_m \times \vec{r}_{d-AR,m} + \vec{\omega}_m \times \vec{r}_{m/m-1}) \\ &= - \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot \vec{v}_m + \vec{F}_{grf} \cdot \vec{v}_m \\ &\quad - \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot (\vec{\omega}_m \times \vec{r}_{d-AR,m}) \\ &\quad + \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{d-AR,m}) - \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \\ &\quad \cdot (\vec{\omega}_m \times \vec{r}_{m/m-1}) + \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{m/m-1}) \end{aligned}$$

The summation of Ia and Ib can be simplified to the following (note the terms **bolded** will be noteworthy later):

$$\begin{aligned} \text{Ic. } \vec{F}_{p,m} \cdot \vec{v}_{p,m} + \vec{F}_{d,m} \cdot \vec{v}_{d-JC,m} &= (m_m \vec{a}_m - m_m \vec{g}) \cdot \vec{v}_m \\ &\quad + \left[ \sum_{n=1}^m (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot (\vec{\omega}_m \times \vec{r}_{p,m}) - \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \\ &\quad \cdot (\vec{\omega}_m \times \vec{r}_{d-AR,m}) - \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot (\vec{\omega}_m \times \vec{r}_{m/m-1}) \\ &\quad - \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{p,m}) + \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{d-AR,m}) + \vec{F}_{grf} \cdot (\vec{\omega}_m \times \vec{r}_{m/m-1}) \end{aligned}$$

Similarly, Eq. (8a) in the text can be parsed into two components based on powers calculated from net joint moments proximally (IIa) and distally (IIb).

$$\text{IIa. } \vec{M}_{p,m} \cdot \vec{\omega}_m = \left[ \sum_{n=1}^m (I_n \vec{\alpha}_n + \vec{\omega}_n \times I_n \vec{\omega}_n + \vec{r}_{COM,n/m} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \\ - \vec{\tau}_{free} - \vec{r}_{COP,m} \times \vec{F}_{grf} \cdot \vec{\omega}_m$$

$$\text{IIb. } \vec{M}_{d,m} \cdot \vec{\omega}_m = - \left[ \sum_{n=1}^{m-1} (I_n \vec{\alpha}_n + \vec{\omega}_n \times I_n \vec{\omega}_n + \vec{r}_{COM,n/m-1} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \\ - \vec{\tau}_{free} - \vec{r}_{COP,m-1} \times \vec{F}_{grf} \cdot \vec{\omega}_m$$

The summation of IIa and IIb can be simplified to the following (note the terms **bolded** will be noteworthy later):

$$\text{IIc. } \vec{M}_{p,m} \cdot \vec{\omega}_m + \vec{M}_{d,m} \cdot \vec{\omega}_m = (I_m \vec{\alpha}_m + \vec{\omega}_m \times I_m \vec{\omega}_m) \cdot \vec{\omega}_m \\ + \left[ \sum_{n=1}^m (\vec{r}_{COM,n/m} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \cdot \vec{\omega}_m \\ - \left[ \sum_{n=1}^{m-1} (\vec{r}_{COM,n/m-1} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \cdot \vec{\omega}_m \\ - (\vec{r}_{COP,m} \times \vec{F}_{grf}) \cdot \vec{\omega}_m + (\vec{r}_{COP,m-1} \times \vec{F}_{grf}) \cdot \vec{\omega}_m$$

Now, considering the terms bolded in IIC,  $\vec{r}_{COM,n/m}$  terms for each summation can be expanded. Here, some terms in these two summations will cancel such that the result of summing IIc and IIe will be IIIf.

$$\text{IIId. } \left[ \sum_{n=1}^m (\vec{r}_{COM,n/m} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \cdot \vec{\omega}_m$$

where...

$$\vec{r}_{COM,m/m} = -\vec{r}_{p,m}$$

$$\vec{r}_{COM,m-1/m} = -\vec{r}_{p,m} + \vec{r}_{d-AR,m} + \vec{r}_{m/m-1} - \vec{r}_{p,m-1}$$

$$\vec{r}_{COM,m-2/m} = -\vec{r}_{p,m} + \vec{r}_{d-AR,m} + \vec{r}_{m/m-1} - \vec{r}_{p,m-1} + \vec{r}_{d-AR,m-1} \\ + \vec{r}_{m-1/m-2} - \vec{r}_{p,m-2}$$

etc.

$$\text{IIe. } - \left[ \sum_{n=1}^{m-1} (\vec{r}_{COM,n/m-1} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \cdot \vec{\omega}_m$$

where...

$$\vec{r}_{COM,m-1/m-1} = -\vec{r}_{p,m-1}$$

$$\vec{r}_{COM,m-2/m-1} = -\vec{r}_{p,m-1} + \vec{r}_{d-AR,m-1} + \vec{r}_{m-1/m-2} - \vec{r}_{p,m-2}$$

$$\text{IIIf. } \left[ \sum_{n=1}^m (\vec{r}_{COM,n/m} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \cdot \vec{\omega}_m \\ - \left[ \sum_{n=1}^{m-1} (\vec{r}_{COM,n/m-1} \times (m_n \vec{a}_n - m_n \vec{g})) \right] \cdot \vec{\omega}_m \\ = \left[ -\vec{r}_{p,m} \times \sum_{n=1}^m (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot \vec{\omega}_m \\ + \left[ \vec{r}_{d-AR,m} \times \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot \vec{\omega}_m$$

$$+ \left[ \vec{r}_{m/m-1} \times \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot \vec{\omega}_m \\ = -\mathbf{1} * \left[ \left[ \sum_{n=1}^m (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot (\vec{\omega}_m \times \vec{r}_{p,m}) \right] \\ - \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot (\vec{\omega}_m \times \vec{r}_{d-AR,m}) \\ - \left[ \sum_{n=1}^{m-1} (m_n \vec{a}_n - m_n \vec{g}) \right] \cdot (\vec{\omega}_m \times \vec{r}_{m/m-1})$$

Rearranging the terms in IIIf and using the properties of cross products, the result is actually the inverse of the bolded term in Ic. Thus, the summation of Ic and IIc will result in Eq. (9) in the text.

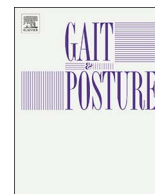
## Appendix B. Supplementary material

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.jbiomech.2017.10.034>.

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## Short communication

# Constituent Lower Extremity Work (CLEW) approach: A novel tool to visualize joint and segment work



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## ABSTRACT

Work can reveal the mechanism by which movements occur. However, work is less physically intuitive than more common clinical variables such as joint angles, and are scalar quantities which do not have a direction. Therefore, there is a need for a clearly reported and comprehensively calculated approach to easily visualize and facilitate the interpretation of work variables in a clinical setting. We propose the Constituent Lower Extremity Work (CLEW) approach, a general methodology to visualize and interpret cyclic tasks performed by the lower limbs. Using six degree-of-freedom power calculations, we calculated the relative work of the four lower limb constituents (hip, knee, ankle, and distal foot). In a single pie chart, the CLEW approach details the mechanical cost-of-transport, the percentage of positive and negative work performed in stance phase and swing phase, and the individual contributions of positive and negative work from each constituent. This approach can be used to compare the constituent-level adaptations occurring between limbs of individuals with impairments, or within a limb at different gait intensities. In this article, we outline how to generate and interpret the CLEW pie charts in a clinical report. As an example of the utility of the approach, we created a CLEW report using average reference data from eight unimpaired adult subjects walking on a treadmill at 0.8 statures/s (1.4 m/s) compared with data from the intact and prosthetic limbs of an individual with a unilateral amputation walking with an above-knee passive prosthesis.

## 1. Introduction

Several researchers have used the principles of energetics to explain the compensatory strategies used by individuals with impairments (e.g., [1–3]). Relative joint work, or the comparative amount each joint's work contributed to absolute limb work, can reveal the primary limb “drivers” (positive) and “brakers” (negative) during a movement task like walking. However, work is less physically intuitive than more common clinical variables such as joint angles, partly because it is a scalar quantity which does not have a direction.

Previously, researchers have reported the work generated (positive) and absorbed (negative) by each of the joints using line [1,4] and bar charts [5]. While these graphs can be used to compare joint work across gait intensity and between limbs of the same joint at one intensity, the overlapping lines and error bars can be confusing to interpret. There is a

need for a clearly reported approach to visualize and facilitate the interpretation of work variables in a clinical setting.

The objective of this article is to introduce the Constituent Lower Extremity Work (CLEW) approach, a general methodology to visualize and interpret cyclic tasks performed by the lower limbs. The term “constituents” will be used to refer to the hip, knee, ankle, and distal foot of the limb. The utility of this tool is demonstrated by presenting a report with the relative work of the four lower limb constituents in both limbs of a sample of healthy, unimpaired individuals and in the prosthetic and intact limbs of an individual with a unilateral amputation walking on a treadmill.

## 2. Methods

As a representative case study, data were collected from an adult

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individual (height 1.68 m, mass 79.15 kg) walking on an instrumented treadmill (Bertec Corp., Columbus, OH) who required use of an above-knee prosthesis due to a congenital proximal femoral focal deficiency. Reflective markers were positioned using a modification of a six-degree-of-freedom (6-DOF) marker set [6]. A seven-camera motion capture system was used to collect kinematic data (Motion Analysis, Santa Rosa, CA). Motion capture and force data were sampled at 240 Hz and 1200 Hz and low-pass filtered at 6 Hz and 25 Hz, respectively. These data were compared to data from unimpaired subjects collected as part of a previous study [7] in which eight healthy adult subjects (height  $1.77 \pm 0.08$  m, mass  $71.8 \pm 15.5$  kg) walked on an instrumented treadmill (Bertec Corp., Columbus, OH) while a six-camera motion capture system was used to collect kinematic data (Vicon, Los Angeles, CA) using the same marker set. All subjects walked at a height-scaled speed of 0.8 statures/s ( $\sim 1.4$  m/s) and provided informed consent under an IRB approved protocol.

Methods previously described in the literature [8,9] were used to calculate 6-DOF constituent powers in Visual3D software (C-Motion, Inc. Germantown, MD). A unified deformable segment model was used to characterize the power from the below-knee structures (i.e. combined ankle-foot) of the prosthetic limb during stance phase of the amputee subject [10].

Integrating the positive and negative portions of the constituent power curves over stance and swing phases resulted in the respective constituent work values. The absolute 6-DOF limb work ( $^{abs}W_{limb}$ ) was defined as positive limb work summed with the absolute value of negative limb work over the gait cycle (where limb work is defined as summed hip, knee, ankle, and distal foot work). The cost-of-transport is  $^{abs}W_{limb}$  scaled by stride length. Relative work (RW) was the absolute value of each constituent's work divided by the absolute 6-DOF limb work. Net limb work was the sum of the positive and negative 6-DOF limb work over both phases. Work values were scaled by body mass and averaged for all unimpaired subjects. Distal foot calculations were not relevant during swing phase. The CLEW approach pie charts were created using the steps depicted in Fig. 1.

### 3. Results

Average net 6-DOF limb work, absolute 6-DOF limb work, stride length, and cost-of-transport are all reported in Table 1 for the left and right limbs of the unimpaired individuals (mean  $\pm$  standard deviation) and the individual with amputation (hereafter noted as subject data). Fig. 2 depicts a typical clinical CLEW report. Fig. 2A summarizes the steps for systematically evaluating a subject's CLEW pie chart and a short interpretation of each variable. Fig. 2B provides an example of a typical CLEW report with reference data from the unimpaired individuals and a subject's data from the individual with a unilateral amputation. A Supplemental Table lists the relative constituent work values for the unimpaired individuals and the subject during stance and swing phases of gait.

### 4. Discussion

The purpose of this study was to introduce the CLEW approach and demonstrate its utility in quantifying relative constituent work in a succinct and visually informative manner. The size of the pie charts, representing the mechanical cost-of-transport, provides a spatial relationship to interpret the total burden of work for the limb. The designation of positive and negative relative constituent work provides a way to readily compare the contribution of work from each constituent during the stance and swing phases of gait, thus identifying the primary “drivers” and “brakers” of the system.

The CLEW approach pie charts (as in Fig. 2B) may be clinically useful as a way to characterize the burden of work over an entire stride rather than an instant in time. For example, visual inspection of the size of the pie charts (scaled by cost-of-transport) appears to show greater

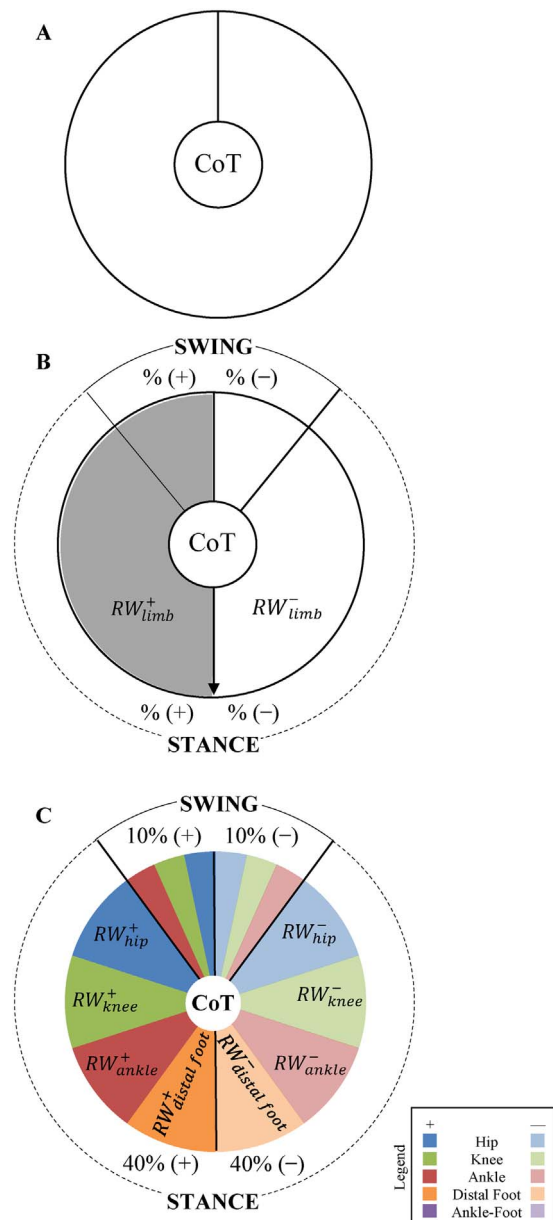


Fig. 1. Steps for creating the CLEW approach pie charts for gait. (A) First, the area of the pie chart is scaled to the cost-of-transport (COT). Here 1 J/kg/m is a circle with area of  $25.0 \text{ cm}^2$ . The central reference line is defined from the center of the circle to the top. The COT is displayed in the center of the pie chart in a white circle. (B) Second, the relative constituent work contributions to absolute 6-DOF limb work during swing phase are grouped together and designated visually by a partial pie slice. From the central reference line, positive work will be to the left side of the circle (dark), while negative work is to the right (light). (C) Third, each relative constituent work is designated its portion of the pie, in the order of hip, knee, ankle, and distal foot (or ankle-foot) for swing, then stance, beginning from the central reference line. The network line at the bottom of the circle separates the positive from the negative work in stance phase.

burden of work (i.e. more absolute 6-DOF limb work) on the intact limb ( $1.49 \text{ J/kg/m}$ ) than on the prosthetic limb ( $0.67 \text{ J/kg/m}$ ) and compared to the unimpaired limbs ( $1.22 \pm 0.15 \text{ J/kg/m}$  on left and  $1.19 \pm 0.14 \text{ J/kg/m}$  on right). On the prosthetic side, there is almost equal relative limb work (summed positive and negative) from stance (49%) and swing (51%), with a majority of the work from the positive hip (24% in stance, 18% in swing). A clinician may use this information to test a powered prosthetic device to reduce the burden of work on the

**Table 1**

Net and absolute 6-DOF limb work, stride length, and cost-of-transport for average of a sample ( $n = 8$ ) of unimpaired individuals (mean  $\pm$  standard deviation), as well as for an individual subject ( $n = 1$ ) with a unilateral amputation wearing an above-knee prosthesis.

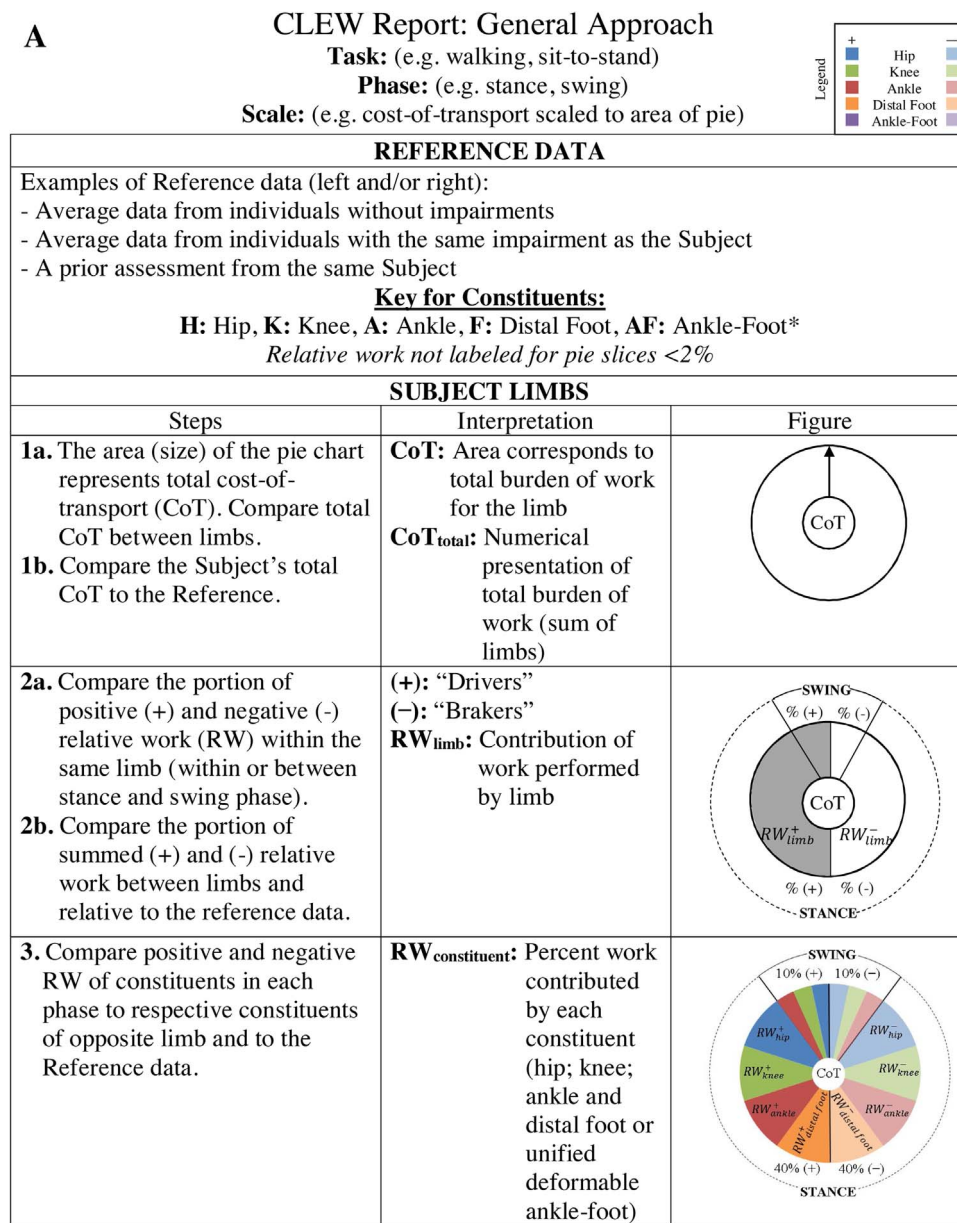
|                            | Unimpaired ( $n = 8$ ) |                 | Subject ( $n = 1$ ) |        |
|----------------------------|------------------------|-----------------|---------------------|--------|
|                            | Left                   | Right           | Prosthetic          | Intact |
| $^{net}W_{limb}$ (J/kg)    | $0.05 \pm 0.05$        | $0.11 \pm 0.09$ | 0.02                | -0.06  |
| $^{abs}W_{limb}$ (J/kg)    | $1.66 \pm 0.31$        | $1.62 \pm 0.28$ | 0.90                | 1.77   |
| Stride length (m)          | $1.36 \pm 0.14$        | $1.36 \pm 0.14$ | 1.34                | 1.19   |
| Cost-of-transport (J/kg/m) | $1.22 \pm 0.15$        | $1.19 \pm 0.14$ | 0.67                | 1.49   |

intact limb and the hip work on the prosthetic limb, as may be hypothesized from the literature [11].

Future clinical studies will be necessary to determine how a clinical

treatment affects the work distribution of the limb. The CLEW approach may be applicable to the upper extremity as well, although this application was not explored here. This was a convenient sample of eight healthy, unimpaired adults, so the values represented here may not be representative of a larger population. A limitation of the 6-DOF approach is that it does not fully capture work due to soft tissue dissipation [12].

The CLEW approach is a comprehensive data visualization tool for representing limb work over a cyclic task, such as over a stride in gait. In a single figure, the CLEW approach details the mechanical cost-of-transport, the percentage of positive and negative work performed in stance phase and swing phase, as well as the individual contributions of positive and negative work from each constituent. Furthermore, the approach can be used to compare the constituent-level adaptations occurring between limbs of individuals with impairments, or within a limb at different gait intensities.



\*See Takahashi et al., 2012.

**Fig. 2.** (A) General approach for evaluating data from the CLEW report. This guide can be used to assess the CLEW pie charts systematically. Note, if unimpaired reference data is used, left and right limbs may be grouped together when appropriate. (B) Example CLEW report with average data from unimpaired individuals ( $n = 8$ ) walking at 0.8 statures/s serving as reference data. Subject data are from an individual with a unilateral amputation ( $n = 1$ ) walking at 0.8 statures/s. The unified deformable segment model [10] was used to characterize the work from the below-knee structures of the prosthetic limb during stance phase, noted here as ankle-foot (AF).

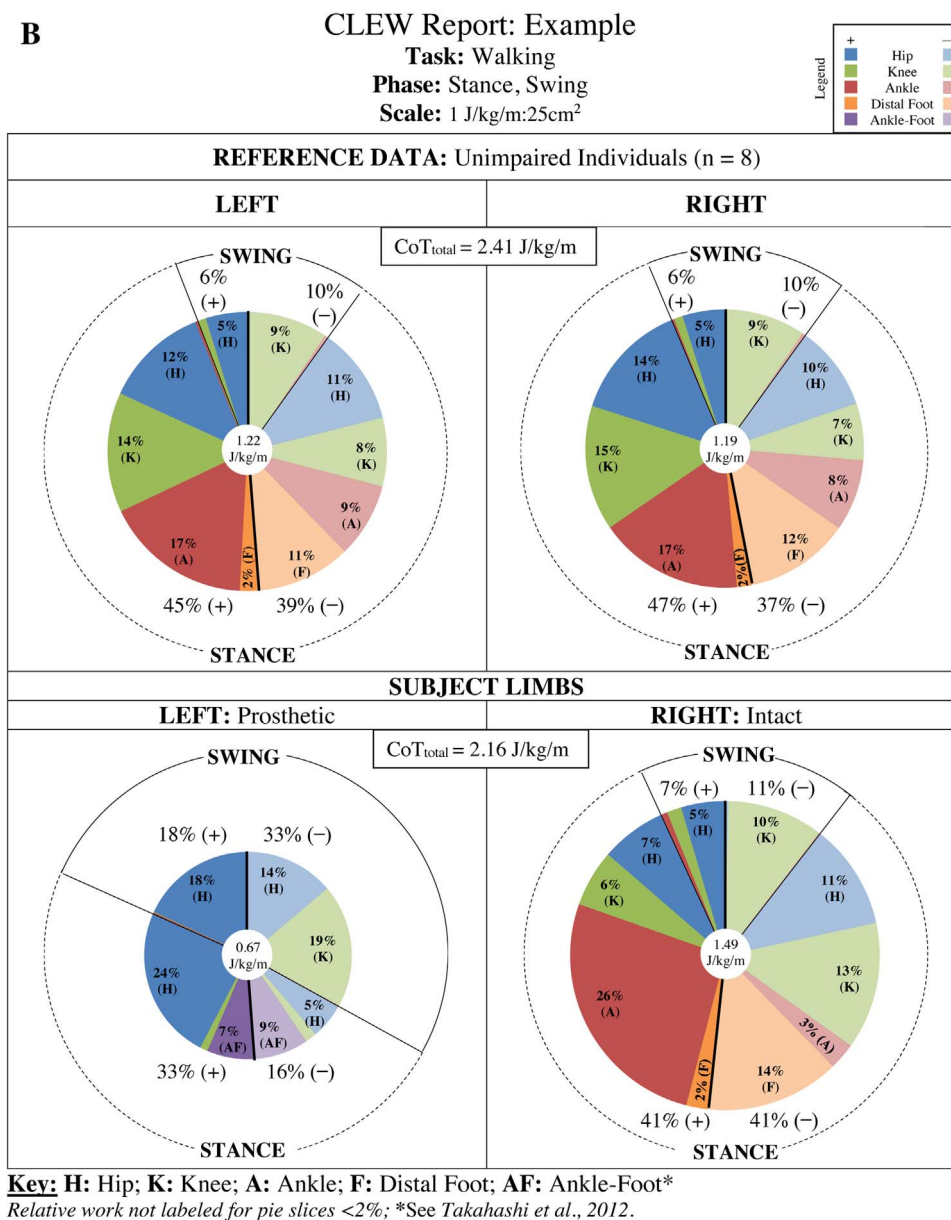


Fig. 2. (continued)

### Conflict of interest statement

The authors have no financial or personal relationships with individuals or organizations that inappropriately influenced this work.

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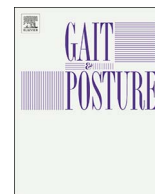
### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.gaitpost.2017.04.024>.

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## Full length article

# Healthy individuals are more maneuverable when walking slower while navigating a virtual obstacle course<sup>☆</sup>

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## ABSTRACT

**Introduction:** Maintaining stability, especially in the mediolateral direction, is important for successful walking. Navigating in the community, however, may require people to reduce stability to make quick lateral transitions, creating a tradeoff between stability and maneuverability. Walking slower can improve stability during steady state walking, but there remains a need to better understand how walking speed influences maneuverability. This study investigated how walking at different speeds influenced how individuals modulate both stability and maneuverability in a virtual obstacle course.

**Methods:** Fifteen healthy adults walked on a treadmill in a virtual environment for 6 trials each at typical and slower speed. Participants made repeated transitions between virtual sets of arches displayed in any of 4 lanes. Participants were instructed to walk under the arches and hit as few arches as possible. To quantify stability, mean step width and mean lateral margin of stability (Mean MOS) were calculated and averaged for ipsilateral and contralateral steps. To quantify maneuverability, the number of arches hit when entering or exiting each arch set was calculated and averaged for each condition.

**Results:** Participants exhibited high levels of variability in their stepping patterns. Mean MOS and mean step width were significantly greater for the typical speed than slower speed for the ipsilateral steps ( $p < 0.001$ ). Participants hit more arches during the typical speed than during the slow speed ( $p = 0.039$ ).

**Conclusion:** When walking at the slower speed, healthy individuals exhibited decreased stability of ipsilateral steps, but increased maneuverability and better transition performance.

## 1. Introduction

When walking, it is important to maintain stability, particularly in the mediolateral direction [1,2]. Having greater stability means reducing the effects of perturbing forces on one's center of mass (COM), thereby resisting movement [3,4]. When navigating through crowded areas however, people often must make quick lateral transitions that require controlled, rapid movement. These maneuvers might be anticipated (e.g., around some fixed object) or unanticipated (e.g., in reaction to a person or object suddenly coming into one's path). These tasks are performed by shifting one's COM towards a new direction, which effectively reduces one's resistance to perturbations applied in

that direction. This reduced stability can help facilitate completing such lateral maneuvers, but also creates a tradeoff between stability and maneuverability. This tradeoff has been studied in animals [5–9], but only a few studies have applied this important concept to humans [10,11]. For people to successfully navigate in the community, they must be able to quickly and effectively shift between strategies that favor stability and those that favor maneuverability.

Margin of stability in the mediolateral direction ( $MOS_{ML}$ ) can quantify lateral stability during locomotor tasks [12–14].  $MOS_{ML}$  is proportional to the amount of force needed to move the COM outside of the base of support (BOS) [15]. Strategies that favor stability then, as defined by  $MOS_{ML}$ , involve resisting perturbations and keeping COM

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within one's BOS.  $MOS_{ML}$  may also elucidate aspects of maneuverability. Reducing resistance to perturbations by changing COM position in a controlled and efficient manner helps facilitate maneuvers. By narrowing step width and decreasing the BOS, people can more easily shift their COM to make lateral transitions. According to Wu et al. [10], people decrease their  $MOS_{ML}$  in the direction of the movement in preparation of making a lateral maneuver. A decrease in  $MOS_{ML}$  on a given side when walking indicates less resistance to perturbations which facilitates making maneuvers in that direction. Therefore, a larger  $MOS_{ML}$  reflects greater stability, while a smaller  $MOS_{ML}$  suggests greater maneuverability.

Slower walking speeds are generally considered to be more stable as determined by step kinematics [16] and dynamic stability measures [17–20]. This is especially seen in older and impaired populations, where slow walking is a nearly universal characteristic of cautious gait [21]. Few studies have examined how  $MOS_{ML}$  changes with walking speed, or how people prioritize stability and maneuverability at different walking speeds. Gates et al. [22] found that when young, healthy individuals walked at faster speeds, they did so with larger  $MOS_{ML}$ . Thus at faster speeds, individuals may be more stable but less maneuverable. However, those individuals did not perform a task that required them to execute lateral maneuvers. Therefore, we cannot determine how walking speed might have influenced their maneuverability.

Previous studies largely focused on steady state walking, a task that does not require rapid, lateral movements. It is unknown how people at a typical or slower walking speed shift their  $MOS_{ML}$  when making lateral transitions. Thus, there is a need to better understand how lateral transitions and walking speed each influence stability and maneuverability. This study determined how healthy individuals modulate their maneuverability and stability while navigating a virtual reality obstacle course at different speeds. We hypothesized that at slower speeds, individuals would be more maneuverable as indicated by a smaller  $MOS_{ML}$  and would exhibit better lateral transition performance.

## 2. Methods

### 2.1. Participants

Fifteen young, healthy adults (Table 1) participated. All participants were screened to ensure they had no medical or psychological conditions that would alter normal gait, uncorrected visual impairment, or pregnancy. All data were collected within a single assessment. All procedures were approved by the Brooke Army Medical Center Institutional Review Board and all participants completed written informed consent prior to participation.

### 2.2. Protocol

All participants walked in a virtual reality environment (Computer Assisted Rehabilitation ENvironment; Motekforce Link, Amsterdam, Netherlands) which included a  $1.8 \times 2.8$  m treadmill within a 7 m dome allowing  $300^\circ$  of virtual reality display. The virtual reality scene included a walking path divided into four distinct lanes that equated to 27 cm wide each in the real-world (Fig. 1). Each trial contained a total

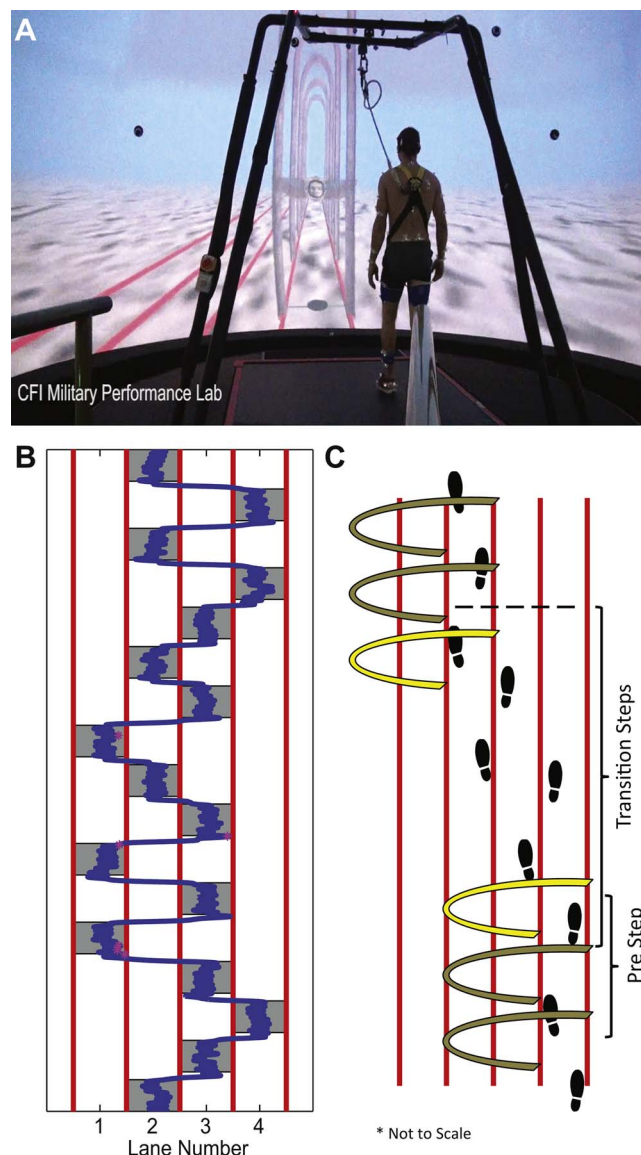


Fig. 1. The virtual obstacle course task. A) Screenshot of a typical participant completing the virtual obstacle course. B) Example of the avatar path through the arch sets during a trial. Direction of travel is from bottom to top. The avatar trajectory is marked in blue and the arch sets are indicated by the gray boxes. C) Schematic (not to scale) of a possible stepping pattern during a transition. The yellow arches indicate the beginning and end of the transition zone. A collision of the avatar with either of these arches constituted an unsuccessful transition. The transition variables were analyzed across all transition steps from the last step originating in the initial arch set to the first step terminating in the new arch set. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

of 17 projected arch sets, requiring 16 transitions. The 16 transitions were made up of a random presentation of 1 or 2 lane transitions to the left or the right with a total of 4 of each combination (Fig. 1B). A virtual avatar whose diameter was 35% of the width of a lane was projected onto the screen, representing the lateral position of the centroid of two markers attached to the participant's pelvis. Participants were instructed to navigate the avatar through the arch sets hitting as few arches as possible. The movement of the participant was scaled to 75% within the virtual environment to account for the amount of excursion and visual distortion. To maintain ecologic validity, we did not constrain the execution of the transitions. Thus, participants were able to choose whatever stepping pattern they wanted to make each maneuver. See video files in Supplementary material for examples of a participant performing this task.

Table 1  
Participant characteristics. All values except Sex are given as Mean  $\pm$  Standard Deviation.

| Characteristic  | Value             |
|-----------------|-------------------|
| Sex             | 11M/4F            |
| Age (years)     | 25.93 $\pm$ 5.25  |
| Body Height (m) | 1.72 $\pm$ 0.09   |
| Body Mass (kg)  | 74.41 $\pm$ 14.57 |

All participants walked on the treadmill at two different speeds: 0.9 m/s reflecting a slower speed and 1.2 m/s reflecting a typical walking speed [23]. Because the transition zones at both speeds were the same fixed distance (1.78 m), participants had less time to make each transition at the typical speed. Arch sets were long enough to allow participants more than ample time to reestablish balance after each transition. To represent different types of real-world scenarios that require lateral transitions, we presented participants with 2 types of transitions: “anticipation” where each upcoming arch set was visible ahead of time and “reaction” where each upcoming arch was not visible until the participant exited the current arch set.

To account for differences in the placement of the pelvis markers, we aligned the virtual scene by centering it to the participant while they stood in the middle of the treadmill. Participants completed two 3-min practice trials at 0.9 m/s to familiarize themselves with the task. They then completed 3 trials of each condition, walking for 6 trials at 0.9 m/s then repeating the same 6 trials at 1.2 m/s with rest between the slow and typical speeds. The presentation of the reaction and anticipation conditions was randomized and counter-balanced across participants.

For all trials, full body kinematic data were collected at 120 Hz using a 27-camera Vicon motion capture system (Vicon Motion Systems, Oxford, UK). The cameras tracked the trajectories of 57 markers affixed to the participant's body segments [24]. The marker positions and digitized locations of joint centers were combined to create a 13-segment model using Visual 3D (C-Motion Inc., Germantown, MD).

### 2.3. Data processing and analysis

Marker position data were filtered with a 4th order low-pass Butterworth filter with a 6 Hz cut-off frequency. Relevant metrics were extracted and further analyzed using Visual 3D and Matlab 2012b (Mathworks Inc., Natick, MA). The transition zone was defined as the area between the end of one arch set and the beginning of the next (Fig. 1C). Steps were divided into ipsilateral steps (taken in the same direction as the transition), and contralateral steps (taken in the opposite direction of the transition).

$MOS_{ML}$  was calculated as the minimum lateral distance between the extrapolated center of mass and the edge of the BOS during the stance phase of each step [10,12,22]. The extrapolated center of mass was determined using the velocity of the center of mass, and the base of support was defined as the lateral boundary estimated by the position of the 5th metatarsal marker. Step width was defined as the mediolateral distance between the heel markers at heel strike. For each trial,  $MOS_{ML}$  and step widths were averaged separately for contralateral and ipsilateral steps across all steps taken in the transition zones.

To quantify transition performance, Response Time was defined as the time elapsed between the participant exiting the last arch of a set and exiting their current lane. We also determined the total number of unsuccessful transitions across all trials. A transition was deemed unsuccessful if the avatar collided with the last arch when exiting a lane or collided with the first arch when entering a new lane. The total number of steps during the transition was also quantified.

### 2.4. Statistical analyses

As no significant asymmetries were observed for the young, healthy population, we pooled the data from transitions to both left and right directions. To simplify analyses, we also only analyzed the more difficult 2-lane transitions. All statistical analyses were run on this reduced dataset. For Mean  $MOS_{ML}$  and step width, 2 factor (Speed  $\times$  Side (ipsilateral vs. contralateral)) ANOVAs with repeated measures were run separately for the anticipation and reaction conditions. Post-hoc analysis with Bonferroni Holm's corrections were conducted when applicable, with  $\alpha = 0.05$ . For the performance variables, Response Time, unsuccessful transitions, and number of steps, single-factor (Speed) ANOVAs with repeated measures were run separately for the

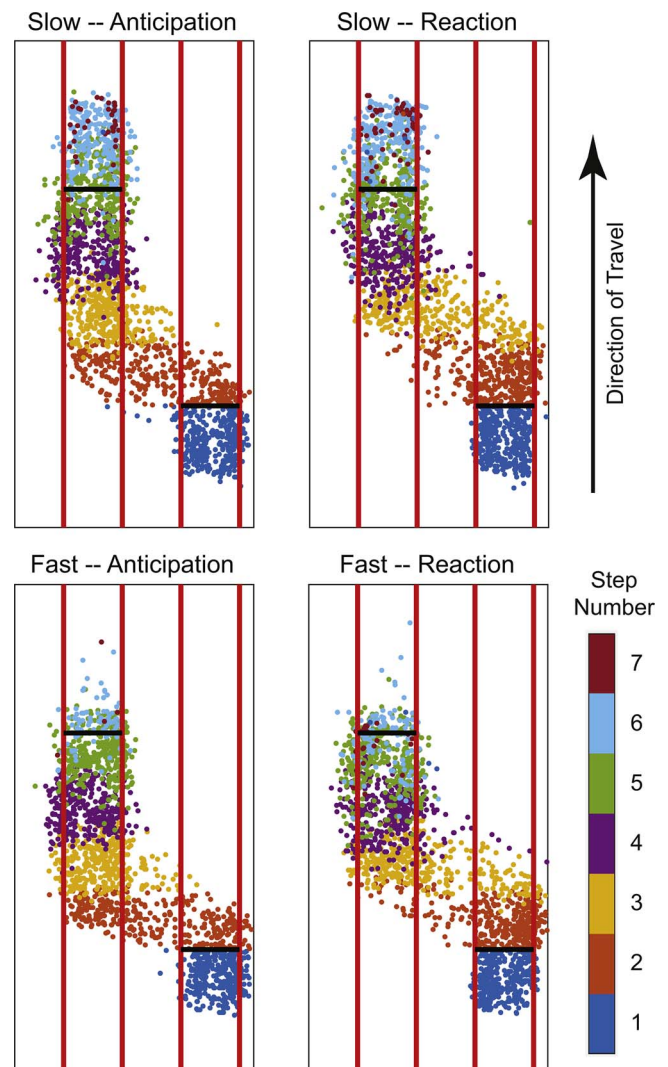


Fig. 2. Footfall locations for all 2-lane transitions for all participants for each of the 4 conditions tested. Step 1 indicates the last step taken within the arch set being exited. Participants completed transitions in typically ~5–7 steps. The figure illustrates the high level of within and between subject variability in the stepping patterns used during the transitions.

anticipation and reaction conditions.

## 3. Results

Because we purposefully did not constrain how participants could execute each transition, they exhibited high levels of variability in their stepping patterns (Fig. 2) within and across subjects as well as throughout the transitions. This included variability in the phase of the gait cycle that the participant was in when exiting the last arch of each set and in subsequent foot placements throughout each transition. Despite this variability, specific trends did emerge.

During both conditions, ipsilateral and contralateral limbs executed different steps to complete each transition (Fig. 3). Contralateral limbs generally took steps with small-to-negative  $MOS_{ML}$  and very narrow step widths, while ipsilateral limbs generally took steps with increased  $MOS_{ML}$  and much wider step widths (Fig. 3).

For both anticipation and reaction conditions, ipsilateral steps exhibited significantly greater Mean  $MOS_{ML}$  than contralateral steps ( $p < 0.001$ ) (Fig. 4A). The main effect for Speed was not significant for the anticipation condition ( $p = 0.121$ ), but neared significance for the reaction condition ( $p = 0.053$ ). However, there were also significant

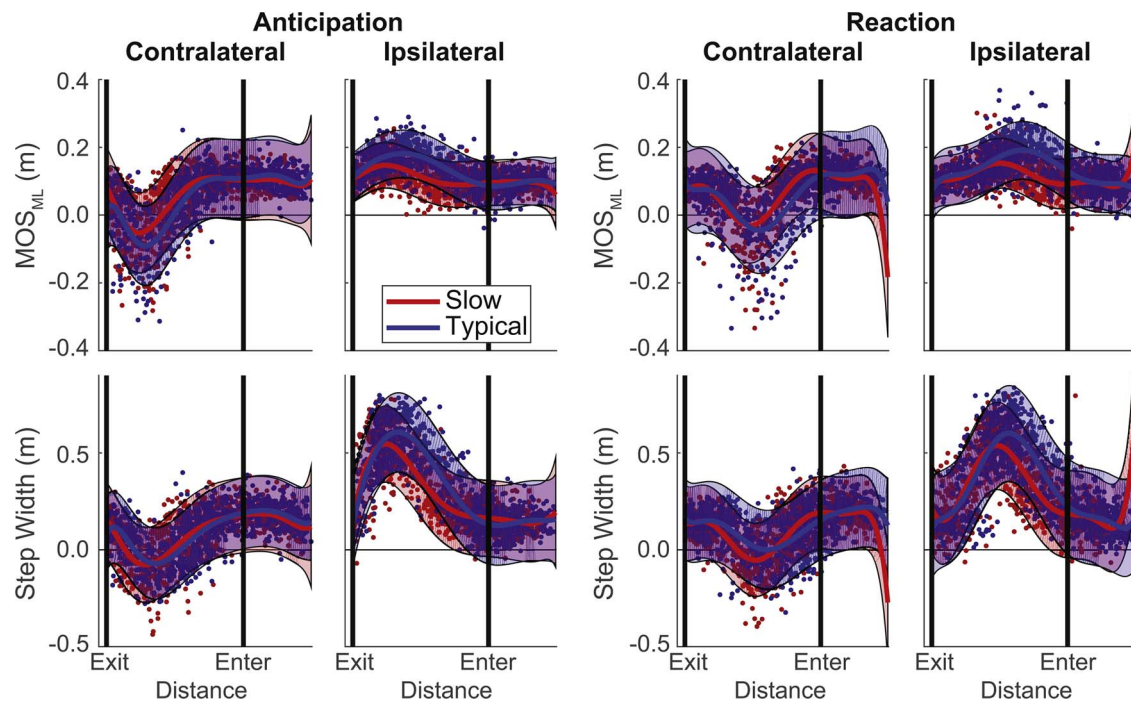


**Fig. 3.** Trends in stepping variables ( $MOS_{ML}$  and Step Width) both across observations and throughout the transition execution. In each plot, the horizontal axis indicates distance traveled (forward progression is from left to right). The vertical black lines define the transition zone: participants Exit one arch set at the first line and then Enter the next arch set (1.78 m later) at the second line. Individual points indicate values of either  $MOS_{ML}$  and Step Width for each step for all participants plotted at the time point in the transition that the step occurred. Solid lines represent 7th order polynomial fits to the stepping data, each shown with a 95% confidence band reflecting the general pattern across the transition. The Slow steps are plotted in red and the Typical are plotted in blue. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

Speed  $\times$  Limb interaction effects for Mean  $MOS_{ML}$  for both conditions ( $p \leq 0.002$ ). Pairwise comparisons revealed significantly larger Mean  $MOS_{ML}$  at typical compared to slow speeds for ipsilateral steps ( $p < 0.001$ ), but no differences for contralateral steps ( $p \geq 0.775$ ).

For both anticipation and reaction conditions, ipsilateral steps also exhibited significantly greater mean step widths than contralateral steps ( $p < 0.001$ ) (Fig. 4B). Main effects for Speed neared significance

for the anticipation condition ( $p = 0.072$ ) and were significant for the reaction condition ( $p = 0.020$ ). However, there were also significant Speed  $\times$  Limb interaction effects for both conditions ( $p \leq 0.001$ ). Pairwise comparisons revealed significantly larger mean step widths at typical compared to slow speeds for ipsilateral steps ( $p \leq 0.026$ ), but no differences for contralateral steps ( $p \geq 0.380$ ).

Participants exited their lane faster at the typical speed than at the

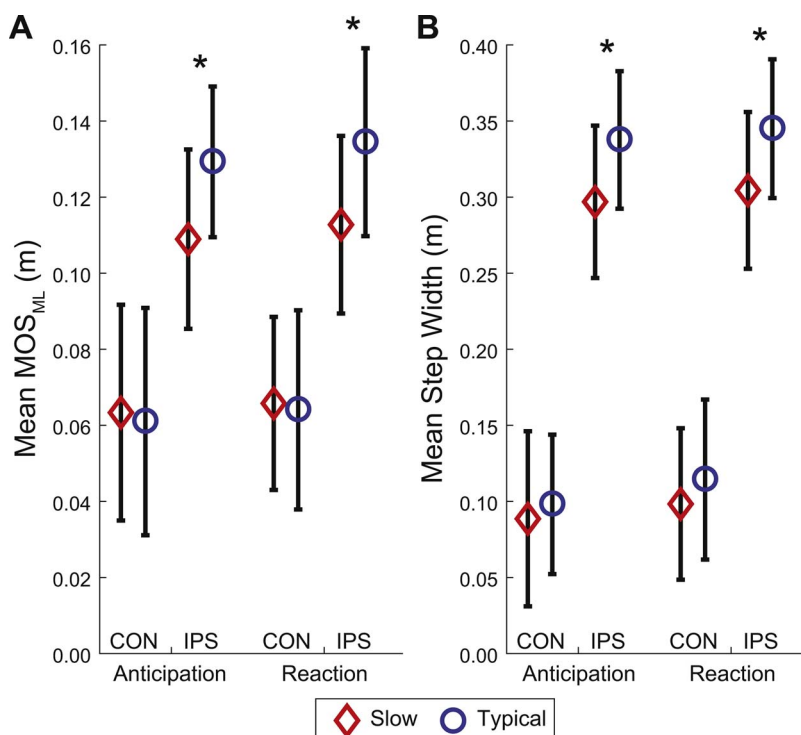


**Fig. 4.** Group mean  $\pm$  SD for variables calculated across all steps of the transition. (A) Average mediolateral margin of stability (Mean  $MOS_{ML}$ ) and (B) mean Step Width. Slow speed is indicated by red diamonds and Typical speed is indicated by blue circles. Main effects differences for Side (Contralateral (CON) vs. Ipsilateral (IPS)) were highly significant ( $p < 0.001$ ) for all comparisons. Main effects differences for Speed (Slow vs. Typical) were not significant for Mean  $MOS_{ML}$  for Anticipation trials ( $p = 0.121$ ), approached significance for Mean  $MOS_{ML}$  for Reaction trials ( $p = 0.053$ ) and were significant for Mean Step Width for Reaction trials ( $p = 0.020$ ). Speed  $\times$  Side interaction effects were significant ( $p \leq 0.002$ ) for all comparisons. Pairwise comparisons revealed significant ( $p \leq 0.026$ ) Speed differences for all Ipsilateral (IPS) steps (indicated by stars: \*). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

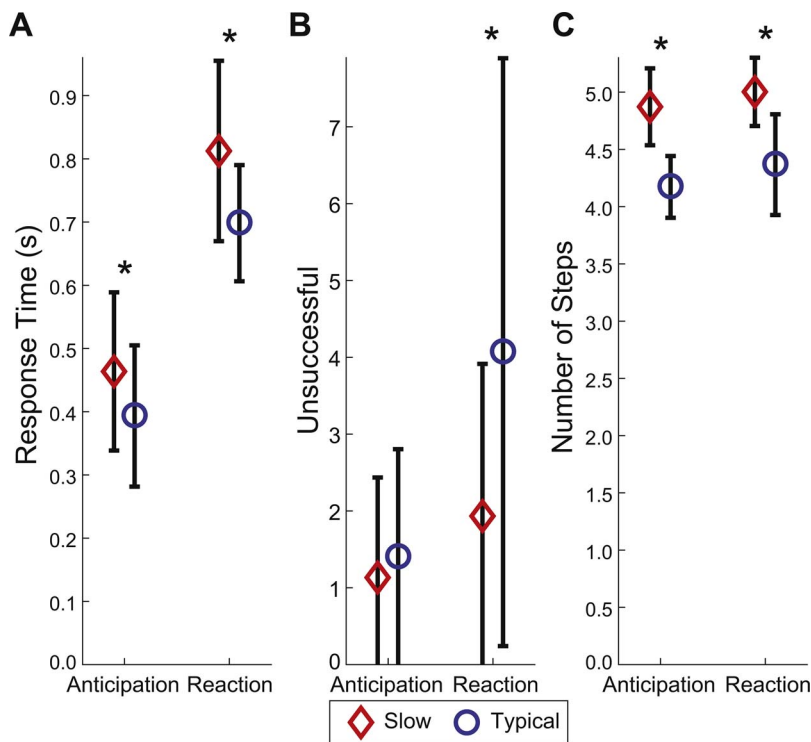


**Fig. 5.** Group mean  $\pm$  SD for transition performance variables. (A) Response Times were quantified as the amount of time between exiting the last arch in a set and exiting their current lane. (B) Total number of unsuccessful transitions where the participant collided with the first or last arch defining the transition zone. Slow speed is indicated by red diamonds and Typical speed is indicated by blue circles. Stars (\*) indicate significant differences. Slow speeds led to slower response times ( $p \leq 0.002$ ) for both conditions, more unsuccessful trials ( $p = 0.039$ ) for Reaction trials, and more steps taken ( $p < 0.001$ ) for both conditions. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

slow speed in both the reaction ( $p < 0.001$ ) and anticipation ( $p = 0.002$ ) conditions (Fig. 5A). In the reaction condition, participants were more unsuccessful when walking at the faster typical speed ( $p = 0.039$ ; Fig. 5B). In both conditions, participants took fewer steps at the faster typical speed than at the slow speed ( $p < 0.001$ ; Fig. 5C).

#### 4. Discussion

The results support our hypothesis that individuals would be more maneuverable at the slower speed. During the reaction condition at the slow speed, individuals adopted strategies on the ipsilateral side that were more conducive to maneuverability than to stability, as indicated by a lower mean  $MOS_{ML}$ , narrower step width, and fewer unsuccessful transitions. When walking at the slow speed, individuals appeared to better control their COM motion and step width to successfully transition.

During both anticipation and reaction transitions, when walking at the slower speed, participants exhibited smaller mean  $MOS_{ML}$  on the ipsilateral side, supporting our hypothesis. This suggests that for the ipsilateral steps, participants decreased their BOS when walking at the slow speed as indicated by a decreased step width, which can decrease  $MOS_{ML}$  [15,25]. However, lateral COM velocity also contributes to  $MOS_{ML}$ . Past studies found that trunk sway and COM motion decreased at slower speeds [26,27] which would potentially increase  $MOS_{ML}$ . It is likely the changes in BOS on the ipsilateral side were large relative to the changes in COM motion, thus reducing the overall  $MOS_{ML}$  at the slow speed. An overall decrease in  $MOS_{ML}$  suggests that at slower speeds, individuals' walking patterns were more unstable, but also more conducive to maneuverability during both conditions.

Individuals also took significantly narrower steps at the slow speed during both anticipation and reaction conditions at the ipsilateral side. These narrower steps suggest individuals were less stable at the slower speed, further supporting our hypothesis. A wider step width is associated with greater stability [28], and people tend to adopt wider steps in response to destabilizing environments [25]. The slower speed may have been less challenging, and therefore individuals were more comfortable taking narrower steps. Slower walking is usually associated

with greater mean step width in injured or older populations [23], but may not be adopted in young, healthy individuals. Additionally, this pattern was seen in steady state walking and not during transitioning tasks. Participants also took more steps at the slow speed, likely a result of the longer transition time. Since participants covered the same lateral distance at both speeds, it is plausible the smaller step width at the ipsilateral side was due to the greater number of steps taken. The narrower step width and smaller  $MOS_{ML}$  together suggest these individuals were less stable but more maneuverable when transitioning at the slower speed. Furthermore, maneuverability at the slow speed appears to be driven by the ipsilateral steps.

While individuals were more maneuverable at the slow speed than at the typical speed, this was only seen for the ipsilateral steps. Participants appeared to take larger steps towards the direction of the transition, followed by smaller contralateral steps. This may explain the differences in  $MOS_{ML}$  and step width for the ipsilateral steps but little differences in the contralateral steps. Furthermore, despite how large steps were taken on the ipsilateral side, step width and  $MOS_{ML}$  remained almost consistent on the contralateral side between speeds. The steps on the ipsilateral side thus drove differences in stepping strategies that contributed to greater maneuverability at the slow speed.

During the reaction condition, individuals at the slow speed were more maneuverable compared to the typical speed as evidenced by the fewer number of unsuccessful transitions. However, the fewer unsuccessful transitions at the slow speed may also reflect the greater amount of time participants had to execute the transitions, as indicated by the longer Response Time at the slow speed. It is plausible that individuals adopted their strategies based on the demands of the task. For instance, given more time at the slow speed, individuals took longer time and adjusted their stepping strategies to complete the transitions.

We investigated two transition conditions that reflect different real-world scenarios. The anticipation conditions emulated navigating around known obstacles in a known direction, thereby allowing transition maneuvers to be planned prior to execution. Conversely, the reaction conditions emulated a situation similar to having a person or object suddenly come into your path requiring you to rapidly identify and execute a maneuver in an unplanned direction. In the anticipation

condition, there were no differences between walking speeds in the number of unsuccessful transitions (Fig. 5B). While the time to make the transition was shorter at the typical speed in both conditions, the additional visual and motor delays during the reaction condition associated with identifying and responding to the new arch set location further reduced the amount of time available to execute the transition. As a result, the effect of walking speed on transition strategies and its impact on stability and maneuverability became more apparent when individuals were more sufficiently challenged during the reaction condition.

The virtual environment consisted of only four lanes. Depending on which lane a participant was in, there was a slightly higher probability the next transition would be in one direction than the other. Thus, of necessity, the reaction condition was not entirely without *some* level of “anticipation”. However, this is a minor limitation. First, there was a high cost for guessing wrong and initiating a movement in the wrong direction. Second, since the same trials and presentation of transitions were used for both anticipation and reaction trials, any effect due to the configuration of the lanes would have both conditions equally. Thus, while the reaction condition was not *completely* unpredictable, we were able to identify the effects of walking speed during the execution of transitions in both of these simulated real-world contexts.

We purposefully designed the task so as to not constrain what transition strategies participants could use. Consequently, participants exhibited high degrees of both between- and within-subject variability (Figs. 2–3), particularly in the side of the step relative to the direction of the transition. This high variability reflects a fundamental feature of how people negotiate real-world tasks that offer redundancy in the options available. In such contexts, healthy humans readily exploit the available redundancy, using a wide range of movements to achieve the same task result [29]. This ability to exploit such redundancies is also a paramount feature that allows humans the necessary flexibility to trade-off stability and maneuverability in the real world.

Although maneuverability was previously quantified and studied in animals [5–9], only a few efforts have quantified maneuverability in humans [10,11]. In addition, there are only a few proposed measures to quantify maneuverability. These are primarily task dependent and there is no general consensus on which to use. Further, the animal studies analyzed turning, dodging, or swerving [8,9,30] whereas our task focused on lateral transitions. Thus, the measures of maneuverability used in those studies, such as turning radius, were not applicable here. While  $MOS_{ML}$  is effective at measuring resistance to perturbations and COM motion, it is only associated with one aspect of maneuverability and does not necessarily fully quantify it. Because “maneuverability” is thus difficult to quantify more generally, we opted to use task performance (number of unsuccessful transitions), as our task-specific measure.

Slower walking speeds may be more stable during level, steady state walking [17–20], but when making rapid, lateral transitions in the community, walking slower may afford people more time to identify, plan and initiate movements that allow for better maneuverability that is executed by steps ipsilateral to the transition direction. Therefore, when navigating in the community, it is important to be able to switch both walking speeds and strategies depending on the specific task. For example, when negotiating obstacles, when possible, people should slow their walking speed and plan the direction of their transitions to improve maneuverability. Or if individuals plan a rapid movement, slowing down and the associated stepping strategies, particularly the ipsilateral steps, can facilitate making such maneuvers. The combination of these walking strategies and switching between tasks will likely improve how individuals modulate between stability and maneuverability when navigating in the community.

#### Conflict of interest statement

The authors declare there are no conflicts of interest associated with

this work. The study sponsors (NIH, DOD) were not involved in the final study design, data collection, analysis, or interpretation, or in the writing of the manuscript or the decision to submit the manuscript for publication.

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#### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.gaitpost.2018.02.015>.

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Mechanical and dynamic characterization of prosthetic feet for high activity users during weighted and unweighted walking  
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## Introduction

The ability to wear or carry loads beyond body weight is important for functional independence and is required in many occupational contexts (e.g., military service, firefighters, farmers, ranchers, construction workers). With regard to the military, the mass of protective gear and weapons/ammunition alone can be upwards of 21 kg (46 lb) and light infantry troops often carry loads of 45 kg (100 lb) or more during dismounted operations [1]. While numerous studies have evaluated the biomechanical and energetic consequences of load carriage in able-bodied individuals (e.g., [2-4]), only a few have investigated the comparable effects of load carriage in Service members with combat-related amputations, many of whom wish to return to active duty or other highly active/demanding occupations. Schnall et al. [5] found that compared to able-bodied individuals, lower-limb prosthesis users exhibit greater metabolic costs while walking with added loads, both at mid-range and high-end speeds of military foot marches. Other studies have shown that during weighted walking, lower-limb prosthesis users exhibit greater (and asymmetrical) demands on the musculoskeletal system [6] and larger deflections of the prosthetic ankle-foot system compared to unweighted walking [7,8]. The latter, in particular, suggests additional work focused specifically on the functional implications of these load responses is warranted.

Clinicians treating Service members and Veterans with a lower-limb amputation have a wide variety of prosthetic components to choose from; yet there remains a general lack of objective criteria for evaluating and prescribing prosthetic ankle-foot components [9,10], and none specifically for load carriage activities. During weighted walking, individuals with a healthy, intact ankle-foot complex maintain similar ankle joint kinematics and ankle-foot roll-over shapes [11,12], suggesting substantial internal joint moments are generated to counter externally applied forces and moments and effectively vary joint stiffness. Most current prosthetic ankle-foot systems, however, are not capable of providing such variations in joint stiffness in response to changing external demands. Instead, most prosthetic feet deflect proportionally with added loads, thereby resulting in increased prosthetic ankle dorsiflexion [7,8] and presumably, decreased roll-over shape radii compared to unweighted walking. To counteract this deflection, recent experimental studies have shown that increasing prosthetic forefoot stiffness can significantly decrease ankle dorsiflexion [13,14]. However, prosthetic feet with stiffer forefoot keel structures have also been shown to provide less late-stance energy return [14], highlighting a potential trade-off in the prescription strategy of feet for highly active users.

Accordingly, the main objective of this study was to investigate the ability of currently available prosthetic ankle-foot systems to accommodate weighted walking by examining the mechanical characteristics (i.e., forefoot stiffness) and dynamic function (i.e., rocker radius, effective foot length ratio, late-stance energy return) of prosthetic feet designed for the highest activity users. In order to evaluate forefoot stiffness, load versus deflection curves were obtained for nine different prosthetic ankle-foot systems using a servohydraulic test frame and load cell. Following mechanical testing, three research participants were recruited to walk with each prosthetic ankle-foot system and quantitative gait analysis was used to obtain effective roll-over shape and energy return data. We hypothesized that for prosthetic ankle-foot systems with compliant forefoot keel structures, added loads would be associated with larger deformations of the prosthetic forefoot, thereby reducing roll-over shape radii compared to unweighted walking (Fig 1, red). In contrast, we hypothesized that prosthetic ankle-foot systems with stiff forefoot keel structures would better accommodate weighted walking, as evidenced by smaller changes in roll-over shape radii with added load (Fig 1, blue). We further hypothesized that ankle-foot systems with compliant forefoot keel structures would provide more late-stance energy return compared to systems with stiff forefoot keel structures. Collectively, we expect the results of this study to be useful in guiding the selection of prosthetic feet for Service members who want to return to active duty and for individuals with lower-limb amputation who want to engage in activities that require carrying added loads.

**Fig 1. Prosthetic feet with stiff forefoot keel structures should conform to more consistent roll-over shapes when walking with added loads compared to feet with compliant forefoot keel structures.** Compliant prosthetic feet (red, middle) will continue to bend when users carry their body weight (BW) plus added loads (AL). This continued bending should lead to a roll-over shape with a smaller radius. Stiff prosthetic feet (blue, right) should have only a slight amount of additional bending when users carry added loads.  $K_{ABW}$  = forefoot stiffness at loads above body weight. [see PDF for image]

## Methods

## Selection of ankle-foot prostheses

Nine prosthetic ankle-foot systems, all marketed for users in the highest Medicare Functional Classification Level (MFCL K4), were investigated in this study: 1) Renegade AT (Freedom Innovations, Irvine, CA), 2) Thrive (Freedom Innovations, Irvine, CA), 3) Variflex XC (Össur, Reykjavik, Iceland), 4) Soleus Tactical (College Park, Warren, MI), 5) Triton Heavy Duty (Otto Bock, Duderstadt, Germany), 6) All Pro (Fillauer, Chattanooga, TN), 7) Rush Foot (Ability Dynamics, Tempe, AZ), 8) Trekk (Makstride Prosthetics, Prescott, AZ), and 9) Panthera CFII (mediUSA, Whitsett, NC). Prosthesis selection was based on several factors important for Service members returning to active duty: 1) no moving parts, which generally require less maintenance and are less prone to failure over time, 2) feet with long, spring-like keel structures, which should experience less strain for a given deflection and therefore be more robust, and 3) feet with thick keel structures, which are recommended for high impact activities required in active duty. Despite the potential for all nine feet to be appropriate for MFCL K4 users, distinguishing features in their mechanical design (e.g., the Thrive's dual-keel configuration) suggested that some feet may exhibit more consistent roll-over shapes when walking with added loads than others. Three units were purchased for each ankle-foot type based on the body weight and foot length of three users identified for human subject testing. Accordingly, twenty-seven ankle-foot prostheses were characterized during mechanical and human subject testing.

## Mechanical characterization of ankle-foot prostheses

Prior to human subject testing, load versus deflection profiles for each foot were obtained using a servohydraulic universal test frame (MTS 858, MTS, Eden Prairie, MN) with axial/torsional capabilities, a computer-based data acquisition system (Wintest, Bose, Framingham, MA), and a load cell (MTS 661-21A-01, MTS, Eden Prairie, MN). The load frame applied a uniaxial load to the foot as shown in Fig 2. The load frame recorded deflection, while the load cell recorded applied load.

**Fig 2. Load versus deflection profiles for each foot were obtained using a servohydraulic universal test frame (MTS 858, MTS, Eden Prairie, MN) with axial/torsional capabilities, a computer-based data acquisition system (Wintest, Bose, Framingham, MA), and a load cell (MTS 661-21A-01, MTS, Eden Prairie, MN).** The load frame applied uniaxial loads to the foot. [see PDF for image]

To approximate conditions expected during active duty military activities, each foot was tested in a "use state" (i.e., placed within a foot shell and a Reebok Men's Hyper Velocity 8-inch UltraLight Performance boot). A sheet of adhesive-backed polytetrafluoroethylene (PTFE) was also placed on the tread of the boot to provide a low friction interface with the loading platform. All feet were mounted in a fixture such that the plantar surface of the boot was set at a 20-degree angle from horizontal, simulating forefoot loading as defined by the ISO 10328 standard (Fig 2). Different foot components were aligned in the load frame with a mark on the boot near the "ball" of the foot. Prior to loading, the 20-degree angle was verified using a digital inclinometer placed on the non-deformed sole of the boot.

Each foot was loaded to body weight + vest weight (22 kg), approximating loading conditions associated with the second peak of the vertical ground reaction force of transtibial prosthesis users walking at speeds between 1.2-1.6 m/s [15]. Test loads were applied at a rate of 100 N/s, held for 1s, then ramped down at a rate of 100 N/s and held at 0 N for 1s. This cycle was applied nine times for each foot. Each foot was visually inspected after the test cycle to ascertain whether there was any evidence of breakage or failure.

To compare the mechanical properties of each foot, load versus deflection profiles from the ninth loading cycle were plotted from 50 N of applied load to the maximum load. The ninth loading cycle was used for analysis to allow the foot to settle into a consistent position on the load frame. The best-fit linear slope of the load versus deflection curve was then calculated between body weight and 22 kg above body weight for each respective subject, corresponding to forefoot stiffness at loads above body weight ( $K_{ABW}$ ). Stiffness values were normalized by body weight in order to calculate means across subjects.

## Dynamic characterization of ankle-foot prostheses

Human subjects testing was approved by the Minneapolis VA Health Care System's Institutional Review Board: 4523-B Characterization of Prosthetic Feet for Weighted Walking in Service Members with Lower-Limb Amputation. Data were collected on three subjects with unilateral, transtibial amputation who provided their informed written consent. Subjects were recruited based on the following inclusion criteria: Veterans between the ages of 18-50 years, transtibial amputation with non-vascular etiology, MFCL K4 as determined by a clinical prosthetist, endoskeletal prosthesis with enough clearance to test the ankle-foot systems under investigation, able to understand informed consent, and six or more months of experience with a definitive prosthesis. Subjects were excluded from the study if they presented with a sore on their residual limb, had a health condition that contraindicated participation in a weighted walking study, or had a poorly fitting socket.

Each subject was involved in the study for one visit, during which time a clinical prosthetist disconnected the subject's residual-limb socket from the rest of their prosthesis using a procedure that preserved the prosthetic alignment of their usual prosthesis for re-attachment at the end of the study [16]. The prosthetist then fit the first prosthetic foot to the subject's residual-limb socket using standard clinical procedures. The military boot used during mechanical characterization was also used during human subject testing. After clinical optimization of the alignment, the subject walked for several minutes over level ground to become accustomed to the foot design. Following this accommodation period, reflective markers were placed on their residual-limb socket to define an anatomically relevant socket coordinate system (Fig 3, right [17]).

**Fig 3. Marker placement for roll-over shape characterization.** Subjects wore a 22-kg vest for all weighted walking conditions (left). Center of pressure data were transformed into an anatomically relevant socket coordinate system (right) in order to calculate roll-over shapes for each prosthetic ankle-foot system under investigation. [see PDF for image]

Subjects then walked without added weight across two AccuGait force platforms (AMTI, Watertown, MA; sampling rate = 1200 Hz) mounted flush within a surrounding 3.4 m walkway while an 8-camera Oqus 100 motion analysis system (Qualisys Motion Capture Systems, Gothenburg, Sweden; sampling rate = 120 Hz) tracked the reflective markers on their socket. Subjects walked at their normal speed until at least five clean force

platform hits had been collected. During this first condition, the subject's walking speed was recorded; during all subsequent trials, walking speed was monitored to ensure that the subject maintained a comparable speed. Subjects were then fitted with a weighted (22 kg) vest (Point Blank Enterprises, Inc., Pompano Beach, FL; Fig 3, left) that simulated the fighting load of Service members currently engaged in combat (i.e., ballistic protective vest with load bearing equipment) and repeated the testing protocol. Once finished, the vest was removed and the prosthetist fit and aligned the next prosthetic foot. Prosthetic feet were tested in random order until subjects had walked with all nine feet.

## Data analysis

Raw marker data were processed using Qualisys Track Manager (QTM 2.11), then exported into MATLAB® (R2010b, Mathworks, Inc., Natick, MA) for further analysis. To calculate the roll-over shape of each prosthetic foot, the center of pressure of the ground reaction force was transformed into a socket-based coordinate system with its origin at the knee center [17]. Given the inherent uncertainty of center of pressure data at low force levels, a force threshold of 150 N was applied to ground reaction force data and roll-over shapes were calculated during the single-support phase of gait (i.e., between contralateral toe off and heel strike). The best-fit circular arc for each roll-over shape was then calculated in order to determine the mean roll-over shape radius (normalized by height) for each foot [12]. To quantify the effect of added weight on roll-over shape radius, within-subject differences were calculated between the mean unweighted and weighted radii for each foot, then averaged across subjects.

From roll-over shape data, the effective foot length ratio of each foot was also calculated according to methods described previously [18]. This measure represents the fraction of the total foot length that is effectively used during the single-support phase of gait. Similar to the roll-over shape analysis, within-subject differences between the mean unweighted and weighted effective foot length ratios were calculated for each foot and averaged across subjects.

Finally, a unified deformable (UD) segment analysis [19] was used to calculate total energy return of the keel using Visual3D (C-Motion, Inc., Germantown, MD). Compared to a traditional inverse dynamics analysis, the UD segment analysis considers all components below a rigid prosthetic socket a deformable mass to more accurately capture the energetics of prosthetic structures. In this study, the proximal rigid segment was defined and tracked using markers on the residual-limb socket (Fig 3, right). Markers placed on the lower limb were used to calculate shank center of mass according to Visual 3D's built-in estimator, which uses able-bodied anthropomorphic tables to calculate segment mass and moment of inertia. Total energy return of the keel was then quantified by integrating all power done by the prosthesis between zero crossings near the end of single support phase and at toe off. These data were averaged for each foot and weight condition across their respective trials and normalized by subject mass (including the 22-kg mass when relevant) to determine the mean energy return values for each prosthesis in both the weighted and unweighted conditions.

## Results

### Subject demographics

Data were collected from three male subjects with unilateral, transtibial amputation. Amputation etiology included trauma (2 subjects) and bone lesion (1 subject). The mean age, mass, and height of the subject population was  $39 \pm 6$  years,  $85 \pm 14$  kg, and  $1.76 \pm 0.05$  m, respectively (Table 1). All subjects had at least 31 months of experience with a definitive prosthesis (Table 1). The self-selected walking speed of the group ranged from 1.23-1.49 m/s. Once selected, subjects maintained a similar walking speed across all test conditions (Table 1).

### Mechanical characterization of ankle-foot prostheses

Fig 4 shows the results of mechanical testing, with load versus deflection curves grouped according to test subject. Although stiffness profiles varied across prosthetic feet, it is interesting to note that for all three subjects, the Soleus and All Pro consistently appeared to be the least stiff (i.e., most displacement per unit load) and the Thrive and Triton appeared to be the most stiff.

**Fig 4. Load versus displacement curves from the ninth loading cycle obtained during mechanical characterization.** The horizontal line represents body weight. Maximum load represents body weight plus the weighted vest (22 kg). Small discontinuities evident in some curves (e.g., near the maximum load of Subject A using the Soleus) represent momentary sticking at the loading interface despite the low-friction PTFE sheet affixed to the boot tread. [see PDF for image]

Mean calculated forefoot stiffness is quantified in Fig 5. Stiffness values are sorted from lowest (All Pro =  $0.04 \pm 0.006\%$ BW/mm) to highest (Thrive =  $0.09 \pm 0.02\%$ BW/mm). The mean coefficient of determination ( $r^2$ ) of the best-fit linear slope of the load versus displacement curve above body weight was  $0.996 \pm 0.006$  (range: 0.969-1.000) across all feet.

**Fig 5. Mean ( $\pm 1$  standard deviation) forefoot stiffness at loads above body weight ( $K_{ABW}$ ).** Results are sorted from least (left) to greatest (right) forefoot stiffness. [see PDF for image]

### Roll-over shape characterization of ankle-foot prostheses

Despite differences observed in forefoot stiffness during mechanical testing, roll-over shape profiles measured during human subject testing appeared relatively similar between the weighted and unweighted walking conditions for all 27 ankle-foot prostheses tested in this study. Fig 6 shows all trials of Subject A wearing the All Pro (i.e., least stiff) and Thrive (i.e., most stiff) during both the weighted and unweighted walking conditions. Fig 7 shows the mean roll-over shape radius across all subjects for each foot. For the unweighted walking condition, the mean roll-over shape radius (normalized by height) across feet was  $0.170 \pm 0.009$  and ranged from  $0.156 \pm 0.023$  for the All Pro to  $0.183 \pm 0.017$  for the Trekk. For the weighted walking condition, the mean roll-over shape radius across feet appeared to decrease to  $0.152 \pm 0.008$  and ranged from  $0.140 \pm 0.019$  for the Variflex to  $0.162 \pm 0.012$  for the Thrive.

**Fig 6. Roll-over shapes from all trials of the All Pro and Thrive during weighted and unweighted walking for Subject A.** Roll-over shapes are shown in a socket-based coordinate system with the origin at the knee center. [see PDF for image]

**Fig 7. Mean ( $\pm 1$  standard deviation) roll-over shape radii (normalized by height) across all subjects.** Results are sorted from smallest (left) to largest (right) mean unweighted roll-over shape radius for each foot. [see PDF for image]

Fig 8 shows the mean change in roll-over shape radius due to added weight across all subjects, sorted from the smallest difference (All Pro =  $0.003 \pm 0.025$ ) to the largest difference (Triton =  $0.028 \pm 0.009$ ). Standard deviation bars for the All Pro, Rush, and Thrive feet are larger than the other six feet due to the fact that Subject B exhibited a smaller roll-over shape radius for the unweighted versus the weighted condition. For all other ankle-foot systems analyzed in this study (i.e., 24 out of 27 feet), roll-over shape radius consistently decreased during weighted versus unweighted walking.

**Fig 8. Mean ( $\pm 1$  standard deviation) change in roll-over shape radius (unweighted-weighted) across all subjects.** Results are sorted from the smallest (left) to largest (right) difference in roll-over shape radii (normalized by height). [see PDF for image]

#### Effective foot length ratio of ankle-foot prostheses

Fig 9 shows the effect of added weight on changes in effective foot length ratio calculated across all subjects. As shown in this figure, mean effective foot length ratio changed less than 0.053 across all feet. Data shown in Fig 9 have been sorted from the foot with the smallest change in effective foot length ratio (Thrive =  $0.026 \pm 0.019$ ) to the foot with the largest change in effective foot length ratio (All Pro =  $0.053 \pm 0.016$  mm). Feet with the lowest forefoot stiffness measured during mechanical testing (All Pro and Variflex) appeared to exhibit the largest change in effective foot length ratio due to added weight, whereas feet with the highest forefoot stiffness (Trek and Thrive) appeared to exhibit the smallest change in effective foot length ratio due to added weight.

**Fig 9. Mean ( $\pm 1$  standard deviation) change in effective foot length ratio (unweighted-weighted) across all subjects.** The effective foot length ratio is a fraction of the total foot length that is effectively used during the single-support phase of gait. Results are sorted from the smallest (left) to largest (right) difference in effective foot length ratio. [see PDF for image]

#### Late-stance energy return of ankle-foot prostheses

Finally, Fig 10 shows the mean late-stance energy return normalized by mass (including the 22-kg mass when relevant) across all subjects for the unweighted and weighted walking conditions. For the unweighted walking condition, the mean late-stance energy return across feet was  $0.159 \pm 0.038$  J/kg and ranged from  $0.094 \pm 0.011$  J/kg for the Thrive to  $0.215 \pm 0.038$  J/kg for the All Pro. For the weighted walking condition, the mean late-stance energy return across feet appeared to increase only slightly to  $0.170 \pm 0.036$  J/kg and ranged from  $0.109 \pm 0.017$  J/kg for the Thrive to  $0.222 \pm 0.015$  J/kg for the All Pro.

**Fig 10. Mean ( $\pm 1$  standard deviation) late-stance energy return across all subjects sorted from the least (left) to most (right) unweighted energy return.** [see PDF for image]

#### Discussion

While many Service members and Veterans with lower-limb amputation have the potential for high function, objective criteria for evaluating and prescribing appropriate ankle-foot prostheses is currently lacking. Specifically, for Service members with a lower-limb amputation, it is unclear which prosthetic ankle-foot systems best accommodate load carriage while also providing good overall function and mobility for unweighted activities. Compared to healthy, intact ankle-foot systems that adapt to added load by maintaining similar ankle motion and effective rocker shapes during walking [12], most prosthetic feet are spring-like and continue to bend with added load. Naturally, preventing this bending through the prescription of prosthetic feet with stiff forefoot keel structures would seem to best mimic the physiologic system that these devices are trying to replace. An important consideration in this prescription strategy, however, is that prosthetic feet with stiff forefoot keel structures are also less likely to provide sufficient late-stance energy return [14], possibly contributing to an increase in metabolic energy expenditure during physically demanding activities such as weighted walking. Understanding the relative tradeoff between roll-over shape invariance, changes in effective foot length ratio, and late-stance energy return as a function of forefoot keel stiffness is therefore an important consideration in prescribing prosthetic feet that meet the needs of high-functioning persons with lower-limb amputation. The goal of this study was to investigate the ability of currently available prosthetic ankle-foot systems to accommodate weighted walking by examining the mechanical characteristics (i.e., forefoot stiffness) and dynamic function (i.e., rocker radius, effective foot length ratio, late-stance energy return) of prosthetic feet designed for the highest activity users.

As expected, mechanical testing revealed that forefoot stiffness varied across all ankle-foot systems, both within foot type and between foot type. Variations within foot type are evident from the different order (left to right) of load versus deflection curves shown for each subject in Fig 4. These variations are likely due to the fact that the body weight and foot length of each subject was different, resulting in different foot sizes, spring categories, and therefore, slightly different mechanical properties within each foot type. Furthermore, the magnitude of loading used to calculate  $K_{ABW}$  was relative to the users' body weight, potentially resulting in load-dependent variability within each foot type. Larger

differences in mechanical designs between foot type resulted in larger variations in forefoot stiffness across feet. According to the results shown in Fig 5, the All Pro, Variflex, and Soleus feet appeared to provide the least forefoot stiffness at loads above body weight and the Triton, Trek, and Thrive feet appeared to provide the most forefoot stiffness. In particular, the Thrive appeared to have the stiffest forefoot, likely owing to its unique design: a full-length primary keel that progressively comes into contact with a secondary, upper keel to provide additional support to added loads. Seemingly this design feature would best accommodate load carriage by resulting in smaller changes in roll-over shape radius and effective foot length ratio during weighted walking.

Contrary to our hypothesis, this result was not readily apparent in the subsequent analysis of ankle-foot roll-over shape data. Instead, while

appreciable changes in forefoot stiffness were observed across all feet during mechanical testing, roll-over shape profiles appeared largely insensitive to the effects of load carriage. Fig 6 shows the effective roll-over shape of two feet on the extremes of forefoot stiffness—the All Pro (i.e., least stiff) and the Thrive (i.e., most stiff). Despite appreciable differences in stiffness profiles between these feet, both exhibited relatively small changes in roll-over shape radii during weighted walking (Fig 8). A possible explanation for this result may be that while wearing the All Pro, Subject B exhibited a smaller roll-over shape radius during unweighted (versus weighted) walking, resulting in a negative change in radius that decreased the overall mean (and increased the standard deviation) reported in Fig 8. However, even without this conflicting result, overall changes in roll-over shape radii, which ranged from  $0.003 \pm 0.025$  (All Pro) to  $0.028 \pm 0.009$  (Triton), correlated poorly with  $K_{ABW}$  (linear curve fit,  $r^2 = 0.03$ ) and were similar in magnitude to the approximate change ( $0.015$ ) in roll-over shape radius observed in the ankle-foot system of an able-bodied population walking with a comparable 23-kg weighted vest [12]. Accordingly, changes observed in roll-over shape radii across prosthetic feet with different forefoot stiffness profiles all appeared to be within a physiological "normal" range.

The clinical implications of varying rocker radius and foot length on the energetic cost of walking have been investigated previously by Adamczyk and Kuo [20], who found that foot length (versus radius) has a much greater effect on both the mechanical work of the step-to-step transition and the overall energetic cost of walking. In this previous study, net metabolic rates were estimated from respiratory gas exchange data collected during treadmill trials while able-bodied subjects wore custom-made walking boots with interchangeable bottom surfaces designed with different foot radii and foot lengths. Five of these surfaces had a foot radius of 0.4 m with different foot lengths (0.203, 0.229, 0.254, 0.279, 0.305 m) and two of these surfaces had a foot length of 0.254 m with different foot radii (0.3 and 0.6 m). Within the range of radii tested (300 mm total), metabolic rate did not change significantly, suggesting that the mean changes observed across feet in the present study (0.003-0.028; equivalent to 6-48 mm) probably did not have a significant effect on the energetic cost of walking. Likewise, while varying foot length (within a 100-mm range) has been shown to more significantly affect walking energetics, the magnitude of changes observed in the present study (Fig 9; minimum =  $0.026 \pm 0.019$ ; equivalent to  $7 \pm 5$  mm with the Thrive; maximum =  $0.053 \pm 0.016$ ; equivalent to  $14 \pm 4$  mm with the All Pro) also appeared relatively small and therefore, did not likely affect walking energetics.

Beyond these studies, others have shown that reductions in effective foot length may also contribute to a drop-off effect that could lead to a shorter step length on the contralateral foot and a more forceful loading of the sound side limb during weighted walking activities [13,16,21]. For example, in a study of transtibial prosthesis users by Hansen et al. [16], simple modifications were used to alter the effective forefoot rocker length of a Shape&Roll prosthetic foot to 62%, 74%, and 82% of its total length. At both normal (1.0-1.2 m/s) and fast (1.4-1.6 m/s) walking speeds, a significant difference in the symmetry of the first peak of the vertical ground reaction force was found between the 74% and 82% foot length conditions, corresponding to a difference in effective foot length of approximately 8%. While the mean changes in effective foot length across all feet in the present study were less than 8%, additional studies are needed to confirm whether these reductions may in fact cause more forceful loading on the sound side, particularly at fast walking speeds, which were not investigated in the present study.

The apparent insensitivity of roll-over shape parameters to weighted walking in the present study suggests that a more important consideration in prescribing prosthetic feet for high activity users may instead be the effect of forefoot stiffness on late-stance energy return. Indeed, late-stance energy return appeared highly sensitive to forefoot stiffness, with the least stiff feet (All Pro, Variflex, Soleus) providing the most late-stance energy return and the stiffest feet (Thrive, Triton, Trekk) providing the least late-stance energy return. These results are also in agreement with those of a previous study by Fey et al. [14], which found that compliant feet tended to increase late-stance dorsiflexion, mid-stance energy storage, late-stance energy return, and intact and residual muscles activity, especially in the muscles responsible for body support. The authors of this previous study concluded that while foot compliance may be beneficial for prosthesis users with strong quadriceps and good control of these muscles, the net contribution to forward propulsion and swing initiation appears limited by the amount of additional muscle activity needed for body support. Furthermore, in a more recent study by the same group, a forward dynamic model was used to find that net metabolic cost was actually minimized when the nominal stiffness of the prosthetic toe and mid-foot was increased and the nominal stiffness of the heel and ankle was decreased [22]. Accordingly, forefoot stiffness clearly has an important effect on late-stance energy return, however the relationship between forefoot stiffness and net metabolic cost is influenced by the stiffness in other regions of the prosthetic forefoot as well as the strength of intact and residual-limb musculature that supports and propels the body forward during walking.

Collectively, these study results highlight several important paths for future investigation. In the current study, three users with different body weights and activity levels each walked with nine commercially available prosthetic feet, applying functionally relevant loading profiles to a total sample size of 27 different ankle-foot systems. This study design allowed for a thorough investigation of prosthetic feet designed for MFCL 4 users, guiding future clinical testing of these systems. However, to understand the statistical and clinical significance of changes observed in the rocker shape and late-stance energy return of these feet, future studies should include activities beyond that of level walking and involve a larger, more diverse study population. Using the roll-over shape radius data collected in this study, we ran a power analysis for a one-tailed paired t-test using G\*Power 3.1. Effect size ( $d$ ) was calculated using the mean and standard deviation difference in rocker radius between the unweighted and weighted conditions (across subjects) for one foot with the consistently lowest (Soleus) and one foot with the consistently highest (Thrive) forefoot stiffness according to Fig 4. Assuming a correlation between groups of 0.5 (resulting in an effect size  $d = 0.97$ ),  $[\alpha] = 0.05$ , and power = 90%, a sample size of 11 subjects would be needed in a future clinical study to determine a significant difference in radii of these two prosthetic ankle-foot systems.

Future studies should also consider the effect of weight distribution about the torso, walking speed, and prosthetic alignment on the dynamic characterization of prosthetic ankle-foot systems designed for high activity users. Indeed, several previous studies of weighted walking have used different weight distribution methods (e.g., backpacks) to simulate common scenarios of load carriage (e.g., [3,6,7]). While the results of these previous studies may not be entirely generalizable to the present study, the methodological decision to utilize a weighted vest in the present study was based on ecological validity, resulting in a protocol that more closely simulates the weight distribution of protective gear and weapons/ammunition carried during dismounted operations in the military. Furthermore, walking speed was controlled in the present study to isolate the effect of added weight on gait. It is possible, however, that subjects may have been forced to walk in a manner that was not optimal or preferred (e.g., subjects may have preferred a slower walking speed while carrying added weight). Finally, in the present study, alignment was clinically optimized for each foot by a certified prosthetist, following standard clinical procedures. Prior work has shown that this approach can reduce differences between feet, compared to an approach of keeping the alignment constant between feet [17]. We believe the approach adopted

in the present study is more clinically relevant and allows the clinician to determine if there are still meaningful differences between feet after clinically optimized alignment.

With regard to mechanical testing, it is important to note that only one angle was used to test and analyze forefoot deflection, and that more comprehensive testing configurations, such as those outlined by ISO 22675, may provide additional insight into the overall dynamic response of prosthetic feet designed for high activity users. Furthermore, future analyses should consider the contribution of overall stiffness and vertical compliance on the assessment of prosthetic feet designed to accommodate heavy load carriage and to what extent heel stiffness affects weighted walking.

## Conclusions

According to the mechanical and human subject testing performed in this study, prosthetic feet with a range of forefoot stiffness profiles exhibited minimal changes in roll-over shape radii and effective foot length ratio measured during weighted walking compared to unweighted walking. At the same time, prosthetic feet with more compliant forefoot keel structures appeared to provide more late-stance energy return compared to feet with stiffer keels, both during the weighted and unweighted walking conditions. The results of this study may be useful in providing a guide for the prescription of prosthetic feet for high activity users. For examples, prosthetic feet that feel too soft or too stiff can be replaced with other foot types that are stiffer or more compliant according to the data presented in Fig 5. The results of this study also suggest that prosthetic ankle-foot systems with compliant forefoot keel structures may better accommodate weighted walking by reducing the metabolic cost of high-impact activities. However, other factors, such as the residual-limb strength of the user, the overall stiffness profile of the prosthetic foot, and the durability of the prosthesis in response to sudden impacts, should be considered in combination with these results to more fully understand the functional implications of prescribing prosthetic feet with different forefoot keel properties.

## Supporting information

**S1 File** Minimal data underlying study results. (XLSX)

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REVIEW ARTICLE (META-ANALYSIS)

# Systematic Review of Measures of Impairment and Activity Limitation for Persons With Upper Limb Trauma and Amputation



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## Abstract

**Objective:** (1) To identify outcome measures used in studies of persons with traumatic upper limb injury and/or amputation; and (2) to evaluate focus, content, and psychometric properties of each measure.

**Data Sources:** Searches of PubMed and CINAHL for terms including *upper extremity, function, activities of daily living, outcome assessment, amputation, and traumatic injuries*.

**Study Selection:** Included articles had a sample of  $\geq 10$  adults with limb trauma or amputation and were in English. Measures containing most items assessing impairment of body function or activity limitation were eligible.

**Data Extraction:** There were 260 articles containing 55 measures that were included. Data on internal consistency; test-retest, interrater, and intrarater reliability; content, structural, construct, concurrent, and predictive validity; responsiveness; and floor/ceiling effects were extracted and confirmed by a second investigator.

**Data Synthesis:** The mostly highly rated performance measures included 2 amputation-specific measures (Activities Measure for Upper Limb Amputees and University of New Brunswick Test of Prosthetic Function skill and spontaneity subscales) and 2 non-amputation-specific measures (Box and Block Test and modified Jebsen-Taylor Hand Function Test light and heavy cans tests). Most highly rated self-report measures were Disabilities of the Arm, Shoulder and Hand; Patient Rated Wrist Evaluation; QuickDASH; Hand Assessment Tool; International Osteoporosis Foundation Quality of Life Questionnaire; and Patient Rated Wrist Evaluation functional recovery subscale. None were amputation specific.

**Conclusions:** Few performance measures were recommended for patients with limb trauma and amputation. All top-rated self-report measures were suitable for use in both groups. These results will inform choice of outcome measures for these patients.

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The high casualty rate of U.S. service members from conflicts in Operation Iraqi Freedom, Operation Enduring Freedom, and Operation New Dawn has stimulated research to address needs of this population.<sup>1</sup> Nearly half of combat-injured service members sustained extremity trauma.<sup>2</sup> Approximately 40% with serious extremity injury sustained major upper limb trauma and/or amputation.<sup>3</sup> Many experience problems with reintegration and/or separation from active duty service.<sup>4</sup> However, to date, there has been no systematic approach to measuring outcomes for these patients across treatment episodes and settings.

Most service members with combat-related amputation and serious limb trauma transition to care within the Department of Veterans Affairs. Individual clinicians and medical centers use a variety of tools to assess patients. The lack of standardization makes tracking progress or comparing outcomes difficult. However, efforts are underway to develop a unified data system across health care systems. Outcome measures are essential for assessing patient progress, guiding the therapeutic process, and determining treatment effectiveness.<sup>5</sup> When used across systems of care they can track longitudinal changes.

Standardized collection of outcomes has applicability beyond military and veteran health care. There is increasing recognition that standardized measurement should be performed across all care settings. However, selected outcome measures should be reliable and

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valid for the intended population and responsive to important change.<sup>6</sup> Because these measurement properties may vary between patient groups, measures should be studied within their target population. Few measures were developed or validated to assess outcomes in persons with upper limb trauma and/or amputation. Prior systematic reviews of measures have only focused on upper limb amputation.<sup>7,8</sup>

The Bridging Advanced Developments for Exceptional Rehabilitation Consortium was funded to improve the lives of wounded warriors with musculoskeletal injuries and optimize functional outcomes. One of Bridging Advanced Developments for Exceptional Rehabilitation's projects was to develop a toolbox of measures for upper limb trauma and amputation. Because these patients often have disability caused by impairments in body structures and function with resulting activity limitations, this review focused on those areas. Study purposes were (1) to identify outcome measures used in research studies of persons who have sustained traumatic upper limb injury; and (2) to evaluate the focus, content, and psychometric properties of each identified measure.

## Methods

This review focused on impairment of body function and activity limitation. These constructs were defined using the taxonomy of the *International Classification of Functioning, Disability and Health*.<sup>9</sup> This review included measures addressing body functions (chapter 7: functions of movement and mobility) and the domain of activity (chapter 4: mobility, chapter 5: self-care, and chapter 6: domestic life). These categories were selected because improving function in these domains is a common rehabilitation goal.

PubMed and CINAHL were searched using terms such as *upper extremity, function, activities of daily living, amputation, and traumatic injuries* (appendix 1). Abstracts were screened for eligibility by 2 investigators. Included articles used a standardized outcome measure, included  $\geq 10$  adults with upper limb amputation or trauma, were written in English, and had an abstract. Dissertations, books or book chapters, and conference proceedings were excluded. If investigators disagreed on eligibility, inclusion was discussed, and decisions were made jointly.

Many measures assess constructs not fully consistent with the *International Classification of Functioning, Disability and Health* categories targeted in our review (ie, functions of movement and mobility, activity [chapter 4: mobility, chapter 5: self-care, and

chapter 6: domestic life]). This review included articles containing measures with most items assessing function/activity. Therefore, the content of each measure was examined. Two authors independently coded measure content to identify aspects covered (eg, speed, movement), need for special equipment, and specific *International Classification of Functioning, Disability and Health* elements addressed. After initial coding, authors discussed discrepancies and final categorization of content was determined. Measures excluded after content analysis are shown in appendix 2.

Relevant details were extracted from each manuscript by one author, and then examined by a second author to ensure completeness and accuracy. When 2 authors disagreed on information extracted, a third author checked the article. Measurement properties were scored based on overall results using methods adapted from others,<sup>5,10-17</sup> and described in prior work.<sup>18</sup> Measurement properties are presented in table 1, and scoring criteria is presented in table 2.

Two authors independently scored each measure. In the event of discrepancies, a consensus score was reached through discussion with a third author and/or a rereview of articles. An overall score was calculated using an unweighted sum of ratings of all measurement properties. The 5 highest scores among self-report and performance measures were used to select the measures with the top scores in each category. When scores were tied,  $>5$  measures were included.

## Results

The searches yielded 1380 publications: 491 met criteria for review, and 260 met inclusion criteria after full review (fig 1). Included articles contained data on 55 eligible outcome measures: 19 performance and 36 self-report. Psychometric ratings for all measures are presented in tables 3 and 4. The highest rated performance measures in descending order of ranking were Activities Measure for Upper Limb Amputees (AM-ULA), University of New Brunswick Test of Prosthetic Function (UNB) skill subscale, UNB spontaneity subscale, Box and Block Test (BBT), and heavy cans and light cans subtests of the modified Jebsen-Taylor Test of Hand Function (JTHF) (tied for fifth place). The highest rated self-report measures were Disabilities of the Arm, Shoulder and Hand (DASH), Patient Rated Wrist Evaluation (PRWE) overall score, QuickDASH, Hand Assessment Tool (HAT), International Osteoporosis Foundation Quality of Life Questionnaire, and PRWE functional recovery subscale. The HAT, International Osteoporosis Foundation Quality of Life Questionnaire, and PRWE functional recovery subscale were tied for fourth place. These measures and their measurement properties are subsequently described; similar details for other measures are in appendix 3.

Most performance measures assessed aspects of hand and arm gross motor use, and carrying and handling objects. Many also addressed fine motor tasks (tables 5 and 6). Far fewer, and no highly rated, non-amputation-specific measures assessed self-care or domestic life activities. In contrast, most self-report measures addressed self-care and domestic life activities. Some self-report measures also addressed difficulty in performing recreational activities and impairments (eg, pain, tingling, sleep disturbance).

## Performance measures

### Activities Measure for upper limb amputees

The AM-ULA contains 18 items for household and self-care tasks, including brushing hair, cutting meat with a knife and fork, and

### List of abbreviations:

|        |                                                         |
|--------|---------------------------------------------------------|
| AM-ULA | Activities Measure for Upper Limb Amputees              |
| BBT    | Box and Block Test                                      |
| DASH   | Disabilities of the Arm, Shoulder and Hand              |
| ES     | effect size                                             |
| HAT    | Hand Assessment Tool                                    |
| ICC    | intraclass correlation coefficient                      |
| JTHF   | Jebsen-Taylor Test Hand Function Test                   |
| MDC90  | minimal detectable change at a 90% confidence interval  |
| MDC95  | minimal detectable change at a 95% confidence interval  |
| PRWE   | Patient Rated Wrist Evaluation                          |
| SF-36  | Medical Outcomes Study 36-Item Short-Form Health Survey |
| SRM    | standardized response mean                              |
| UNB    | University of New Brunswick Test of Prosthetic Function |

**Table 1** Measurement properties evaluated in the systematic review

| Psychometric Attribute                         | Methodologic Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Reliability</b>                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Internal consistency                           | Internal consistency is a measure based on the correlation between items of a measure. It measures whether separate items are similar enough that they are capturing the same general construct. Typically Cronbach $\alpha$ is used to test internal consistency— excellent scores for coefficients are $\geq .80$ , adequate are from $.60$ to $.79$ , and poor are $< .60$ . Person-separation reliability index from Rasch analyses may also be used where good scores are $\geq .80$ and excellent ones are $\geq .90$ .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Test-retest reliability                        | Test-retest reliability (or repeatability) is a measure of stability of a test over time, under the same conditions. Test-retest reliability is typically evaluated using ICCs for continuous data or $\kappa$ statistics for categorical data. Coefficients $> .80$ are considered excellent, scores from $.60$ to $.79$ are considered good, and anything $< .60$ is considered poor. Test-retest interval should be stated and be at least several days apart and well justified. Overall sample size should be at least 30 participants (may have smaller subgroups for exploratory analyses). Training of assessors/ interviewers and test administration details should be clearly outlined.                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Interrater reliability                         | Interrater reliability is the degree of agreement among different raters. Interrater reliability is evaluated using the same metrics as test-retest reliability.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Intrarater reliability                         | Intrarater reliability is the degree of agreement among repeated measurements by a single rater. It is evaluated using the same metrics as test-retest reliability.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Validity</b>                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Face and content validity (scale construction) | Face validity is a subjective determination of how well a measure covers the construct it is meant to measure. Content validity is similar, but typically involves an evaluation by experts on whether the measure covers all aspects of the given construct. For face validity, there should be evidence that the test is intuitively meaningful to the tester and patient. For content validity, there should be description of a formal content validity evaluation. This would typically involve a description of the literature review process and the stakeholders involved in item generation, item reduction, and final review of content (items and response sets) within the clinical population to which the measure will be applied. For content validation, there should be representation from clinicians/experts and investigators, and from patients/clients (if a self-report questionnaire).                                                                                                                                                                                                                                                           |
| Criterion validity                             | Criterion validity is a measure of good agreement between test scores, and scores of current criterion standard are demonstrated. Choice of criterion standard needs to be well substantiated. <sup>20</sup> For most rehabilitation measures, criterion standards are not available; hence, evaluation of criterion validity will not be commonly done                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Predictive validity                            | Predictive validity is a measure's ability to predict outcomes or scores of another measure at a future point in time. Predictive validity is determined by examining the strength of the relation between test scores and a future event or behavior. Predictive validity can be examined by a variety of statistical methods, including correlation and regression.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Construct validity                             | Construct validity is the degree to which a test measures what it claims, or purports, to be measuring. Construct validity can be demonstrated in several ways, including the known-groups method, hypotheses testing, and factor analysis. The known-groups method is used to assess test's ability to discriminate between groups with trait or condition of interest known to be related to the measure construct and those without. Use of hypothesis testing with a priori hypothesis to demonstrate that the measure performs as expected. Use of diagnostic test methodology to examine area under the curve, sensitivity, and specificity for groups classified as impaired or not impaired on a related or more general construct. Use of factor analysis or principle component analysis reveals meaningful structure underpinning the construct. For confirmatory factor analysis, the sample size should be adequate (approximately 5–10 subjects per item). Ideally, RMSEA should be $\leq .05$ (adequate if $\leq .08$ ), SRMR should be $\leq .08$ , and other model fit statistics (NFI, NNFI/TLI, CFI, and RNI) should be $\geq .95$ . <sup>31,32</sup> |
| Concurrent/discriminant validity               | Concurrent and discriminant validity assess how much a measure correlates with other validated measures of similar or different constructs. Strength and direction of correlations (expressed as $r$ or $r_s$ ) should be hypothesized a priori, and results/discussion should include comment on the results of testing these validity hypotheses and the extent to which these hypotheses were met. For a correlation to be considered large, it should be $> .50$ , moderate correlations are $0.3$ – $0.5$ , small correlations are $0.1$ to $< 0.3$ . If an association is tested through regression modeling, concurrent validity can be assessed as the presence of a statistically significant association with variables or constructs hypothesized to be related. For discriminant validity, comparisons with tests of very different concept coefficients should be low (close to 0).                                                                                                                                                                                                                                                                         |

(continued on next page)

**Table 1** (continued)

| Psychometric Attribute    | Methodologic Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rasch scaling             | Rasch measurement is used in a family of statistical models to assess the quality of tests and questionnaires, and to construct true interval scale measures from the raw scores obtained from instruments. Most or all of the following should be specified about measures developed or evaluated using a Rasch measurement approach: the Rasch model selected, ordering of items, item and person fit to the models (including fit statistics), person separation reliability, $\geq 1$ test of unidimensionality, and presence of differential item functioning (or item bias) and approaches to handle. <sup>28</sup> Significant fit statistics $<.05$ or $>1.5$ indicate an item or person misfits model expectation. Mean location values should be close to 0, and the separation index (or item separation ratio) should be 0.70 (1.5) for group use or 0.85 (2.5) for individual use. |
| Minimal detectable change | The minimal detectable change is a statistical estimate of the smallest change outside of measurement error that can be detected by the measure. This is typically derived from the results of the test-retest reliability work. Typically expressed as the MDC90 or MDC95.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Responsiveness evaluation | Responsiveness is the ability of a measure to detect meaningful change over time. This is done in the context of before-after evaluations of specific interventions or significant event/time period within clinical groups. Look for evaluation of change as determined by statistical approaches (eg, effect size with pooled SD, effect size with baseline SD, SRM, Guyatt Responsiveness Index, ROC curves). <sup>22,33</sup> Look for evidence of minimally clinically important differences or improvements gleaned from anchor-based methods (eg, external rating of change from clinicians or patients) or consensus approaches (expert or patient ratings of clinical change scenarios). <sup>34</sup>                                                                                                                                                                                 |
| Floor/ceiling effects     | Floor and ceiling effects refer to the lower and upper bounds of a measurement past which the measure cannot be considered accurate or reliable. Generally, these effects occur when a substantial proportion of tests score at or near these bounds. These effects are evaluated by examining the distribution of the scores and determining the percentage of scores that lie $>90\%$ or $<10\%$ , but they can also be estimable from review of descriptive statistics tables if mean scores are very high/low and SDs are large. Ideally, there should be $<15\%$ of respondents in these outer ranges. <sup>20,22</sup>                                                                                                                                                                                                                                                                    |

Abbreviations: CFI, Comparative Fit Index; NFI, Normed Fit Index; NNFI/TLI, Non-Normed Fit Index (Tucker-Lewis Index); RMSEA, root mean square error of approximation; RNI, Relative Noncentrality Index; ROC, receiver operating characteristic; SRMR, standardized root mean square residual.

zippering a jacket.<sup>19</sup> Scoring considers task completion, speed, movement quality, skillfulness of prosthetic use, and independence. Administration requires 30 minutes.

Internal consistency ( $\alpha$ ) was .89 to .91, test-retest reliability (intraclass correlation coefficient [ICC]) was .88 to .91, and ICC for interrater reliability was .84 to .85.<sup>19</sup> Minimal detectable change at a 95% confidence interval (MDC95) was 4.4 points. Persons with more distal levels of limb loss had higher AM-ULA scores than those with more proximal levels.<sup>19</sup> AM-ULA scores were significantly correlated with the BBT ( $r=.63$ ), several JTHF items ( $r=.42-.69$ ), and self-reported activity limitations (Upper Extremity Functional Status) ( $r=-.44$ ).<sup>19</sup> AM-ULA was used in a study quantifying outcomes for DEKA Arm<sup>a</sup> users, and significant differences were reported by configuration level users.<sup>20</sup> No significant differences were noted between scores of those using a current prosthesis and scores using the DEKA Arm, except in persons using a shoulder configuration where scores were higher. No floor or ceiling effects were observed. Responsiveness was examined in upper limb amputees who used the DEKA Arm, and the effect sizes calculated after 20 hours of training was 1.33.<sup>21</sup>

### Box and Block Test

The BBT is a measure of manual dexterity. The subject moves square blocks from one side of a box to another for 60 seconds.<sup>22</sup> The number of blocks moved is counted. Psychometric properties of the BBT in persons with upper limb amputation have been examined.<sup>19-21,23,24</sup> The ICC was .91, demonstrating excellent

test-retest reliability, and the corresponding MDC95 was 7.77. A significant correlation was found between the BBT and UNB skill and spontaneity scores ( $r=.42$ , and  $r=.43$  respectively).<sup>24</sup> A strong significant correlation ( $r=.63$ ) was reported between the AM-ULA and BBT.<sup>19</sup>

Significant differences were found across levels of amputation, supporting validity for upper limb amputees.<sup>23</sup> Transradial amputees had better scores compared with persons with more proximal amputation. Known group validity was further supported by an analysis comparing DEKA Arm configuration levels, with an average BBT score of 13.4 for radial, 9.1 for humeral, and 4.5 for shoulder configuration levels.<sup>20</sup> Significant improvement in the BBT was found after  $\geq 10$  hours of training with the DEKA Arm.<sup>20,21</sup> The ES was reported as .74 after 10 hours of training and .91 after  $\geq 18$  hours of training.

### Modified JTHF heavy cans and light cans tests

The modified JTHF heavy cans and light cans tests were created to minimize administration time by capping the maximum time to complete each subtest at 2 minutes.<sup>23</sup> The JTHF assesses dexterity through the use of 7 timed subtests related to functional tasks, including printing a sentence, simulated page turning, picking up small objects and placing them in a container, stacking checkers, simulated feeding, moving light cans, and moving heavy cans. In the original JTHF, subtests are scored by recording seconds required to complete each task.<sup>25</sup> In the modified form, the score is the number of items completed per second for each task.

**Table 2** Scoring criteria for the quality assessment of each measure

| Psychometric Property                   | Excellent ++                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Adequate +                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Poor –                                                                                                                                                                                                                                                                                 | No Evidence            |
|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Overall ratings of strength of evidence | ≥3 separate, well-designed studies with positive results and strong methodology for the specific measurement property as subsequently defined.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1–2 well-designed studies with positive results—any other studies have no more than fair methodology but showed positive results.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | ≥1 studies did not strongly support the property or indicated issues and/or were limited by issues in the study design, or a study not well designed to examine psychometric properties.                                                                                               | No evidence available. |
| Reliability                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                        |                        |
| Internal consistency                    | Demonstrate adequate to excellent reliability values.*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Demonstrate adequate to excellent reliability values.*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Instrument has poor reliability values.*                                                                                                                                                                                                                                               | No evidence available. |
| Test-retest                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                        |                        |
| Intrarater                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                        |                        |
| Interrater                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                        |                        |
| Validity                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                        |                        |
| Face and content                        | Used judgmental method; the measure is comprehensive and includes items suited to the measurement purpose. Description of a content validity evaluation should be included.                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Used judgmental method; the measure is comprehensive and includes items suited to the measurement purpose. Description of a content validity evaluation should be included.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Instrument is not comprehensive and does not address relevant content areas. Content validity evaluation not described.                                                                                                                                                                | No evidence available. |
| Criterion validity                      | Demonstrates adequate agreement with a criterion standard.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Demonstrates adequate agreement with a criterion standard.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Demonstrates inadequate agreement with a criterion standard measure.                                                                                                                                                                                                                   | No evidence available. |
| Predictive validity                     | Presence of a statistically significant relation between test scores and future important event, behavior, or measure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Presence of a statistically significant relation between test scores and future important event, behavior, or measure.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | No evidence of a statistically significant relation between test scores and future important event, behavior, or measure.                                                                                                                                                              | No evidence available. |
| Construct                               | At least one of the following criteria must be met:<br>(1) Statistically significant results for known-groups analyses.<br>(2) Results of a priori hypothesis testing support the construct.<br>(3) Factor analysis (exploratory and confirmatory) or principle component analysis was conducted and supports the structural validity of the scale.<br>(4) For confirmatory factor analysis, has adequate sample (approximately 5–10 subjects per item) and shows excellent structure as gauged by $SRMR \leq 0.08$ , $RMSEA \leq 0.05$ as well as $CFI$ or $RNI \geq 0.90$ , $NFI$ or $NNFI(TFI) \geq 0.95$ . <sup>21,22</sup> | At least one of the following criteria must be met:<br>(1) Statistically significant results for known-groups analyses or hypothesis tests established a priori.<br>(2) Results of a priori hypothesis testing support the construct.<br>(3) Factor analysis (exploratory and confirmatory) or principle component analysis was conducted and supports the structural validity of the scale.<br>(4) For confirmatory factor analysis, has adequate sample (approximately 5–10 subjects per item) and shows acceptable structure as gauged by $SRMR \leq 0.08$ , $RMSEA \leq 0.05$ as well as $CFI$ or $RNI \geq 0.90$ , $NFI$ or $NNFI(TFI) \geq 0.95$ . <sup>22</sup> | No statistically significant results for known-groups analyses or no hypothesis tests established a priori. Factor analyses or principle component analyses were not conducted or were conducted but there was an unacceptably small sample size or inadequate findings for model fit. | No evidence available. |

(continued on next page)

**Table 2** (continued)

| Psychometric Property       | Excellent ++                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Adequate +                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Poor –                                                                                                                                                                                                                                                                                                                                                                          | No Evidence            |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Concurrent and discriminant | Exhibits strong correlation ( $\geq 0.5$ ) with most measures considered related, or low correlation (close to 0) when testing for differing constructs (discriminant validity). <sup>19,20</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Exhibits moderate correlation ( $\geq 0.3$ ) with most measures considered related or low correlation (close to 0) when testing for differing constructs (discriminant validity).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Exhibits only weak correlation ( $< 0.3$ ) with concurrent measures (or nonstatistically significant relation), or a statistically significant association in a regression model with variables or constructs hypothesized to be related, and shows fair or greater correlations when testing for differing constructs (discriminant validity).                                 | No evidence available. |
| Rasch scaling               | Rasch model and ordering of response categories specified, items and persons fit to model, reliability high enough for individual use with person separation $\geq .85$ (or item separation ratio $\geq 2.5$ ), and mean location values close to 0. Differential item functioning should be evaluated. Significant fit statistics are between .05 and 1.5.                                                                                                                                                                                                                                                                                                                                                                                                     | Rasch model and ordering of response categories specified, items and persons mostly fit to model, reliability high enough for group use with person separation $\geq .75$ (or item separation ratio $\geq 1.5$ ), and mean location values close to 0. Differential item functioning should be evaluated. Significant fit statistics are between .05 and 1.5.                                                                                                                                                                                                                                                                                                                                                             | Rasch model or item scoring not clearly specified, few items and persons fit to model, low reliability with person separation $< .75$ (or item separation ratio $< 1.5$ ), and mean location values not close to 0. No evaluation of differential item functioning. Significant fit statistics are $< .05$ or $> 1.5$ , indicating an item or person misfits model expectation. | No evidence available. |
| Minimal detectable change   | Data shown on MDC90 or MDC95.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Data shown on MDC90 or MDC95.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Not applicable                                                                                                                                                                                                                                                                                                                                                                  | No evidence available. |
| Responsiveness              | At least one of the following criteria must be met:<br>(1) Strong hypothesized relations between changes in the measure and other measures of change on the same attribute (anchor-based methods, consensus approaches, etc).<br>(2) Evidence of responsiveness as determined by statistical approaches (eg, effect size with pooled SD, effect size with baseline SD, SRM, Guyatt Responsiveness Index, ROC curves with confidence intervals that do not cross 0). <sup>24</sup><br>(3) Data available on minimally clinically important differences or improvements from anchor-based methods.<br>(4) Responsiveness tested by <i>t</i> test or ANOVA. However, if no articles use the listed responsiveness statistics, an excellent rating is not possible. | Responsiveness only tested by <i>t</i> test or ANOVA with no responsiveness statistics calculated (regardless of number of articles) OR at least one of the following criteria must be met:<br>(1) Strong hypothesized relations between changes in the measure and other measures of change on the same attribute (anchor-based methods, consensus approaches etc).<br>(2) Evidence of responsiveness as determined by statistical approaches (eg, effect size with pooled SD, effect size with baseline SD, SRM, Guyatt Responsiveness Index, ROC curves with confidence intervals that do not cross 0).<br>(3) Data available on minimally clinically important differences or improvements from anchor-based methods. | No statistically significant evidence of responsiveness as determined by any approach described.                                                                                                                                                                                                                                                                                | No evidence available. |

(continued on next page)

Table 2 (continued)

| Psychometric Property     | Excellent ++                                                                                                                                  | Adequate +                                                                                                                                    | Poor –                                                                                                                                    | No Evidence            |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|------------------------|
| Floor and ceiling effects | Evaluation of score distribution does not reveal a floor or ceiling effect defined as <15% of the target population with scores >90% or <10%. | Evaluation of score distribution does not reveal a floor or ceiling effect defined as <15% of the target population with scores >90% or <10%. | Evidence of a floor and/or ceiling effect, defined as at least 15% of target population reported in the top or bottom 10% of scale range. | No evidence available. |

Abbreviations: ANOVA, analysis of variance; CFI, Comparative Fit Index; NFI, Normed Fit Index; NNFI(TLI), Non-Normed Fit Index (Tucker-Lewis Index); RMSEA, root mean square error of approximation; RNI, Relative Noncentrality Index; ROC, receiver operating characteristic; SRMR, standardized root mean square residual.

\* Guidelines for reliability coefficients (ICC): excellent:  $\geq .80$ , adequate:  $\geq .75$ , and poor:  $< .70$ , and poor:  $< .60$ . For  $\kappa$  values, excellent:  $\geq .75$ , adequate:  $\geq .40$ , and poor:  $< .40$ . For Rasch person-separation reliability, excellent scores are  $\geq .90$ , and adequate scores are  $\geq .80$ .

Reliability and validity of the modified tests were reported in patients with upper limb amputations.<sup>23</sup> The ICC for test-retest reliability was excellent (range, .82–.92) for 4 tests. The ICC for the light cans and small items were .73 and .79, respectively, whereas the ICC for the checkers was .68. Corresponding minimal detectable change at a 90% confidence interval (MDC90) and MDC95 values ranged from .09 to .18 and .10 to .21, respectively. Significantly worse scores were reported for subjects with more distal amputation levels.<sup>23</sup> Significant differences in scores were reported by DEKA Arm configuration levels for all subtests except checkers.<sup>20</sup> Writing, checkers, light cans, and heavy cans showed no signs of floor or ceiling effects; however, page turning, feeding, and small items showed evidence of a floor effect.<sup>20</sup>

Correlations between the JTHF and AM-ULA were reported as page turning ( $r = .52$ ), small items ( $r = .55$ ), checkers ( $r = .42$ ), feeding ( $r = .61$ ), light cans ( $r = .69$ ), and heavy cans ( $r = .60$ ).<sup>19</sup> The writing score was not correlated with the AM-ULA.<sup>19</sup> Correlation of the JTHF and UNB subscales of prosthetic skill ranged from  $r = .36$  to .47, whereas correlations of the UNB skill ranged from  $r = .32$  to .39.<sup>24</sup>

JTHF responsiveness was reported in subjects trained to use the DEKA Arm.<sup>21</sup> Significant ESs were reported for the light cans ( $ES = .65$ ) and heavy cans ( $ES = .64$ ).<sup>21</sup>

### UNB spontaneity and skill tests

The UNB spontaneity and skill tests were designed for pediatric amputees, with tests organized by age category.<sup>26</sup> Higher scores indicate better performance. A UNB subtest designed for 11- to 13-year-old children that included wrapping a parcel, sewing a button on cloth, cutting meat, drying dishes, and sweeping floors was used in several studies.<sup>21,24</sup> The subtest had acceptable internal consistency ( $\alpha = .69$ –.79).<sup>24</sup> The ICC for test-retest reliability for the skill and spontaneity subscales were .79 and .74, respectively, and ICCs for interrater reliability were .73 and .72.<sup>24</sup> The MDC90 was 0.7 points for both subscales, and the MDC95 was 0.8 for skill and 0.9 for spontaneity.<sup>24</sup>

Known group validity was supported by findings of a 0.4-point higher average score among full-time prosthetic users compared with part-time users in both subscales. Skill and spontaneity subscales were moderately ( $>0.3$ ) correlated with the BBT and several JTHF items, and strongly correlated with each other ( $r = .92$ ). Only spontaneity was significantly, but weakly, correlated with the Upper Extremity Functional Status total score ( $r = -.20$ ). In a study examining responsiveness to training with the DEKA Arm, significant improvements were reported in both skill ( $ES = 1.18$ ) and spontaneity ( $ES = 1.10$ ) scores.<sup>21</sup> No data evaluating floor or ceiling effects were reported.

## Self-report measures

### Disabilities of the Arm, Shoulder and Hand

The DASH is a 30-item self-report measure designed for use with upper extremity musculoskeletal conditions. Twenty-one items address activities such as food preparation, writing, and turning a key. Respondents rate difficulty in performing tasks on a scale of 1 (none) to 5 (unable). The DASH contains 9 items related to symptoms of pain, tingling, numbness and stiffness, and difficulty sleeping and takes approximately 10 minutes to administer. Values for completed responses are summed, averaged, and transformed to a score out of 100 by subtracting one and multiplying by 25.<sup>27</sup> DASH scores range from 0 to 100, with higher scores indicating

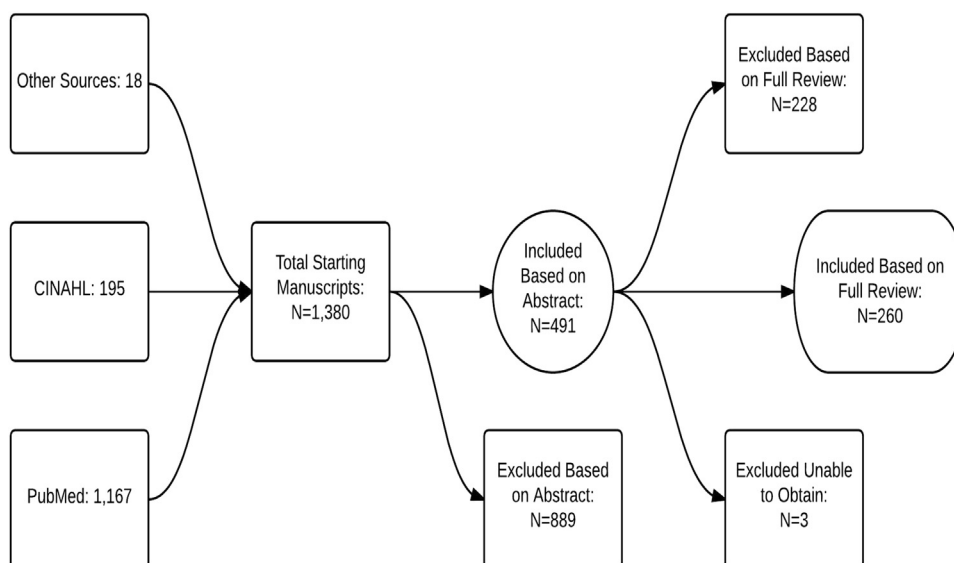


Fig 1 Summary of literature review.

greater disability. The DASH has 2 separately scored 4-item optional modules, sports/music and work activities.

We identified 148 articles that used the DASH with patients with amputation, distal radius fractures, humeral fractures, rotator cuff tears, and shoulder dislocations.<sup>28-173</sup> Eighteen articles used non-English versions.<sup>39,41,55,62,68,81,82,89,104,112,129,130,137,138,154,160,173,302</sup> Excellent internal consistency of the total score was reported in 5 studies ( $\alpha=.88-.96$ ).<sup>68,115,137,154,160</sup> Internal consistency of the optional modules was reported as .94 and .97 for the sports/music and work modules, respectively.<sup>115</sup>

Seven studies reported ICCs for the total score ranging from .81 to .93, demonstrating excellent test-retest reliability.<sup>42,75,112,136,137,142,157</sup> Themistocleous et al<sup>154</sup> evaluated test-retest reliability, reporting a significant correlation ( $r=.91$ ) and a  $\kappa$  of .68. Reported MDC90 ranged from 10.7 to 13.7,<sup>42,75,136</sup> and MDC95 values were reported as 12.8.<sup>42</sup>

Efforts to maximize face/content validity of non-English versions of DASH were reported.<sup>68,154</sup> Activities that did not align with typical Greek activities were modified to be more relevant.<sup>154</sup> Content validity of the Canadian French translation was assessed through comments of participants, experts, and clinicians.<sup>68</sup>

The literature contains an abundance of evidence supporting DASH construct validity. For structural validity, exploratory factor analysis of the Portuguese translation resulted in a 3-factor solution explaining 59% of the variance, and discriminant validity analysis correctly classified 93.3% of the sample to acute or chronic groups.<sup>55</sup> The first factor explained >50% of the variance. Principal component analysis of the Greek translation identified 1 major factor.<sup>154</sup>

There were 36 studies providing evidence of DASH known group validity.<sup>31,36,39,42,51,55,56,58,63-65,71,81,84,95,102,110-112,115,118,120,122,127,129,144,153-155,158,160,162,167-169,174</sup>

Studies reported worse scores for those with forearm fractures (compared with normative scores),<sup>65</sup> those with osteoporosis (vs without),<sup>56</sup> those who could not work (compared with those who could), those with complete brachial plexus injuries (compared with incomplete injuries),<sup>71</sup> those with cold intolerance (vs without),<sup>95</sup> those with a correct surgical restoration (compared with incorrect),<sup>81</sup> those with a

nonunion fracture (vs healed),<sup>127,162</sup> and those with worse scores among older age groups.<sup>84,115</sup> Themistocleous et al<sup>154</sup> reported progressively better DASH scores for patients with poor, fair, and good states of health.

Concurrent validity of the DASH was examined in patients with humeral fractures; the measure was strongly correlated with Oxford Shoulder Scores ( $r=-.80$ ), subjective shoulder values ( $r=-.78$ ), and UCLA Shoulder Rating Scale scores ( $r=-.65$ ).<sup>157</sup> Several studies examined concurrent validity of the DASH with the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36). A study of 10-year outcomes of patients with humeral fractures found a correlation ( $r=-.83$ ) with total SF-36 score.<sup>116</sup> Strong correlations were reported with SF-36 Physical Component Summary ( $r=-.75$ )<sup>65</sup> and SF-36 total score ( $r=-.63$ ),<sup>154</sup> and moderate correlations were reported with the Mental Component Summary ( $r=-.49$ )<sup>65</sup> and mental health, role emotional, and vitality subscales.<sup>154</sup> The DASH was strongly correlated with Short-Form 6D ( $r=-.73$ ), Short Form-12 Physical Component Summary ( $r=-.75$ ), EuroQol-5D ( $r=-.75$ ), Health Utilities Index Mark 3 ( $r=-.58$ ), and self-reported overall shoulder function ( $r=-.76$ ).<sup>142</sup> Correlations were also reported with the QuickDASH ( $r=.96-.98$ ),<sup>31,75</sup> ABILHAND ( $r=.92$ ),<sup>40</sup> Canadian Occupational Performance Measure satisfaction ( $r=-.53$ ) and performance ( $r=.50$ ) subscales,<sup>62</sup> Musculoskeletal Functional Attachment total score ( $r=.82$ ),<sup>79</sup> PRWE ( $r=.74-.92$ ),<sup>80,89,112</sup> PRWE function ( $r=.76$ ),<sup>89</sup> Western Ontario Rotator Cuff Index ( $r=-.86$ ), HAT ( $r=.91$ ),<sup>114</sup> EuroQol-5D ( $r=-.72$ ),<sup>129</sup> Modified Mayo Wrist Score ( $r=.69$ ),<sup>150</sup> and measures of hand grip strength ( $r=-.63$ ), pronation ( $r=-.66$ ), and flexion ( $r=-.64$ ).<sup>43</sup>

Several other measures were found to be moderately correlated with DASH, including the Hand Injury Severity Score ( $r=.38$ ),<sup>72</sup> EuroQol-5D ( $r=.47$ ),<sup>118</sup> Push-Off Test ( $r=-.47$ ),<sup>161</sup> Center for Epidemiologic Studies Depression Scale ( $r=.42$ ),<sup>144</sup> Pain Catastrophizing Scale ( $r=-.38$ ), Pain Anxiety Symptoms Scale ( $r=.37$ ), Hand Injury Severity Score ( $r=.34$ ),<sup>103</sup> and measures of supination ( $r=.47$ ) and wrist extension ( $r=-.46$ ).<sup>79</sup>

There were 32 studies with evidence of DASH responsiveness, and almost all showed that DASH scores improved after treatment,

**Table 3** Quality ratings for performance assessment measures

| Measure                                                    | Reliability: Internal Consistency | Reliability: Test-Rest Reliability | Reliability: Interrater Reliability | Reliability: Intrarater Reliability | Face and Content Validity | Criterion Validity | Predictive Validity | Construct Validity | Concurrent/ Discriminant Validity | Rasch Scaling | Minimal Detectable Change | Responsiveness | Floor and Ceiling Effects | Overall Score* | No. of Articles Included |
|------------------------------------------------------------|-----------------------------------|------------------------------------|-------------------------------------|-------------------------------------|---------------------------|--------------------|---------------------|--------------------|-----------------------------------|---------------|---------------------------|----------------|---------------------------|----------------|--------------------------|
| AM-ULA                                                     | +                                 | +                                  | +                                   | ?                                   | ?                         | ?                  | ?                   | +                  | +                                 | ?             | +                         | +              | +                         | 8              | 3                        |
| Assessment of a Score for Activities of Daily Living       | ?                                 | ?                                  | NA                                  | NA                                  | ?                         | ?                  | ?                   | ?                  | +                                 | ?             | ?                         | ?              | ?                         | 1              | 1                        |
| Assessment of Capacity for Myoelectric Control             | +                                 | ?                                  | +                                   | +                                   | ?                         | ?                  | ?                   | ?                  | +                                 | +             | ?                         | ?              | ?                         | 5              | 3                        |
| Assessment of Capacity for Myoelectric Control 2.0         | ?                                 | +                                  | +                                   | +                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | +                         | ?              | ?                         | 4              | 1                        |
| BBT                                                        | ?                                 | +                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | +                  | +                                 | ?             | +                         | +              | +                         | 6              | 5                        |
| Carroll Test                                               | ?                                 | ?                                  | +                                   | ?                                   | ?                         | ?                  | ?                   | +                  | ?                                 | ?             | ?                         | ?              | ?                         | 2              | 1                        |
| Carroll Test, modified                                     | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 1                        |
| Functional Impairment Test - Hand, Neck, Shoulder, and Arm | ?                                 | ?                                  | NA                                  | NA                                  | ?                         | ?                  | ?                   | ?                  | +                                 | ?             | ?                         | ?              | ?                         | 1              | 1                        |
| FIM                                                        |                                   |                                    |                                     |                                     |                           |                    |                     |                    |                                   |               |                           |                |                           |                |                          |
| FIM motor score                                            | ?                                 | ?                                  | NA                                  | NA                                  | ?                         | ?                  | ?                   | —                  | ?                                 | ?             | ?                         | +              | ?                         | 0              | 1                        |
| Jarus Hand Function Evaluation                             |                                   |                                    |                                     |                                     |                           |                    |                     |                    |                                   |               |                           |                |                           |                |                          |
| Jarus Hand Function Evaluation, activities of daily living | +                                 | ?                                  | NA                                  | NA                                  | ?                         | ?                  | ?                   | +                  | ?                                 | ?             | ?                         | ?              | ?                         | 2              | 1                        |
| Jarus Hand Function Evaluation, grasp                      | +                                 | ?                                  | NA                                  | NA                                  | ?                         | ?                  | ?                   | +                  | ?                                 | ?             | ?                         | ?              | ?                         | 2              | 1                        |
| Jarus Hand Function Evaluation, pinch                      | +                                 | ?                                  | NA                                  | NA                                  | ?                         | ?                  | ?                   | +                  | ?                                 | ?             | ?                         | ?              | ?                         | 2              | 1                        |
| Jarus Hand Function Evaluation, target accuracy            | +                                 | ?                                  | NA                                  | NA                                  | ?                         | ?                  | ?                   | +                  | ?                                 | ?             | ?                         | ?              | ?                         | 2              | 1                        |
| JTHF                                                       | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 1                        |
| JTHF, checkers                                             | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 0                        |
| JTHF, feeding                                              | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 0                        |
| JTHF, heavy cans                                           | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 0                        |
| JTHF, light cans                                           | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 0                        |
| JTHF, page turning                                         | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 0                        |
| JTHF, small items                                          | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 0                        |
| JTHF, writing                                              | ?                                 | ?                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | ?                  | ?                                 | ?             | ?                         | ?              | ?                         | 0              | 0                        |
| Modified JTHF                                              |                                   |                                    |                                     |                                     |                           |                    |                     |                    |                                   |               |                           |                |                           |                |                          |
| Modified JTHF, checkers                                    | ?                                 | +                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | +                  | +                                 | ?             | +                         | —              | +                         | 4              | 4                        |
| Modified JTHF, feeding                                     | ?                                 | +                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | +                  | +                                 | ?             | +                         | —              | —                         | 2              | 5                        |
| Modified JTHF, heavy cans                                  | ?                                 | +                                  | ?                                   | ?                                   | ?                         | ?                  | ?                   | +                  | +                                 | ?             | +                         | +              | +                         | 6              | 5                        |

(continued on next page)

Table 3 (continued)

| Measure                                                                       | Reliability:<br>Internal<br>Consistency | Reliability:<br>Test-Rest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | Minimal<br>Detectable<br>Change | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score* | No. of<br>Articles<br>Included |
|-------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|---------------------------------|----------------|---------------------------------|-------------------|--------------------------------|
| Modified JTHF, light cans ?                                                   | ?                                       | +                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +                               | +              | +                               | 6                 | 5                              |
| Modified JTHF, page<br>turning                                                | ?                                       | +                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +                               | —              | —                               | 2                 | 5                              |
| Modified JTHF, small<br>items                                                 | ?                                       | +                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +                               | —              | —                               | 2                 | 5                              |
| Modified JTHF, writing                                                        | ?                                       | +                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | +                     | —                                       | ?                | +                               | —              | +                               | 2                 | 5                              |
| Minnesota Rate of Manipulation Test                                           |                                         |                                          |                                           |                                           |                                 |                       |                        |                       |                                         |                  |                                 |                |                                 |                   |                                |
| Minnesota Rate of<br>Manipulation Test,<br>displacing test                    | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| Minnesota Rate of<br>Manipulation Test,<br>1-hand turning and<br>placing test | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| Minnesota Rate of<br>Manipulation Test,<br>placing test                       | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| Minnesota Rate of<br>Manipulation Test,<br>2-hand turning and<br>placing test | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| Nine Hole Peg Test                                                            | ?                                       | ?                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| O'Connor Finger Dexterity<br>Test                                             | ?                                       | ?                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| Purdue Pegboard                                                               | ?                                       | ?                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Sollerman Hand Function<br>Test                                               | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| Tapping Test                                                                  | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| UNB                                                                           |                                         |                                          |                                           |                                           |                                 |                       |                        |                       |                                         |                  |                                 |                |                                 |                   |                                |
| UNB, skill                                                                    | +                                       | +                                        | +                                         | ?                                         | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +                               | +              | ?                               | 7                 | 3                              |
| UNB, spontaneity                                                              | +                                       | +                                        | +                                         | ?                                         | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +                               | +              | ?                               | 7                 | 3                              |

NOTE. To calculate a total score ++ = 2; + = 1; — = -1; ? = 0, and NA = 0 (scale of -13 to 26).

\* Overall score calculated as unweighted sum of subscale level scores.

improved with time after injury, or improved postoperatively compared with preinjury (assessed retrospectively).<sup>31,42,48,51,57,71,75,78,91,99,103,112,117,126-129,133,154,160,164,165,169,173,174</sup> One study noted improvement between 2 weeks and 1 year postoperatively for patients with plating for humeral fractures.<sup>99</sup> Significant improvement was reported in patients with distal radius fractures 1 year after surgery compared with scores 10 to 14 days postsurgery.<sup>165</sup> Among patients with radius fractures treated nonoperatively or surgically, median DASH score decreased from 3 to 12 months after treatment. DASH scores improved between 1 and 5 weeks after removal of external fixator or cast.<sup>112</sup> Significant differences between pre- and postoperative DASH scores were reported in several other studies.<sup>71,164,165,169</sup> Improvement in DASH scores was reported for patients with triangular fibrocartilage complex tears 31 months after arthroscopic treatment and for patients who underwent shoulder reconstruction.<sup>169</sup> Improvement in scores was reported after physical therapy for shoulder surgery and after occupational therapy for patients with a variety of upper limb disorders ( $ES = .09$ ).<sup>48,160</sup>

One study used both anchor-based and distribution-based approaches to calculate the minimal clinically important difference (13.0 and 8.1, respectively).<sup>157</sup> Another study reported a significant association between improvement in DASH scores and improvement in Global Disability Rating status, and reported an SEM of 5.35, a minimally important difference of 12.6, an ES of 1.21, a Guyatt Responsiveness Index of 1.66, and a standardized response mean (SRM) of 1.26 for their total sample.<sup>136</sup> Floor/ceiling effects were examined in 7 studies using samples with upper limb injuries, and no floor or ceiling effects were found among patients expected to have disabilities.<sup>42,68,75,112,137,142,160</sup>

### Hand Assessment Tool

The HAT is a 14-item self-report measure that assesses activity limitation in patients with hand and wrist injuries. The HAT items address activities such as grooming and manipulating buttons/zippers. Respondents rate the difficulty they have performing the task on a scale of 1 (none) to 5 (unable). The questionnaire also addresses pain, numbness/tingling, and the effect of appearance of the injured hand.<sup>114</sup> The HAT scores range from 0 to 100. The values for completed responses are summed and averaged. The value is transformed to a score out of 100 by subtracting one and multiplying by 25.

The HAT was developed and validated for subjects with hand/wrist injuries. Principal component analysis identified a 7-factor solution, but ultimately a single score was calculated because all included items loaded on 1 rotated factor. No ceiling effects were observed. A possible floor effect was detected, and a single item was removed from the final version.

The scale has excellent internal consistency ( $\alpha = .91$ ) and good test-retest reliability as exhibited by a concordance correlation of .73.<sup>114</sup> The HAT was strongly correlated with the DASH ( $r = .91$ ) and was correlated with the SF-12 Physical Component Summary ( $r = .52$ ). No data on responsiveness to change were found.

### International Osteoporosis Foundation Quality of Life Questionnaire

The International Osteoporosis Foundation Quality of Life Questionnaire is a 12-item self-report measure developed to assess health-related quality of life in patients after a wrist fracture.<sup>175</sup> The International Osteoporosis Foundation Quality of Life Questionnaire is composed of 4 domains: pain (1 question), upper limb symptoms (3 questions), physical function (7 questions), and general health (1 question). The responses are scored on a 5-point

Likert scale (where 1 is no difficulty, 2 is a little difficulty, 3 is moderate difficulty, 4 is may need some help, and 5 is impossible).<sup>175</sup> The total score is calculated by adding up individual answers (overall score range, 12–60) and then normalizing to a 0 to 100 scale (0 representing the best and 100 the worst quality of life).<sup>26</sup> We considered the total score and the domain of body function relevant to our review.

Bonczar et al<sup>176</sup> reported preliminary validation data on the Polish International Osteoporosis Foundation Quality of Life Questionnaire in patients with radius fractures. Internal consistency was reported for the total score ( $\alpha = .87$ ) and physical function domain ( $\alpha = .85$ ). ICCs for test-retest reliability ranged from .82 to .93 for the domains and total score.<sup>176</sup>

Concurrent validity was supported by correlations between International Osteoporosis Foundation Quality of Life Questionnaire domains and SF-36; most correlations ( $r = -.47$  to  $-.71$ ) were significant.<sup>176</sup> In particular, the physical function domain was correlated with the SF-36 physical function ( $r = -.65$ ) and role physical ( $r = -.58$ ) subscales, respectively. Bonczar et al<sup>176</sup> reported that International Osteoporosis Foundation Quality of Life Questionnaire scores decreased for physical function and overall score at various intervals after surgery. No floor or ceiling effects were examined.

### Patient Rated Wrist Evaluation

The PRWE is a 15-item self-report questionnaire that assesses wrist pain (5 items) and function (10 items) with activities of daily living. Pain is rated at rest, with repeated movement, lifting a heavy object, and at its worst. Function is categorized by specific activities (eg, turning door knob, cutting meat) and usual activities (eg, personal care, household work). Questions are rated on a 10-point scale (where 0 is no pain and 10 is worst pain). A total score is calculated by dividing the total function score by 2 and adding that to the total pain score. The PRWE was originally designed for assessment of distal radius fractures and wrist injuries. Reliability was established for the full instrument and for the individual subscales.<sup>177</sup> The function subscale (including both specific and usual activities scores) and total score met our study inclusion criteria.

We identified 21 articles which used the PRWE<sup>58,61,78,80,83,89,106,112,125,136-138,168,178-185</sup> in a variety of patient groups, including those with distal radius fractures, chronic static scapholunate dissociation,<sup>61</sup> general wrist injury,<sup>112</sup> and musculoskeletal problems.<sup>136</sup> Schmitt and Di Fabio<sup>136</sup> reported excellent test-retest reliability for the total score (ICC = .91) in patients with distal musculoskeletal problems. A minimal detectable change of 12.2 was estimated. Reliability was also examined for 3 translated versions of the PRWE in studies on patients with wrist fractures. Kim and Kang<sup>89</sup> translated and cross-culturally adapted the PRWE into Korean and reported Cronbach  $\alpha$  values of .94 for both total score and function subscales and excellent test-retest reliability (total ICC = .95; function ICC = .96). Internal consistency and test-retest reliability of the Swedish version were also excellent (total  $\alpha = .97$ , ICC = .93; function  $\alpha = .97$ , ICC = .92).<sup>112</sup> Finally, the Danish version total score was shown to have excellent internal consistency ( $\alpha = .94$ ) and test-retest reliability (ICC = .88).<sup>138</sup>

We found one study in which patients and health care workers assessed content validity and face validity of the translated total score and functional recovery scores,<sup>112</sup> and another where an expert panel discussed interpretation, translation, and word choice of the Danish PRWE, supporting content validity of the translated form.<sup>138</sup>

**Table 4** Quality ratings for self-report measures

| Measure                                                                                                                  | Reliability:<br>Internal<br>Consistency | Reliability:<br>Test-Rest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | Minimal<br>Detectable<br>Change | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score* | No. of<br>Articles<br>Included |
|--------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|---------------------------------|----------------|---------------------------------|-------------------|--------------------------------|
| ABILHAND                                                                                                                 | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | —                | ?                               | ?              | ?                               | 0                 | 2                              |
| ABILHAND-UCLA                                                                                                            | +                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | +                | ?                               | ?              | —                               | 3                 | 1                              |
| ADL Score <sup>194</sup>                                                                                                 | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | +              | ?                               | 2                 | 2                              |
| American Shoulder and<br>Elbow Surgeons Elbow<br>Score                                                                   | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | +              | ?                               | 2                 | 2                              |
| American Shoulder and<br>Elbow Surgeons<br>Standardized<br>Shoulder Assessment<br>Form                                   | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | ++             | ?                               | 3                 | 26                             |
| American Shoulder<br>and Elbow Surgeons<br>Standardized<br>Shoulder<br>Assessment Form,<br>activities of daily<br>living | ?                                       | ?                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 2                              |
| American Shoulder and<br>Elbow Surgeons Score,<br>modified                                                               | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| American Shoulder<br>and Elbow Surgeons<br>Score, modified,<br>activities of daily<br>living                             | ?                                       | ?                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Brigham questionnaire<br>Brigham<br>questionnaire,<br>functional status                                                  | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 2                              |
| Canadian Occupational<br>Performance Measure<br>Canadian<br>Occupational<br>Performance<br>Measure,<br>performance       | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 4                              |

(continued on next page)

Table 4 (continued)

| Measure                                                                                       | Reliability:<br>Internal<br>Consistency | Reliability:<br>Test-Rest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | Minimal<br>Detectable<br>Change | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score* | No. of<br>Articles<br>Included |
|-----------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|---------------------------------|----------------|---------------------------------|-------------------|--------------------------------|
| Canadian Occupational Performance Measure, satisfaction                                       | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 4                              |
| Croft Shoulder Disability Questionnaire                                                       | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| DASH                                                                                          | ++                                      | ++                                       | NA                                        | NA                                        | +                               | ?                     | ?                      | ++                    | ++                                      | ?                | ?                               | ++             | ++                              | 13                | 148                            |
| DASH, sport/music module                                                                      | +                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | -                                       | ?                | ?                               | ?              | ?                               | 0                 | 6                              |
| DASH, work module                                                                             | +                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | -                                       | ?                | ?                               | ?              | ?                               | 0                 | 6                              |
| Functional Evaluation of the Upper Limb                                                       | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 1                              |
| Functional Questionnaire                                                                      | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Groningen Activity Restriction Scale                                                          | +                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | +              | ?                               | 3                 | 2                              |
| Groningen Activity Restriction Scale, ADL subscale                                            | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 1                              |
| HAT                                                                                           | +                                       | +                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?                               | ?              | +                               | 5                 | 1                              |
| International Osteoporosis Foundation Quality of Life Questionnaire                           | +                                       | +                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | +              | +                               | 5                 | 1                              |
| International Osteoporosis Foundation Quality of Life Questionnaire, physical function domain | +                                       | +                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | +              | ?                               | 4                 | 1                              |
| Liverpool Elbow Score                                                                         | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Modified Health Assessment Questionnaire                                                      | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |

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Table 4 (continued)

| Measure                                                                       | Reliability:<br>Internal<br>Consistency | Reliability:<br>Test-Rest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | Minimal<br>Detectable<br>Change | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score* | No. of<br>Articles<br>Included |
|-------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------|-----------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|---------------------------------|----------------|---------------------------------|-------------------|--------------------------------|
| Musculoskeletal<br>Functional<br>Attachment                                   | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 4                              |
| Musculoskeletal<br>Functional<br>Attachment, hand<br>and fine motor<br>skills | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Musculoskeletal<br>Functional<br>Attachment,<br>housework                     | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Musculoskeletal<br>Functional<br>Attachment,<br>self-care                     | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Oxford Shoulder Score                                                         | ?                                       | +                                        | NA                                        | NA                                      | +                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | +              | ?                               | 4                 | 7                              |
| Patient Evaluation<br>Measure                                                 | +                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 2                 | 1                              |
| Patient Evaluation<br>Measure, hand<br>health profile<br>section              | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| PRWE                                                                          | ++                                      | ++                                       | NA                                        | NA                                      | +                               | ?                     | ?                      | +                     | ++                                      | ?                | +                               | ++             | +                               | 12                | 20                             |
| PRWE, functional<br>recovery                                                  | +                                       | +                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | +                               | +              | ?                               | 5                 | 4                              |
| PRWE, specific<br>activities                                                  | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | +              | ?                               | 2                 | 3                              |
| PRWE, usual activities                                                        | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | +              | ?                               | 2                 | 3                              |
| Patient Specific<br>Functional Scale                                          | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | +              | +                               | 3                 | 3                              |
| Penn Shoulder Score                                                           |                                         |                                          |                                           |                                         |                                 |                       |                        |                       |                                         |                  |                                 |                |                                 |                   |                                |
| Penn Shoulder Score,<br>function                                              | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Questionnaire for<br>Bilateral Activities                                     | ?                                       | ?                                        | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |

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Table 4 (continued)

| Measure                                                                                | Reliability:<br>Internal<br>Consistency | Reliability:<br>Test-Rest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | Minimal<br>Detectable<br>Change | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score* | No. of<br>Articles<br>Included |
|----------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|---------------------------------|----------------|---------------------------------|-------------------|--------------------------------|
| QuickDASH                                                                              | ?                                       | +                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ++                    | ++                                      | ?                | +                               | ++             | ?                               | 8                 | 18                             |
| QuickDASH, sports<br>module                                                            | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | +              | ?                               | 1                 | 2                              |
| QuickDASH, work<br>module                                                              | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | ?              | ?                               | 1                 | 1                              |
| Short Musculoskeletal Functional Assessment                                            |                                         |                                          |                                           |                                           |                                 |                       |                        |                       |                                         |                  |                                 |                |                                 |                   |                                |
| Short Musculoskeletal<br>Functional<br>Assessment,<br>dysfunction<br>subscale          | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | ?              | ?                               | 1                 | 2                              |
| Short Musculoskeletal<br>Functional<br>Assessment,<br>arm/hand<br>function category    | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Short Musculoskeletal<br>Functional<br>Assessment, daily<br>activities category        | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Shoulder Pain and<br>Disability Index                                                  | ?                                       | +                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | +                               | +              | ?                               | 4                 | 2                              |
| Shoulder Pain and<br>Disability Index,<br>function subscale                            | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | +              | ?                               | 2                 | 1                              |
| Shoulder Rating<br>Questionnaire                                                       | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Simple Shoulder Test                                                                   | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?                               | ++             | —                               | 2                 | 12                             |
| Upper Extremity<br>Functional Status of<br>Orthotics and<br>Prosthetics User<br>Survey | ?                                       | +                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?                               | ?              | ?                               | 2                 | 3                              |

(continued on next page)

Table 4 (continued)

| Measure                                                                                                                                               | Reliability:<br>Internal<br>Consistency | Reliability:<br>Test-Rest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | Minimal<br>Detectable<br>Change | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score* | No. of<br>Articles<br>Included |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|---------------------------------|----------------|---------------------------------|-------------------|--------------------------------|
| Upper Extremity<br>Functional Status of<br>Orthotics and<br>Prosthetics User<br>Survey, modified by<br>Burger <sup>289</sup>                          | +                                       | ?                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | +                     | ?                                       | +                | ?                               | ?              | ?                               | 3                 | 3                              |
| Upper Extremity<br>Functional Status of<br>Orthotics and<br>Prosthetics User<br>Survey, modified by<br>Jarl <sup>291</sup>                            | +                                       | +                                        | ?                                         | ?                                         | +                               | ?                     | ?                      | —                     | ?                                       | +                | +                               | ?              | ?                               | 4                 | 2                              |
| Upper Extremity<br>Functional Status of<br>Orthotics and<br>Prosthetics User<br>Survey, modified by<br>Resnik <sup>23</sup>                           | ?                                       | +                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | —                     | +                                       | ?                | +                               | —              | +                               | 2                 | 5                              |
| Upper Extremity<br>Functional Status of<br>Orthotics and<br>Prosthetics User<br>Survey, modified by<br>Resnik, no. of items<br>of prosthesis was used | ?                                       | ?                                        | ?                                         | ?                                         | ?                               | ?                     | ?                      | —                     | —                                       | ?                | ?                               | ?              | ?                               | -2                | 2                              |
| Upper Extremity<br>Functional Index                                                                                                                   | ?                                       | ?                                        | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?                               | ?              | ?                               | 0                 | 1                              |
| Western Ontario Rotator<br>Cuff Index                                                                                                                 |                                         |                                          |                                           |                                           |                                 |                       |                        |                       |                                         |                  |                                 |                |                                 |                   |                                |
| Western Ontario<br>Rotator Cuff Index,<br>lifestyle domain                                                                                            | +                                       | +                                        | +                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | +                               | ?              | ?                               | 4                 | 2                              |
| Western Ontario<br>Rotator Cuff Index,<br>work domain                                                                                                 | +                                       | +                                        | +                                         | ?                                         | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | +                               | ?              | ?                               | 4                 | 2                              |

(continued on next page)

Table 4 (continued)

| Measure                                    | Reliability: Internal Consistency |   |    | Reliability: Test-Retest Reliability |   |   | Reliability: Interrater Reliability |   |   | Reliability: Face and Content Validity |   |   | Criterion Validity |   |   | Predictive Construct Validity |   |   | Concurrent/ Discriminant Validity |   |   | Minimal Detectable Change |   | Responsiveness |   | Floor and Ceiling Effects | No. of Overall Articles Included |
|--------------------------------------------|-----------------------------------|---|----|--------------------------------------|---|---|-------------------------------------|---|---|----------------------------------------|---|---|--------------------|---|---|-------------------------------|---|---|-----------------------------------|---|---|---------------------------|---|----------------|---|---------------------------|----------------------------------|
|                                            | ?                                 | ? | ?  | ?                                    | ? | ? | ?                                   | ? | ? | ?                                      | ? | ? | ?                  | ? | ? | ?                             | ? | ? | ?                                 | ? | ? | ?                         | ? | ?              | ? | ?                         | ?                                |
| Wrist Outcome Instrument                   | ?                                 |   |    |                                      |   |   |                                     |   |   |                                        |   |   |                    |   |   |                               |   |   |                                   |   |   |                           |   |                |   |                           |                                  |
| Wrist Outcome Instrument, individual score | ?                                 | ? | NA | NA                                   | + | ? | ?                                   | ? | ? | ?                                      | ? | ? | ?                  | ? | ? | ?                             | ? | ? | ?                                 | ? | ? | ?                         | ? | ?              | ? | ?                         | 2                                |
| Wrist Outcome Instrument, standard score   | ?                                 | ? | NA | NA                                   | + | ? | ?                                   | ? | ? | ?                                      | ? | ? | ?                  | ? | ? | ?                             | ? | ? | ?                                 | ? | ? | ?                         | ? | ?              | ? | ?                         | 2                                |

NOTE. To calculate a total score ++ = 2; + = 1; - = -1; ? = 0, and NA = 0 (scale of -13 to 26).

Abbreviations: ADL, activities of daily living; ULA, upper limb amputee.

\* Overall score calculated as unweighted sum of subscale level scores.

The PRWE was used in several studies comparing outcomes of patients with wrist injuries.<sup>112</sup> Significant differences in total scores were reported between chronic and acute wrist injury groups at baseline and 5-week follow-up.<sup>112</sup> Costa,<sup>58</sup> Dzaja,<sup>179</sup> and colleagues did not find significant differences in total scores between patients with displaced dorsal fracture of the radius treated by wire and plate treatment groups. Wilcke et al<sup>168</sup> showed that PRWE total scores were significantly better for the volar locked plating treatment rather than external fixation of displaced distal radius fracture at 3 and 6 months, but not at 12 months postoperatively. Krischak et al<sup>182</sup> reported that patients performing independent home exercise training after an operation had better total PRWE scores than those treated by a physical therapist (ES = 1.18).

Several studies showed correlations between PRWE total score and DASH ( $r = .76-.90$ ).<sup>80,89,112</sup> Moderate correlations were reported between total PRWE and Nottingham Health Profile domains of sleep, energy, pain, physical mobility, and social isolation.<sup>137,138</sup> The PRWE was also strongly correlated with a visual analog scale pain score ( $r = .69$ ) and moderately correlated with measures of grip strength ( $r = -.42$ ), wrist flexion ( $r = -.30$ ), and wrist extension ( $r = -.34$ ).<sup>89</sup> Schmitt and Di Fabio<sup>136</sup> reported a significant correlation with a global disability rating at 3 months ( $r = .69$ ), at 6 months ( $r = .64$ ), and for change scores ( $r = .64$ ).

The PRWE function subscale was strongly correlated with DASH ( $r = .74$ ) and moderately correlated with visual analog scale pain score ( $r = .53$ ), grip strength ( $r = -.64$ ), and wrist flexion ( $r = -.40$ ).<sup>89</sup> Harris et al<sup>180</sup> examined concurrent validity and found significant correlations between the specific activities subscale and PRWE pain ( $r = .46-.79$ ), usual activities ( $r = .34-.57$ ), and SF-36 physical health ( $r = -.29$  to  $-.52$ ) at 1 week, 3 months, and 1 year postinjury, and at 3 months and 1 year with the SF-36 mental health subscale ( $r = -.23$  and  $-.30$ ) and Wrist Outcome Measure ( $r = -.35$  and  $-.46$ ). Similarly, for the usual activities subscale, Harris reported significant correlations with PRWE pain ( $r = .34-.53$ ), specific activities ( $r = .34-.57$ ), and SF-36 physical health ( $r = -.16$  to  $-.42$ ) subscales at all time points, and at 3 months and 1 year with the SF-36 mental health subscale ( $r = -.26$  and  $-.10$ ) and Wrist Outcome Measure ( $r = -.20$  and  $-.44$ ).

Several studies reported on responsiveness of the PRWE. MacDermid et al<sup>106</sup> reported improvements throughout the first 6 months after wrist fracture for total score (ES = 3.91, SRM = 2.95) and specific (ES = 7.01, SRM = 3.62) and usual activities (ES = 2.29, SRM = 2.24) subscales. Gavaskar et al<sup>78</sup> calculated total score at preinjury baseline (evaluated retrospectively), 6 weeks, 6 months, and 1 year and noted significant improvements between contiguous time frames over the study period. Maciel et al<sup>183</sup> found significant main effects for time (baseline, 6 weeks, and 24 weeks) in patients with conservatively treated distal radius fractures, suggesting improvement in total, usual activities, and specific activity scores with time after cast removal. Total PRWE scores improved at weeks 12 and 26 post distal radius fracture.<sup>184</sup> Total score improved over a 3-month period after initial physical therapy or occupational therapy clinic visit for patients with musculoskeletal diagnoses (ES = 1.87, minimal clinically important difference = 24.0, SRM = 1.94, Guyatt Responsiveness Index = 1.16).<sup>136</sup> Other studies reported improvement in total score after treatment for patients with wrist fractures,<sup>89,112</sup> and Schonemann et al<sup>138</sup> reported an ES of .62. No floor or ceiling effects were reported in the patient populations.

**Table 5** Content analysis of included performance measures

| Measure                                                    | Specific to amputees or Prosthetic/Orthotic Users | How Assessed |                   |         |            |                            |                  |            |                                       | Content                                 |                                     |                                           |                       |                           |
|------------------------------------------------------------|---------------------------------------------------|--------------|-------------------|---------|------------|----------------------------|------------------|------------|---------------------------------------|-----------------------------------------|-------------------------------------|-------------------------------------------|-----------------------|---------------------------|
|                                                            |                                                   |              |                   |         |            |                            |                  |            |                                       | Activities and Participation Categories |                                     |                                           |                       |                           |
|                                                            |                                                   | Timed Speed  | Qualitative Speed | Ability | Difficulty | Requires Special Equipment | Movement Quality | Assistance | Skillfulness of Prosthetic Device Use | Fine Motor Tasks (d440)                 | Hand and Arm Use Gross Motor (d448) | Carrying and Handling Objects (d430–d439) | Self-Care (d510–d599) | Domestic Life (d610–d699) |
| AM-ULA                                                     | X                                                 |              | X                 |         |            |                            | X                |            | X                                     | X                                       | X                                   | X                                         | X                     | X                         |
| Assessment of a Score for Activities of Daily Living       |                                                   |              | X                 | X       | X          |                            |                  |            |                                       | X                                       | X                                   | X                                         | X                     | X                         |
| Assessment of Capacity for Myoelectric Control             | X                                                 |              |                   | X       |            |                            |                  |            | X                                     |                                         | X                                   | X                                         |                       |                           |
| Assessment of Capacity for Myoelectric Control 2.0         | X                                                 |              |                   | X       |            |                            |                  |            | X                                     |                                         | X                                   | X                                         |                       |                           |
| BBT                                                        |                                                   |              | X                 |         |            |                            |                  |            |                                       |                                         | X                                   | X                                         |                       |                           |
| Carroll Test                                               |                                                   |              | X                 | X       |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Carroll Test, modified                                     |                                                   |              | X                 | X       |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| FIM                                                        |                                                   |              |                   | X       |            |                            |                  | X          |                                       |                                         | X                                   |                                           | X                     |                           |
| Motor score                                                |                                                   |              |                   | X       |            |                            |                  | X          |                                       |                                         | X                                   |                                           | X                     |                           |
| Functional Impairment Test - Hand, Neck, Shoulder, and Arm |                                                   | X            |                   |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Jarus Hand Function Evaluation                             |                                                   |              |                   |         |            |                            |                  |            |                                       |                                         |                                     |                                           |                       |                           |
| Activities of daily living                                 |                                                   | X            |                   |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Grasp                                                      |                                                   | X            |                   |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Pinch                                                      |                                                   | X            |                   |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Target accuracy                                            |                                                   | X            |                   |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| JTHF                                                       |                                                   |              |                   |         |            |                            |                  |            |                                       |                                         |                                     |                                           |                       |                           |
| Checkers                                                   |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       |                                     | X                                         |                       |                           |
| Feeding                                                    |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Heavy cans                                                 |                                                   |              | X                 |         |            | X                          |                  |            |                                       |                                         | X                                   | X                                         |                       |                           |
| Light cans                                                 |                                                   |              | X                 |         |            | X                          |                  |            |                                       |                                         | X                                   | X                                         |                       |                           |
| Page turning                                               |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Small items                                                |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Writing                                                    |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Modified JTHF                                              |                                                   |              |                   |         |            |                            |                  |            |                                       |                                         |                                     |                                           |                       |                           |
| Checkers                                                   |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Feeding                                                    |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Heavy cans                                                 |                                                   |              | X                 |         |            | X                          |                  |            |                                       |                                         | X                                   | X                                         |                       |                           |
| Light cans                                                 |                                                   |              | X                 |         |            | X                          |                  |            |                                       |                                         | X                                   | X                                         |                       |                           |
| Page turning                                               |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Small items                                                |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |
| Writing                                                    |                                                   |              | X                 |         |            | X                          |                  |            |                                       | X                                       | X                                   | X                                         |                       |                           |

(continued on next page)

Table 5 (continued)

| Measure                             | Specific to<br>amputees or<br>Prosthetic/<br>Orthotic<br>Users | How Assessed   |                      |         |            |                                  |                     |            |                                             | Content                                 |                                                 |                                                    |                          |                              |
|-------------------------------------|----------------------------------------------------------------|----------------|----------------------|---------|------------|----------------------------------|---------------------|------------|---------------------------------------------|-----------------------------------------|-------------------------------------------------|----------------------------------------------------|--------------------------|------------------------------|
|                                     |                                                                |                |                      |         |            |                                  |                     |            |                                             | Activities and Participation Categories |                                                 |                                                    |                          |                              |
|                                     |                                                                | Timed<br>Speed | Qualitative<br>Speed | Ability | Difficulty | Requires<br>Special<br>Equipment | Movement<br>Quality | Assistance | Skillfulness<br>of Prosthetic<br>Device Use | Fine Motor<br>Tasks<br>(d440)           | Hand and<br>Arm Use<br>Gross<br>Motor<br>(d448) | Carrying and<br>Handling<br>Objects<br>(d430–d439) | Self-Care<br>(d510–d599) | Domestic Life<br>(d610–d699) |
| Minnesota Rate of Manipulation Test |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       | X                                               | X                                                  |                          |                              |
| Displacing test                     |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       | X                                               | X                                                  |                          |                              |
| One-hand turning and placing test   |                                                                |                |                      |         |            |                                  |                     |            |                                             |                                         |                                                 |                                                    |                          |                              |
| Placing test                        |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       | X                                               | X                                                  |                          |                              |
| Two-hand turning and placing test   |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       | X                                               | X                                                  |                          |                              |
| Nine Hole Peg Test                  |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       |                                                 | X                                                  |                          |                              |
| O'Connor Finger Dexterity Test      |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       |                                                 | X                                                  |                          |                              |
| Purdue Pegboard                     |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       | X                                               | X                                                  |                          |                              |
| Sollerman Hand Function Test        |                                                                |                | X                    |         | X          | X                                | X                   |            |                                             | X                                       | X                                               | X                                                  |                          |                              |
| Tapping Test                        |                                                                |                | X                    |         |            | X                                |                     |            |                                             | X                                       | X                                               | X                                                  |                          |                              |
| UNB                                 |                                                                |                |                      |         |            |                                  |                     |            |                                             |                                         |                                                 |                                                    |                          |                              |
| Skill                               | X                                                              |                |                      |         |            |                                  |                     |            | X                                           | X                                       | X                                               | X                                                  | X                        | X                            |
| Spontaneity                         | X                                                              |                |                      |         |            |                                  |                     |            |                                             | X                                       | X                                               | X                                                  | X                        | X                            |

NOTE. No items addressed: burden (min); recreation and leisure (d920); using transportation (d470); work and employment (d840–d859); intimate relations, sexual activities (d770); unspecified activities (patient named); sleep functions (b134); sensation of pain (b280); mobility of joint functions: stiffness (b710); and strength: muscle power functions (b73).

Abbreviation: X, yes.

**Table 6** Content analysis of included self-report measures

| Measure                                                                                                          | Specific to<br>Amputees or<br>Prosthetic/<br>Orthotic<br>Users | Burden<br>(min) | Qualitative<br>Speed | Ability | Difficulty | How Assessed         |                                     |                     |            |                                         |                                             |
|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|-----------------|----------------------|---------|------------|----------------------|-------------------------------------|---------------------|------------|-----------------------------------------|---------------------------------------------|
|                                                                                                                  |                                                                |                 |                      |         |            | Special<br>Equipment | Satisfaction<br>With<br>performance | Movement<br>Quality | Assistance | Prosthesis<br>Use<br>During<br>Activity | Skillfulness<br>of Prosthetic<br>Device Use |
| ABILHAND                                                                                                         |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| ABILHAND-ULA                                                                                                     | X                                                              |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| ADL Score <sup>194</sup>                                                                                         |                                                                |                 |                      |         | X          |                      |                                     |                     | X          |                                         |                                             |
| American Shoulder and Elbow Surgeons Elbow Score                                                                 |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| American Shoulder and Elbow Surgeons Standardized Shoulder<br>Assessment Form                                    |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Activities of Daily Living                                                                                       |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| American Shoulder and Elbow Surgeons Score, modified                                                             |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Activities of Daily Living                                                                                       |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Brigham questionnaire                                                                                            |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Functional status                                                                                                |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Canadian Occupational Performance Measure                                                                        |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Performance                                                                                                      |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Satisfaction                                                                                                     |                                                                |                 |                      |         |            |                      | X                                   |                     |            |                                         |                                             |
| Croft Shoulder Disability Questionnaire                                                                          |                                                                |                 |                      |         | X          |                      |                                     |                     | X          |                                         |                                             |
| DASH                                                                                                             |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Sport/music module                                                                                               |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Work module                                                                                                      |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Functional Evaluation of the Upper Limb                                                                          |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Functional Questionnaire                                                                                         |                                                                |                 |                      | X       |            |                      |                                     |                     |            |                                         |                                             |
| Groningen Activity Restriction Scale                                                                             |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| BADL subscale                                                                                                    |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| HAT                                                                                                              |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| International Osteoporosis Foundation Quality of Life<br>Questionnaire                                           |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Physical function domain                                                                                         |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Liverpool Elbow score                                                                                            |                                                                |                 |                      | X       | X          |                      |                                     |                     |            |                                         |                                             |
| Modified Health Assessment Questionnaire                                                                         |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Musculoskeletal Functional Attachment                                                                            |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Hand and fine motor skills                                                                                       |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Housework                                                                                                        |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Self-care                                                                                                        |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Oxford Shoulder Score                                                                                            |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Patient Evaluation Measure                                                                                       |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Hand health profile section                                                                                      |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| PRWE                                                                                                             |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Functional recovery                                                                                              |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Specific activities                                                                                              |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Usual activities                                                                                                 |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Patient Specific Functional Scale                                                                                |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Penn Shoulder Score                                                                                              |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Function                                                                                                         |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Questionnaire for Bilateral Activities                                                                           |                                                                |                 |                      | X       |            |                      |                                     |                     | X          |                                         |                                             |
| QuickDASH                                                                                                        |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Sports/performing arts module                                                                                    |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Work module                                                                                                      |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Short Musculoskeletal Functional Assessment                                                                      |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Arm/hand function category                                                                                       |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Daily activities category                                                                                        |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Shoulder Pain and Disability Index                                                                               |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Function subscale                                                                                                |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Shoulder Rating Questionnaire                                                                                    |                                                                | 10              |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Simple Shoulder Test                                                                                             |                                                                |                 |                      | X       |            |                      |                                     |                     |            |                                         |                                             |
| Upper Extremity Functional Status of Orthotics and<br>Prosthetics User Survey                                    | X                                                              |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Upper Extremity Functional Status of Orthotics and<br>Prosthetics User Survey, modified by Burger <sup>289</sup> | X                                                              |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Upper Extremity Functional Status of Orthotics and<br>Prosthetics User Survey, modified by Jarl <sup>291</sup>   | X                                                              |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Upper Extremity Functional Status of Orthotics and<br>Prosthetics User Survey, modified by Resnik <sup>23</sup>  | X                                                              |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Upper Extremity Functional Status of Orthotics and<br>Prosthetics User Survey, use                               | X                                                              |                 |                      |         |            |                      |                                     |                     |            | X                                       |                                             |
| Upper Extremity Functional Index                                                                                 |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Western Ontario Rotator Cuff Index                                                                               |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Lifestyle domain                                                                                                 |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Work domain                                                                                                      |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Wrist Outcome Instrument                                                                                         |                                                                |                 |                      |         |            |                      |                                     |                     |            |                                         |                                             |
| Individual score                                                                                                 |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |
| Standard score                                                                                                   |                                                                |                 |                      |         | X          |                      |                                     |                     |            |                                         |                                             |

Abbreviations: ULA, upper limb amputee; X, yes.

Table 6 Continued

[illegible]

## QuickDASH

The QuickDASH is a shorter version of DASH consisting of 11 items assessing functioning and symptoms in musculoskeletal disorders of the upper limb. The QuickDASH includes 2 optional scales to assess a patient's function with work activities and sports or playing an instrument. The QuickDASH is scored in 2 components: the 11-item disability section where each item is scored from 1 to 5, and the optional work and sport/music modules (4 items) where items are scored from 1 to 5. Respondents indicate difficulty performing the items (where 1 is no difficulty and 6 is unable). Scores are summed and averaged, and the value is transformed to a score out of 100 by subtracting 1 and multiplying by 25. A higher score indicates greater disability.

The QuickDASH was used in a report examining adjustments and activity limitations of Operation Iraqi Freedom, Operation Enduring Freedom, and Operation New Dawn veterans with amputations. The only study we found which reported on QuickDASH's reliability in our target patient population evaluated patients with upper limb musculoskeletal disorders and reported a test-retest ICC of .91 and an MDC90 of 12.85.<sup>75</sup>

Among patients with humeral fractures 1 year after fixation, those with perioperative complications scored worse on QuickDASH total score and work module.<sup>186</sup> Sports/music module scores were worse for patients with complications, but not significantly so. Worse QuickDASH scores were reported for those with greater pain.<sup>187</sup> Significant differences were reported between pre- and postoperative assessments for patients with diagnoses such as carpal tunnel syndrome, acute injuries, osteoarthritis, nonspecific arm pain, and ganglion.<sup>188</sup>

Several studies show that the QuickDASH was very strongly correlated with DASH ( $r=.96-.98$ ),<sup>31,75</sup> and change scores were correlated with DASH change ( $r=.92$ ) and Global Rating of Change Scale ( $r=.71$ ). A significant correlation between the QuickDASH and Constant score ( $r=-.60$ ) was reported among patients with humeral fractures. Moderate correlations were reported between the QuickDASH and Patient Activation Measure at first visit to orthopedic surgeon ( $r=-.30$ ), follow-up ( $r=-.41$ ), and between change scores ( $r=-.23$ ).<sup>188</sup> The QuickDASH scores were also moderately or strongly correlated with the Patient Health Questionnaire-2 and Pain Self-Efficacy Questionnaire.<sup>188</sup> Finally, among patients with arm or hand injuries, the QuickDASH was correlated with measures of psychosocial functioning, including the Impact of Events Scale-Revised total score ( $r=.51$ ), and intrusion ( $r=.57$ ) and hyperarousal ( $r=.45$ ) subscales.<sup>189</sup>

Several studies support the QuickDASH's responsiveness. Significant improvements were noted among subgroups after physical therapy, arthroscopic treatment of triangular fibrocartilage wrist injuries,<sup>190</sup> and screw fixation after distal radius fracture.<sup>191</sup> Franchignoni et al<sup>75</sup> reported a minimal clinically important difference of 5.9. No floor/ceiling effect analyses were reported.

## Discussion

Our review identified 55 measures, 36 as self-report measures and 19 performance measures. Two of the most highly rated performance measures were amputation specific (AM-ULA and UNB) and therefore only appropriate for use with patients with amputation. Another performance measure (modified JTHF) is generic; however, it was only examined in persons with upper limb amputation.

These findings highlight the need for additional research to develop and test performance measures of body function and activity in patients with limb trauma and amputation. Our review identified only 1 performance measure (BBT) with strong measurement properties, which we could recommend without qualification for persons with limb trauma or amputation. The BBT is an easy to administer, widely used, brief measure of dexterity with population norms available. It does require specialized equipment, but the cost is modest. Its disadvantages are that its content coverage is limited, focusing predominantly on a single timed grasp and release activity. It does not assess activity performance in basic or instrumental activities of daily living, often the target of therapy interventions. Therefore, there is a dearth of research on functional outcomes of persons with upper limb trauma. Most articles in our review used performance measures of impairment (strength and range of motion), but no performance-based measures of activity limitation.

In contrast, there are more options for patient-reported outcome measures for patients with both limb trauma and amputation. Several measures, notably the DASH and QuickDASH, were validated in samples of patients with limb trauma and amputation. Either are good choices for use with these groups.

## Study limitations

Our study has several limitations. First, findings regarding strength of evidence on measurement properties are specific to persons with limb trauma and/or amputation, and not generalizable beyond these groups. Second, overall scores were unweighted. Weighting scores could result in differing results and interpretation. Findings from detailed scoring should be considered when selecting a measure for a particular purpose or population to ensure that it meets those needs. Finally, we pooled findings from self-report measures administered in different languages because studies of patients with upper limb amputation are scarce, and we did not wish to eliminate important studies from other countries. However, we acknowledge that there may be subtle differences in psychometric properties by language. The body of evidence in the published literature will continue to grow; therefore, it is possible that the ratings will change as new data becomes available.

## Conclusions

Measurement properties and the content of 55 measures were evaluated: 19 performance-based and 36 self-report measures. The most highly rated performance measures were 3 amputation-specific measures (AM-ULA, UNB skill, and UNB spontaneity) and 3 non-amputation-specific measures (BBT and modified JTHF heavy cans and light cans subtests). The most highly rated self-report measures were the DASH, PRWE, QuickDASH, HAT, International Osteoporosis Foundation Quality of Life Questionnaire, and PRWE functional recovery subscale. None were amputation specific. Content comparison of all measures was conducted. We conclude that few performance measures can be recommended for use in both patients with limb trauma and amputation. The 2 measures recommended for use across both groups, the BBT and JTHF, focus on dexterity and do not assess performance of self-care or domestic tasks.

## Supplier

a. DEKA Arm; DEKA Research & Dev Corporation.

## Keywords

Amputation; Disability evaluation; Rehabilitation; Upper extremity; Wounds and injuries

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## Appendix 1 Search Terms

### PubMed

#### Search 1

(outcome OR assessment OR questionnaires OR treatment outcome OR recovery of function[MeSH Terms] OR activity of daily living [MeSH Terms] OR observer variation[MeSH Terms] OR "functional assessment" OR "functional status") AND ("upper extremity" OR "upper limb" OR "Arm") AND ("Amputation"[Majr] OR "Amputees"[Majr] OR "Artificial limb" OR "Artificial limbs") AND hasabstract[text] AND "humans"[MeSH Terms] AND (Classical Article[ptyp] OR Clinical Trial[ptyp] OR Journal Article [ptyp] OR Randomized Controlled Trial[ptyp]) AND English[lang] AND ("aged, 80 and over"[MeSH Terms] OR "adult"[MeSH Terms] OR "adult"[MeSH Terms:noexp] OR "aged"[MeSH Terms] OR ("middle aged"[MeSH Terms] OR "aged"[MeSH Terms]) OR "middle aged"[MeSH Terms] OR "young adult"[MeSH Terms]) NOT Practice Guideline[ptyp] NOT Case Reports[ptyp] NOT "blood vessel prosthesis"[MeSH Terms] NOT transplantation NOT organ NOT stents NOT "arthroplasty"[MeSH Terms]

#### Search 2

("Upper Extremity"[MeSH Terms] OR "Upper Limb" OR "Arm") AND ("Rehabilitation"[MeSH Terms] OR "Recovery of Function"[MeSH Terms] OR "Activities of Daily Living"[MeSH Terms] OR "Health Status" OR "Occupational Therapy"[MeSH Terms] OR "Questionnaires"[MeSH Terms] OR "Outcome Assessment (Health Care)"[MeSH Terms] OR "Disability Evaluation"[MeSH Terms] OR "Observer Variation"[MeSH Terms] OR "Health Surveys" [MeSH Terms] OR "Psychometrics"[MeSH Terms] OR "Functional Assessment" OR "Functional Status")) AND ("Wounds and Injuries" OR "Amputation"[Majr] OR "Amputees"[Majr] OR "Artificial Limb" OR "Artificial Limbs" OR "Amputation/Rehabilitation" OR "Amputation Methods" OR "Blast Injuries" OR "Traumatic Injuries" OR "Arm Injuries") AND "hasabstract"[text] AND "Humans"[MeSH Terms] AND ("Classical Article"[ptyp] OR "Clinical Trial"[ptyp] OR "Journal Article"[ptyp] OR "Randomized Controlled Trial"[ptyp]) AND English[lang] AND ("adult"[MeSH Terms] OR "adult"[MeSH Terms:noexp] OR "aged"[MeSH Terms] OR "middle aged"[MeSH Terms] OR "young adult"[MeSH Terms]) NOT "Practice Guideline"[ptyp] NOT "Case Reports"[ptyp] NOT "Blood vessel prosthesis"[MeSH Terms] NOT "Transplantation" NOT "Organ" NOT "Stents" NOT "Vascular" NOT "Arthroplasty"[MeSH Terms] NOT "Stroke" NOT "Qualitative" NOT "Pulmonary" NOT "Arthritis" NOT "Multiple sclerosis" NOT "Congenital" NOT "Lower extremity"[MeSH Terms]

#### Search 3

("Upper Extremity"[MeSH Terms] OR "Arm Injuries"[MeSH]) AND ("Rehabilitation"[MeSH Terms] OR "Recovery of Function"[MeSH Terms] OR "Activities of Daily Living"[MeSH Terms] OR "Health Status"[All Fields] OR "Occupational Therapy"[MeSH Terms] OR "Treatment Outcome"[MeSH Terms] OR Treatment Outcome[All Fields] OR Functional Assessment[All Fields] OR Functional Status[All Fields] OR "Questionnaires"[MeSH Terms] OR "Outcome Assessment (Health Care)"[MeSH Terms] OR "Disability Evaluation"[MeSH Terms] OR "Observer Variation"[MeSH Terms] OR "Health

Surveys"[MeSH Terms] OR "Psychometrics"[MeSH Terms] OR "Learning"[All Fields] OR Assessment[All Fields]) AND

("Wounds and Injuries"[MeSH Terms] OR "Wounds and Injuries"[All Fields] OR "Amputation"[MeSH Terms] OR "Amputees"[MeSH Terms] OR "Artificial Limbs"[MeSH Terms] OR "Artificial Limbs"[All Fields] OR "Amputation/Rehabilitation"[All Fields] OR "Amputation Methods"[All Fields] OR "Blast Injuries"[All Fields] OR "Traumatic Injuries"[All Fields] OR Myoelectric [All Fields]) AND "hasabstract"[text] AND "Humans" [MeSH Terms] AND English[lang] AND ("adult"[MeSH Terms] OR "aged"[MeSH Terms] OR "middle aged"[MeSH Terms] OR "young adult"[MeSH Terms]) AND ("Classical Article"[ptyp] OR "Clinical Trial"[ptyp] OR "Journal Article"[ptyp] OR "Randomized Controlled Trial"[ptyp]) NOT "Practice Guideline"[ptyp] NOT "Case Reports"[ptyp] NOT "Blood vessel prosthesis"[MeSH Terms] NOT "Transplantation"[All Fields] NOT "Organ"[All Fields] NOT "Stents"[All Fields] NOT "Vascular"[All Fields] NOT "Arthroplasty"[MeSH Terms] NOT "Stroke"[All Fields] NOT "Qualitative"[All Fields] NOT "Pulmonary"[All Fields] NOT "Arthritis"[All Fields] NOT "Multiple sclerosis"[All Fields] NOT "Congenital"[All Fields] NOT "Neoplasms"[MeSH Terms] NOT "Brain"[All Fields] NOT "Diabetes Mellitus"[MeSH Terms] NOT "Athletic Injuries"[MeSH Terms] NOT "Sprains and Strains"[MeSH Terms] NOT "Sports"[-MeSH Terms] NOT "Return to Work"[MeSH Terms] NOT "Review"[ptyp] NOT "Spinal Cord"[MeSH Terms] NOT "Spinal Cord Injuries"[MeSH Terms] NOT "Bone Diseases"[MeSH Terms] NOT "Neonatal"[All Fields] NOT "Bariatrics"[MeSH Terms] NOT "Tennis Elbow"[MeSH Terms] NOT "Manual Labor"[All Fields] NOT "Obstetrics"[MeSH Terms] NOT Dental[All Fields] NOT Ruptures[All Fields] NOT "Transplantation"[MeSH] NOT "Diagnostic Imaging"[MeSH] NOT "Radiology"[MeSH] NOT "Bone Density"[MeSH] NOT "Spine"[MeSH] NOT "Brain Diseases"[MeSH] NOT "Osteoporotic Fractures"[MeSH] NOT Radiography[All Fields] NOT Radiology[All Fields] NOT "Infant"[All Fields] NOT "Spinal Nerves"[MeSH] NOT "Bites and Stings" [MeSH] NOT "Workers' Compensation"[MeSH] NOT "Obesity" [MeSH] NOT "Ultrasonography"[MeSH] NOT "Phantom Limb" [MeSH] NOT "Postoperative Complications"[MeSH] NOT "Pain Measurement"[MeSH] NOT "Cadaver"[MeSH] NOT "Chemically-Induced Disorders"[MeSH] NOT "Chemically Induced"[subheading] NOT "Cadaver"[MeSH] NOT "Skin Physiological Phenomena"[MeSH] NOT "Cranio cerebral Trauma"[MeSH] NOT "Musculoskeletal Diseases"[MeSH]

### CINAHL

#### Search 1

(outcome OR assessment OR questionnaires OR treatment outcome OR recovery of function OR activity of daily living OR observer variation OR "functional assessment" OR "functional status") AND ("upper extremity" OR "upper limb" OR "Arm") AND ("Amputation" OR "Amputees" OR "Artificial limb" OR "Artificial limbs") NOT PT case study NOT PT Practice Guideline NOT "blood vessel prosthesis" NOT transplantation NOT organ NOT stents NOT "arthroplasty"

#### Limiters

Abstract Available; Human; Language: English; Publication Type: Clinical Trial, Journal Article, Randomized Controlled Trial, Research; Age Groups: All Adult

**Search modes**

Boolean/Phrase

**Search 2**

("Upper Extremity" OR "Upper Limb" OR "Arm") AND ("Rehabilitation" OR "Recovery of Function" OR "Activities of Daily Living" OR "Role Function" OR "Health Status" OR "Occupational Therapy" OR "Physical Therapy" OR "Questionnaires" OR "Outcome Assessment" OR "Outcome Measures" OR "Disability Assessment" OR "Disability Evaluation" OR "Observer Variation" OR "Health Surveys" OR "Psychometrics" OR "Functional Assessment" OR "Functional Status") AND ("Wounds and Injuries" OR "Orthopaedic" OR "Orthopedic" OR "Amputation" OR "Amputees" OR "Artificial Limb" OR "Artificial Limbs" OR "Amputation/Rehabilitation" OR "Disabled Person" OR "Amputation Methods" OR "Blast Injuries" OR "Traumatic Injuries" OR "Arm Injuries") NOT PT "Case Study" NOT PT "Practice Guideline" NOT "Blood Vessel Prosthesis" NOT "Transplantation" NOT "Organ" NOT "Stents" NOT "Vascular" NOT "Arthroplasty" NOT "Stroke" NOT "Qualitative" NOT "Pulmonary" NOT "Arthritis" NOT "Multiple Sclerosis" NOT "Congenital" NOT "Lower Extremity"

**Limiters**

Abstract Available; Human; Language: English; Publication Type: Clinical Trial, Journal Article, Randomized Controlled Trial, Research; Age Groups: All Adult

**Search modes**

Boolean/Phrase

**Search 3**

("Upper Extremity" OR "Arm Injuries" OR "Upper Limb" OR "Arm") AND ("Rehabilitation" OR "Role Function" OR "Recovery of Function" OR "Activities of Daily Living" OR "Health Status" OR "Occupational Therapy" OR "Treatment Outcome" OR Treatment Outcome OR Functional Assessment OR Functional Status OR "Questionnaires" OR "Outcome Assessment" OR "Disability Assessment" OR "Disability Evaluation" OR "Observer Variation" OR "Health Surveys" OR "Psychometrics" OR "Learning" OR Assessment) AND ("Wounds and Injuries" OR "Orthopaedic" OR "Orthopedic" OR "Amputation" OR "Amputees" OR "Artificial Limbs" OR "Artificial Limb" OR "Amputation/Rehabilitation" OR "Disabled Person" OR "Blast Injuries" OR "Traumatic Injuries")

NOT PT "Case Study" NOT PT "Practice Guideline" NOT "Blood Vessel Prosthesis" NOT "Transplantation" NOT "Organ" NOT "Stents" NOT "Vascular" NOT "Arthroplasty" NOT "Stroke" NOT "Qualitative" NOT "Pulmonary" NOT "Arthritis" NOT "Multiple Sclerosis" NOT "Congenital" NOT "Lower Extremity" NOT "Neoplasms" NOT "Brain" NOT "Diabetes" NOT "Athletic Injuries" NOT "Sprains" NOT "Sports" NOT "Return to Work" NOT "Spinal Cord" NOT "Spinal Cord Injuries" NOT "Bone Diseases" NOT "Neonatal" NOT "Bariatrics" NOT "Tennis Elbow" NOT "Manual Labor" NOT "Obstetrics" NOT Dental NOT "Transplantation" NOT "Diagnostic Imaging" NOT "Radiology" NOT "Bone Density" NOT "Spine" NOT "Brain Diseases" NOT "Osteoporotic Fractures" NOT "Radiography" NOT "Radiology" NOT "Infant" NOT "Burns" NOT "Spinal Nerves" NOT "Bites and Stings" NOT "Workers' Compensation" NOT

"Obesity" NOT "Ultrasonography" NOT "Phantom Limb" NOT "Postoperative Complications" NOT "Pain Measurement" NOT "Cadaver" NOT "Chemically-Induced Disorders" NOT "Chemically Induced"[subheading] NOT "Cadaver" NOT "Skin Physiological Phenomena" NOT "Craniocerebral Trauma" NOT "Musculoskeletal Diseases"

**Limiters**

Abstract Available; Human; Language: English; Publication Type: Clinical Trial, Journal Article, Randomized Controlled Trial, Research; Age Groups: All Adult

**Search modes**

Boolean/Phrase

**Appendix 2 Ineligible Measures**

1. Active Range of Motion
2. Activities of Daily Living
3. American Orthopedic Foot and Ankle Surgeons score
4. American Shoulder and Elbow Surgeons Score
5. Athletic Shoulder Outcomes Rating Scale/Kerlan-Jobe Orthopaedic Clinic Score
6. Barthel Index
7. Berg Balance Scale
8. Bostrom's Shoulder Movement Impairment Scale
9. Brief Michigan Hand Questionnaire
10. Broberg and Morrey scores
11. Broberg and Morrey Elbow Score
12. Broberg and Morrey grading system
13. Burn Specific Health Scale Questionnaire: general domain
14. Burn Specific Health Scale Questionnaire: psychological domain
15. Burn Specific Health Scale Questionnaire: social domain
16. Castaing scoring system
17. Chen's Criteria
18. Constant score
19. Constant-Murley Score
20. Cooney's Wrist Function Score
21. Craig Handicap Assessment & Reporting Technique, mobility
22. Craig Handicap Assessment & Reporting Technique, occupation
23. Enforced Social Dependency Scale
24. Enforced Social Dependency Scale
25. European Shoulder Association assessment charts.
26. EuroQol-5D
27. Functional capacity evaluation
28. Gartland and Werley assessment system
29. Geldmacher score
30. German Extra Short Musculoskeletal Function Assessment Questionnaire
31. Green and O'Brien Scoring system
32. Greenleaf Medical Hand and Upper Extremity Evaluation System
33. Hand Dynamometer Test
34. Hand Injury Severity Score
35. Hannover Shoulder Score
36. Health Utilities Index Mark 3
37. Hospital for Special Surgery Score
38. Japanese Orthopaedic Association shoulder score
39. Kawashima's scoring criteria

40. Krimmer wrist score
41. Lidstrom wrist function scores
42. Lysholm shoulder score
43. Mangled Extremity Severity Score
44. Manual Prosthesis Rehabilitation Score
45. Mayo Clinic Wrist Score
46. Mayo Elbow Performance Score
47. Mayo modification of the clinical scoring system
48. Mayo Modified Wrist Score
49. Modified Hand Injury Severity Score
50. Modified Mayo Wrist Score
51. Modified Rowe
52. Morrey elbow score
53. Motor Assessment Scale
54. Musculoskeletal Tumor Society Functional Score Neer score
55. Nottingham Health Profile
56. Original Strickland test
57. Ostlie's Measure of Prosthesis use
58. Oxford Elbow Score
59. Oxford Instability Score/Oxford Instability Shoulder Score
60. Paffenbarger Physical Activity Questionnaire
61. Patient Evaluation Measure: Hand Health Profile section
62. Physical Impairment Score total score
63. Physical Impairment Score total score, dexterity component
64. Pick-Up Test
65. Prosthetic Rehabilitation Scoring
66. Push-Off Test
67. Quality of Life Scale
68. Quality of Recovery-23
69. Rowe and Zarins Score
70. Rowe Score
71. Rowe Score for Instability Questionnaire
72. Repetitive Strain Injury Quick Scan
73. Short Form 12, physical function
74. Short Form 36, physical function
75. Short Form 6D
76. Short Musculoskeletal Functional Assessment, overall
77. Short Musculoskeletal Functional Assessment, bother index
78. Short Musculoskeletal Functional Assessment, emotional status category
79. Short Musculoskeletal Functional Assessment, mobility category
80. Shoulder Disability Questionnaire
81. Shoulder, Pain and Disability Index pain scale
82. Smith and Cooney outcome score
83. Specific Extensor Indicis to Extensor Pollicis Longus Evaluation Method
84. Shoulder Severity Index
85. Subjective Shoulder Rating Scale
86. Steward and Hundley Classification
87. Stewart 2 Score
88. Subjective Shoulder Value
89. Swedish Post-discharge Surgery Recovery Scale
90. Tamai system
91. Total active motion
92. Total active motion scoring system of The American Society of Surgery of Hand
93. Trinity Amputation and Prosthesis Experience Survey
94. University of California at Los Angeles Shoulder Scale
95. Western Ontario Shoulder Instability Index

96. Work Limitations Questionnaire
97. Wrist Outcome Measure
98. Young and Rockwood shoulder score

## Appendix 3 Detailed Findings for Measures Not Ranked in the Top 5

### ABILHAND

The ABILHAND measure contains 46 self-reported items pertaining to the ease of performing common manual activities (eg, carrying, handling objects, domestic life, household tasks, self-care).<sup>192</sup> Ayong et al<sup>40</sup> used the Rasch method to analyze the ABILHAND to evaluate the levels of function, disability, and quality of life of patients with unstable distal radius fractures treated with an angle-stable volar T plate. They reported a significant correlation between the ABILHAND and DASH ( $r = -.918$ ); no reliability or responsiveness data were reported.

### ABILHAND upper limb amputee

The ABILHAND upper limb amputee (ABILHAND-ULA) is a modified version of the ABILHAND.<sup>192</sup> Burger et al<sup>193</sup> used Rasch analysis to examine the dimensionality and hierarchy of the original 46-item self-reported ABILHAND measure in a sample of persons with upper limb amputation who had completed rehabilitation. Their analyses led them to select 22 items for inclusion in a revised measure which they called the ABILHAND-ULA. Items on the revised measure are largely bimanual activities that would require prosthetic use, and rating scales were collapsed into 4 levels (where 0 is not able to do, 1 is difficult, 2 is easy, and 3 is very easy). All 22 items fit the Rasch model (item-separation reliability = .98) and showed excellent internal consistency (person-separation reliability = .92). The Rasch model explained 87% of the variance. No differential item functioning (DIF) was observed by age, sex, amputation level, dominance, or ability. Correlation with the modified Upper Extremity Functional Scale (UEFS) from the Orthotic and Prosthetics User Survey (OPUS) was strong ( $r = .71$ ). A potential ceiling effect was observed suggesting that additional items at the higher end of the scale should be considered.

### ADL Score

The ADL Score was designed for a study of functional status of elderly patients who had sustained upper limb fractures.<sup>194</sup> The measure assesses 24 separate activities of daily living (ADL) tasks that include bathing, dressing, toileting, functional transfers, continence, money management, writing, use of transportation, and caring for pets. An overall score is determined by rating each task on a 4-point scale (where 0 is unable to perform activity, 1 is able to perform activity with assistance, 2 is able to perform activity without assist but with difficulty, and 3 is able to perform activity independent without difficulty).<sup>194</sup> Madhok and Bhopal<sup>195</sup> reported that elderly patients with shoulder immobilization post-fracture had significantly worse ADL scores than those with wrist immobilization. After a mean follow-up of 18.9 years, scores

showed a 15-point improvement.<sup>194</sup> Reliability and floor/ceiling effects were not examined in either article.

## American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form

The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form is a self-reported measure developed by the research committee of the American Shoulder and Elbow Surgeons to create a scoring system that could be applied to all shoulder patients regardless of diagnosis.<sup>196</sup> The instrument is divided into 2 domains: pain, captured on a visual analog scale (VAS), and a total of 10 ADL questions, scored on a 4-point ordinal scale (from 0 to 3). The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form is scored on a 100-point scale, with higher scores indicating better outcomes, and the 2 domains are given equal weight (50 points each). The VAS for pain ranges from 0 to 10 and is then converted to 50 points. A total of 30 points are possible for the ADL questions, which is then converted to 50 points. The total score calculation can be expressed as follows:

Total American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form Score

$$= \text{ADL Total Score} \times \left(\frac{5}{3}\right) + \text{Pain Score} \times 5$$

The American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form also contains a clinician-reported component which consists of range of motion, specific physical signs, strength, and instability evaluation. This portion is rarely reported in clinical studies<sup>197</sup> and was not included in our review. We identified 26 articles that used the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form total score,<sup>35,87,108,198-218,300,301</sup> and 2 that used only the ADL subscale, also called the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form function subscale.<sup>215,219</sup> The reliability of the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form total score was not assessed in any of the included studies. Limited evidence was found supporting the construct validity of the measure in patients with limb trauma. Chung et al<sup>200</sup> found that among a sample of 288 patients with rotator cuff tear who underwent surgical repair, stiffness after repair was associated with a significantly worse score at final follow-up, but those differences were not significant at 3 and 6 months posttreatment. Oh et al<sup>208</sup> found significant differences in preoperative American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form scores between 125 patients with rotator cuff tears who did and did not present with stiffness.

In 22 studies, the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form total score was used to evaluate results of a specific surgical technique or treatment.<sup>35,87,108,198-218</sup> Fourteen studies reported significant improvement in American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form scores between baseline and follow-up, suggesting that the measure is responsive to change.<sup>87,108,198-216</sup>

Sakeb et al<sup>219</sup> reported that ADL subscale scores improved for patients with posttraumatic recurrent anterior shoulder dislocation at 2 years postoperatively. Tjoumakaris et al<sup>215</sup> found no

differences in long-term outcome between patients who underwent arthroscopic and open Bankart repair for chronic shoulder instability. No other data were reported that supported reliability, validity, or responsiveness of the ADL subscale.

## American Shoulder and Elbow Surgeons Score Shoulder Outcome Score (modified)

The American Shoulder and Elbow Surgeons Score (ASES) Shoulder Outcome Score (modified) was created by Sallay and Reed.<sup>220</sup> The modified version was a condensed assessment containing the VAS pain scale and the 10-question self-evaluation of ADL. Also, the question relating to sports participation included an added option to indicate that the respondent did not play any sports; and a question was added asking whether the respondent considers his/her dominant shoulder to be normative. Their study assessed baseline scores of patients without impairment and so was not included in our review. Klein et al<sup>92</sup> used the ASES (modified) when evaluating clinical and radiologic results after implantation of the total shoulder joint reverse prosthesis in 20 elderly patients with comminuted proximal humerus fractures. No

data to support reliability or validity of the ASES (modified) were identified in our target population. Liedel et al<sup>221</sup> investigated the operative outcome of acute grade II acromioclavicular joint separations after temporary K-wire transfixation of the acromioclavicular joint using the ADL subscale of the modified ASES (modified). Leidel reported that ASES scores improved with time, providing preliminary evidence of responsiveness; however, no statistical test results were shown.<sup>221</sup>

## ASES Elbow Score

The ASES Elbow Score is a self-reported measure of elbow function developed by the Research Committee of the American Shoulder and Elbow Surgeons.<sup>222</sup> It consists of 2 portions: a patient questionnaire and a physician form that addresses motion, stability, strength, and physical findings. The patient questionnaire covers the domains of pain, function, and satisfaction. Only the patient portion is included in this review of measures. The survey on function covers 12 items ranging from buttoning the top button of a shirt to throwing a ball. These items are rated from 0 to 3 (unable to do to not difficult). Scores range from 0 to 36, with lower scores indicating worse function.

Paschos et al<sup>223</sup> compared 2 different protocols of early mobilization with a protocol of delayed mobilization in patients with simple radial head fractures. They observed an improvement over time but did not evaluate group differences statistically. Jockel et al<sup>224</sup> described patient outcomes after floating elbow injury using the ASES-E, and found that nerve injury was associated with lower ASES-E scores. They also found that later follow-up was significantly associated with better ASES scores. Reliability and other forms of validity of the ASES-E were not reported in any of the articles in our review.

## Assessment of a Score for Activities of Daily Living

The Assessment of a Score for Activities of Daily Living is a 25-item self-report assessment designed for and used in a study to assess improvement of 25 ADL tasks after surgical reconstruction of the upper limb in patients who have sustained traumatic tetraplegia.<sup>225</sup> The 25 ADL tasks are grouped in 6 categories: mobility (use of wheelchair, including raise self in seat, propelling on level ground, propelling up gentle incline, transfer to bed, and ability to drive a car), dressing (upper and lower), communication (using a telephone, writing/typing, and handling money), washing and toilet (bath transfer, washing/drying upper limbs, washing/drying lower limbs, clean teeth, shaving or applying make-up, brush hair, bladder management and bowel management), feeding and drinking (use of cutlery, cut meat, and hold cup/glass), and miscellaneous (meal preparation, reach to above shelf, open/close drawer, and operating buttons). The response options include improved (4 points), unchanged (2 points), and worse (0 points). The total score ranges from 0 to 100 with the following total score interpretation: excellent (>90 points), good (70–89 points), fair (50–69 points), and poor (<50 points).<sup>225</sup> Lamb and Chan<sup>225</sup> reported a significant correlation with a hand function scale they also created; however, the magnitude of the correlation was not reported. Construct validity, reliability, responsiveness, and floor/ceiling effects were not examined.

## Assessment of Capacity for Myoelectric Control

The Assessment of Capacity for Myoelectric Control (ACMC) is a 30-item performance-based assessment that assesses a person's capacity to control a myoelectric prosthetic hand during ordinary daily tasks.<sup>8,226,227</sup> The items comprising the ACMC describe different levels of difficulty of control of the myoelectric hand. The 30 items are grouped into 4 categories: gripping (12 items), holding (6 items), releasing (10 items), and coordinating between hands (2 items).

Hermansson et al<sup>227</sup> performed a Rasch rating scale analysis of the ACMC using a sample of children and adults (mean age, 8y) and reported that the measure was unidimensional and fairly well targeted to the sample used (little evidence of floor or ceiling in person-ability measures compared with item difficulty). In a later reliability study of the ACMC, Hermansson et al<sup>226</sup> examined a sample of children and adults (mean age, 10y) with a myoelectric prosthetic hand. Intrarater agreement in items was reported to be excellent ( $\kappa=.81$ ) in more experienced raters and .65 for inexperienced raters. However, mean interrater agreement in items varied between experienced and less experienced raters;  $\kappa$  was .60 between the experienced raters and .47 between the less experienced raters.<sup>226</sup>

Lindner et al<sup>228</sup> examined the construct and rating scale of the ACMC and analyzed data with a Rasch rating scale model. A principle components analysis supported the unidimensionality of the ACMC, and excellent internal consistency (person-reliability index=.97) was found. Person-separation index (5.21) indicated the ACMC was sensitive to persons with a wide range of prosthetic ability, and mean person ability (.48) was near mean item difficulty (0). Three items exhibited DIF by sex; after removing these items, mean person ability increased to .60 logits. Only 2 items had a mean-square statistic (MnSq) >1.5, but these were retained after a sample idiosyncrasy was discovered; 5 items had a MnSq <0.5, but these were mostly nonsignificant and ultimately kept because validity was not threatened.

## ACMC version 2.0

ACMC version 2.0 resulted from analysis of the original ACMC and led to item combination, clarification of item definition, and rating category redefinition.<sup>228</sup> The resulting ACMC version 2.0 consists of 22 items that assess 6 different aspects related to capacity for myoelectric control: the need for external support, grip force, coordination of both hands, different positions and in motion (timing), repetitive grasp and release, and the need for visual feedback.<sup>229</sup> In the ACMC version 2.0, the prosthesis user performs a bimanual activity, either self-chosen or standardized. A certified ACMC rater observes how the prosthesis user controls the myoelectric prosthetic hand during the activity and rates the items.<sup>229,230</sup> All items are rated on a 4-point rating scale: 0 (not capable), 1 (somewhat capable), 2 (generally capable), and 3 (extremely capable). This gives a maximum raw score of 66.

In a study of reliability of the ACMC version 2.0, 25 participants performed the standardized activities twice, at 2 to 5 weeks apart.<sup>229</sup> The standardized activities were repotting a plant ( $n=4$ ), a ready-to-assemble project ( $n=5$ ), setting a table for 4 persons ( $n=4$ ), mixing a store-bought cake/pudding mix ( $n=4$ ), sorting bills or pictures ( $n=4$ ), and packing a suitcase for overnight stay ( $n=4$ ). Two experienced ACMC raters assessed the prosthesis users using the ACMC version 2.0 manual.<sup>229</sup> They reported excellent test-retest reliability ( $ICC=.94$ ), interrater reliability for test ( $ICC=.95$ ) and retest ( $ICC=.92$ ), and intrarater reliability ( $ICC=.98$ ). The MDC95 was calculated as .69. No validity, responsiveness, or floor/ceiling analyses were reported in articles that included traumatic amputees.

## Brigham Questionnaire

The Brigham Questionnaire, also known as the Brigham and Women's Carpal Tunnel Instrument and the Levine instrument, is a self-report measure consisting of 2 subscales to measure severity of symptoms and functional status associated with carpal tunnel syndrome. The severity of symptoms scale consists of 11 items that include questions on daytime pain, nocturnal pain, paresthesia, numbness, and weakness.<sup>231</sup> The functional status scale, included in this review, consists of 8 items, including questions on writing, buttoning clothes, holding a book, gripping a telephone, opening jars, performing household chores, carrying grocery bags, and bathing and dressing. These items have 5 possible responses, including no difficulty; mild, moderate, and severe difficulty; and so difficult cannot do it. The answers for each scale are rated from 1 point (none and no difficulty) to 5 points (very severe and cannot perform activity). The overall score for each of the subscales is calculated as the mean of the responses to the individual items.<sup>12</sup> Although the measure was developed to assess patients with carpal tunnel syndrome, it has been used in studies of patients with a broad range of upper extremity disorders, including traumatic injury.

Beaton et al<sup>42</sup> used the Brigham questionnaire when evaluating the validity of the DASH with patients waiting for treatment for either wrist, hand, or shoulder problems. Beaton reported a Pearson correlation of  $r=.71$  (Spearman  $\rho=.70$ ) between the functional status subscale and the DASH but did not report the significance level. The SRM, calculated by comparing measurements before and after treatment, was .64. Koman et al<sup>95</sup> used the function subscale to evaluate the relation between functional status and degree of cold intolerance and examined correlations between measures of health-related quality of life and symptoms of cold intolerance in a sample of 162 patients with and without

traumatic upper extremity injury in a tertiary care center for upper extremity disorders. Patients with cold intolerance scored significantly higher (worse) than those with more severe cold intolerance (from mild to extreme). No data on reliability of this measure in patients with traumatic injury were reported.

## Canadian Occupational Performance Measure

The Canadian Occupational Performance Measure (COPM) is an individualized, client-centered measure designed to detect change in a client's self-perception of occupational performance over time.<sup>232</sup> The semi-structured interview is intended to identify concerns regarding performance during self-care, productivity, and leisure activity. The client selects the 5 most important activities and rates those activities on a 10-point performance scale, from 1 (not at all able) to 10 (able to perform extremely well), and a satisfaction scale, from 1 (not at all satisfied) to 10 (extremely satisfied).<sup>232</sup> The importance of each activity is also rated on a scale from 1 (not important at all) to 10 (extremely important). We considered the performance and satisfaction ratings in this review. The COPM is designed for use with a variety of disabilities and across all developmental stages. The COPM takes approximately 20 to 40 minutes to administer.

Four studies were found that used the COPM with persons with upper extremity injury in Brazil, Sweden, Denmark, and The Netherlands.<sup>173,233-235</sup> Knygsand-Roehoej and Maribo<sup>233</sup> used the COPM subscales to compare 2 techniques for treatment of edema after a distal radius fracture, but found no significant differences in proportion of patients experiencing a clinically important improvement in COPM. Ehrenborg and Archenholtz<sup>234</sup> used the Swedish version of the COPM to evaluate the effectiveness of supplemental surface electromyographic biofeedback training compared with controls for subjects with chronic whiplash-associated disorders. They found significant improvement between admission to rehabilitation and discharge and admission and 6-month follow-up in both COPM performance and satisfaction scores. ESs ranged from 0.9 to 1.2. Sampaio et al<sup>235</sup> reported a 100% increase in subscale scores in patients with hand injury who received treatment in a public Brazilian hospital. Their reported ESs were 2.0 and 1.6 for the performance and satisfaction subscales, respectively. Sampaio also found a significant association between the performance subscale and grip strength ( $r=.31$ ), and changes in grip strength and COPM performance. Finally, Ydreborg et al<sup>173</sup> investigated performance and satisfaction subscale scores for patients with distal radius fractures at 6 and 24 months after plate fixation but found no significant differences. No data on reliability, validity, or floor and ceiling analyses were reported.

## Carroll test

The Carroll test is a performance measure that consists of 33 items related to grasping objects of varying size and shape, supination, pronation, and accurate placement of the hand in space. Items are scored from 0 to 3. The scores are interpreted as follows: 0 (can perform no part of the test), 1 (performs test partially), 2 (completes tests, but takes abnormally long or has great difficulty), and 3 (performs tests normally). The total score is summed. Graham et al<sup>236</sup> used the Carroll test to compare function in patients with upper limb amputation and limb replantation and reported that 37% of those in the replantation group had a satisfactory result ( $\geq 75$  points) compared with 0% in the prosthetic group. We did

not consider this as evidence of known-group validity. Age-adjusted scores showed no significant differences by mechanism of injury, but by level of injury, patients with wrist injuries scored best and those with above forearm scored worst.<sup>236</sup> Graham also reported no interobserver variation in scores ( $ICC=.99$ ), supporting the scale's interrater reliability. No responsiveness analyses or floor/ceiling effects were reported.

## Carroll test modified

The Carroll test modified is similar to the Carroll test but eliminates 12 items that require digital prehension, decreasing the maximum number of points attainable to 63 from 99. In the Carroll test modified items are scored from 0 to 3. The scores are interpreted as following: 0 (can perform no part of the test), 1 (performs test partially), 2 (completes tests, but takes abnormally long or has great difficulty), and 3 (performs tests normally). The total score is summed. Graham<sup>236</sup> used the modified Carroll test to compare function in patients with upper limb amputation or limb replantation. Although they reported significant differences between groups (68% of persons in the replantation group had excellent results compared with 27% in the prosthesis group), we did not consider this as evidence of construct (known-group) validity. No validity, reliability, or responsiveness analyses or floor/ceiling effects were reported.<sup>236</sup>

## Croft Shoulder Disability Questionnaire

The Croft Shoulder Disability Questionnaire is a 22-item self-report scale that assesses shoulder disability. The subject answers a series of yes or no questions about activities such as ability to complete various dressing tasks, carrying heavy objects, writing, bathing, shopping, sports, and leisure activities. The questions are based on 11 of the 12 disability categories in the Functional Limitations Profile.<sup>237</sup> A score of 0 indicates no shoulder disability and  $\geq 5$  indicates a significant level of disability.

Hodgson et al<sup>238</sup> used the Croft questionnaire, dichotomizing the score (no disability or any disability), in a study of patients with proximal humeral fractures and found that a significantly lower proportion of patients who had immediate mobilization (instead of an initial period of immobilization) had disability 1 year after injury. At 2 years there were no significant differences. No data on reliability, validity, or responsiveness were reported.

## Functional Evaluation of the Upper Limb

Functional Evaluation of the Upper Limb is a 15-item self-report measure adapted in part from the American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form.<sup>239</sup> The questionnaire contains items assessing the following functional activities: donning a coat, washing back, wash/comb hair, meal preparation, toileting, reaching overhead and to opposite shoulder, turning a key, opening a new jar, carrying a shopping bag and heavy object, household tasks, recreational activities, and gardening. Respondents rate their ability to perform each of the listed activities on a 4-point scale (where 0 is unable, 1 is very difficult, 2 is somewhat difficult, and 3 is not difficult). A total score is calculated as the sum of the scores for the individual items (maximum score, 45), with a higher score indicating better function.

Patel et al<sup>239</sup> used this measure in a study on a circular external fixator for persistent nonunion of the diaphysis of the humerus and found nearly all patients showed improvement after treatment,

with the mean score increasing from 10.5 to 31.3. No data on reliability or validity were reported.

## Functional Impairment Test—Hand, Neck, Shoulder and Arm Test

The Functional Impairment Test—Hand, Neck, Shoulder and Arm Test (FIT-HaNSA) is a performance-based measure designed to test the endurance of the shoulder through the completion of 3 tasks that simulate activities of lifting and sustained overhead work in the house or workplace.<sup>240</sup> This assessment is designed for use with patients with a broad range of shoulder pathologies. The 3 tasks include the following: task 1 (waist up), lifting three 1-kg weights between a shelf positioned at waist level and a second shelf 25cm above; task 2 (eyes down), the weights are lifted between a shelf positioned at eye level and a shelf 25cm below; and task 3, screwing and unscrewing bolts on an overhead plate.<sup>240</sup> The FIT-HaNSA can be completed in 20 minutes; subjects perform each task either for 5 minutes or until a stopping criterion is met. Each task is scored as a percentage of completion.<sup>240</sup>

Hawkes et al<sup>241</sup> used the FIT-HaNSA to compare healthy subjects with those with massive rotator cuff tears and found a 68-point lower score on average in the massive rotator cuff tear group than in the healthy group. No data on reliability or responsiveness to change were reported.

## FIM

The FIM is an observational measure completed by a clinician consisting of 18 items grouped into 6 domains: self-care (eating, grooming, bathing, upper body dressing, lower body dressing, and toileting), sphincter control (bladder management and bowel management), transfers (bed/chair/wheelchair, toilet, and tub/shower), locomotion (walk/wheelchair and stairs), communication (comprehension and expression), and social cognition (social interaction, problem solving, and memory).<sup>242</sup> Each item is scored on a 7-point scale (where 1 is total assist, 2 is maximal assist, 3 is moderate assist, 4 is minimal assist, 5 is supervision, 6 is modified independence, and 7 is complete independence). Certification is required for clinicians who use the FIM. Two subscale scores can be calculated. The self-care, sphincter control, transfer, and locomotion domains make up a motor subtotal score and the communication and social cognition domains make up the cognitive subtotal score.<sup>242</sup> The motor FIM meets the criteria for inclusion into our study.

Czyrny et al<sup>243</sup> used the motor FIM to assess the effects of acute care hospital-based rehabilitation in patients with multiple limb trauma. They found no statistical difference on the motor FIM when compared across injury subgroups classified based on the number of limbs involved (upper or lower) and whether involvement was contralateral, ipsilateral, or bilateral at admission, discharge, or by change score. No reliability or floor/ceiling effect analyses were reported. The motor FIM score increased (improved) by 29 points from admission to discharge. Similar improvement was noted in every subgroup except among those with trauma to a single lower limb and bilateral upper limbs.

## Functional Questionnaire

The Functional Questionnaire is a 15-item self-report measure that was designed for a study that assessed the functional status of patients who had sustained unstable intra-articular distal radius fractures (Frykman grade 7 or 8) treated with an external fixator that permitted movement of the wrist and hand.<sup>244</sup> The questionnaire

assesses the following activities: combing hair, tie/untie shirt buttons, cleaning teeth, toileting, turning taps on/off, pour water from jug, drink from glass, cut meat with knife, open/close jar lid, turn a key in a lock, turn a door knob, turn a steering wheel, bring telephone to ear, and writing. The patient is asked the following: Are you able to perform the following activities with you affected hand? Answers are scored on a scale from 0 to 2 (where 0 is not at all, 1 is some of the time, and 2 is all of the time). The responses for each of the questions are summed for a total score ranging from 0 to 30 (0 indicating unable to perform any of the tasks and 30 indicating able to perform all the tasks, all the time).

Krishnan et al<sup>244</sup> report on the results of a new configuration using an Arbeitsgemeinschaft für Osteosynthesefragen interfracture external fixator for intra-articular fractures of the distal radius. They showed progressive improvement in Functional Questionnaire scores from 1 to 52 weeks postoperation, but they did not report tests to quantify whether or not differences were statistical significant. No reliability or validity analyses or floor/ceiling effects were examined.

## Groningen Activity Restriction Scale

The Groningen Activity Restriction Scale (GARS) is an 18-item self-report measure that assesses perceived ability to perform 11 basic activities of daily living (BADL) tasks (grooming, dressing, bathing, and mobility) and 7 instrumental ADL tasks (meal preparation, household tasks, and shopping).<sup>245</sup> Respondents are required to rate the amount of difficulty they have completing each task (where 1 is yes I can do it fully independently without difficulty, 2 is yes I can do it fully independently with some difficulty, 3 is yes I can do it fully independently with great difficulty, 4 is no I cannot do it independently and require someone's help, and 5 is no I cannot do it at all and require complete help). The GARS score is calculated by adding the points for all 18 items with a minimum score of 18 and a maximum score of 72 (higher scores are associated with greater disability). Kempen et al<sup>245</sup> created a subscale score for the BADL items only that range from 11 (no restriction) to 44 (maximum restriction).

We found 3 studies which used the GARS in samples from the Groningen Longitudinal Aging Study, a population-based study of elderly patients in The Netherlands with fall-related injuries to the extremity.<sup>246-248</sup> One of these articles reported on the BADL score,<sup>247</sup> whereas the other 2 studies used the total score. Internal consistency for the total GARS score was reported as .91.<sup>246</sup> Severity of injury was a significant predictor of total GARS scores at 8 weeks, and age was a predictor at 12 months.<sup>248</sup> In persons with fall-related injuries, total GARS scores improved between 8 weeks, 5 months, and 12 months, providing evidence of responsiveness to change.<sup>246</sup>

In a sample of elderly persons, the BADL score after extremity injury (8wk, 5mo, and 12mo) was significantly worse than pre-injury scores.<sup>247</sup> Sex was found to be a predictor of BADL recovery from extremity injury with men at 12 months compared with women. No data on internal consistency of the BADL subscore or test-retest reliability of the measure were reported.

## Jarus Hand Function

Jarus Hand Function is a performance-based measure that combines the 7-item JTHF and the 13-item Smith Hand Function Evaluation. Jarus and Poremba<sup>249</sup> performed factor analysis on all items collected from a sample that included healthy subjects and those

with Colles fractures. Single-hand items were performed with both dominant and nondominant hands, resulting in a 34-item pool. A 4-factor solution with each factor solution accounting for at least 5% of the variance (63% of variance explained overall) was identified. The factors were named pinch, grasp, target accuracy, and ADL. Each factor included items for both hands. Internal consistency was investigated, and 18 items were excluded. Final internal consistency was excellent for all scales. The pinch factor contained the small pegs and large pegs items from the Smith Hand Function Evaluation and had a Cronbach  $\alpha$  of .93. The grasp factor contained the large heavy object and large light object items from the JHFT and had a final Cronbach  $\alpha$  of .96. The target accuracy factor contained the checkers item from the JHFT and the blocks and nails items from the Smith Hand Function Evaluation and had a Cronbach  $\alpha$  of .85. The fourth factor, ADL, contained the eating item from the JHFT and had a Cronbach  $\alpha$  of .80. Mean factor scores were calculated, and Jarus<sup>249</sup> reported that subjects with Colles fractures scored significantly lower (better) on all 4 factors than subjects without fractures. No responsiveness or floor/ceiling effect analyses were reported.

### Jebsen-Taylor Test of Hand Function

The JTHF is a performance-based measure that assesses fine and manual finger dexterity through the use of 7 timed subtests related to functional tasks. These functional tasks include the following: (1) writing a 24-letter, third-grade reading difficulty sentence; (2) turning 3- × 5-in cards in simulated page turning; (3) picking up small common objects, including pennies, paper clips, and bottle caps, and placing them in a container; (4) stacking checkers; (5) simulated feeding; (6) moving light cans; and (7) moving 1-lb cans. In the original scoring system, the subtests are scored by recording the number of seconds required to complete each task.<sup>25</sup> Increased time to complete the test is related to decreased function of the hand. Normative data from the original scoring system are available for dominant and nondominant hands.

Kreder et al<sup>250</sup> examined patients with distal radius fractures treated with closed reduction techniques and reported statistically significant differences in JTHF total score with time from surgery (at 6mo, 1y, and 2y). Although Kreder administered all 7 JTHF subtests, only the total score was reported.

### Liverpool Elbow Score

The Liverpool Elbow Score is an elbow-specific score that consists of 2 subscales: the 6-item clinical assessment score and the 9-item patient-answered questionnaire (PAQ).<sup>251</sup> The clinical assessment score includes range of motion measurements (including elbow flexion, elbow extension, forearm pronation, and forearm supination), a strength assessment (average of elbow flexion, elbow extension, forearm pronation, and forearm supination), and an ulnar nerve assessment.<sup>28</sup> The PAQ items address daily functioning (use of opposite arm, combing hair, washing, feeding, dressing, household activities, lifting, sport, and leisure) over the last 4 weeks. Only the PAQ meets criteria for inclusion in our study. In the PAQ, each task is scored on a 5-point scale, from 0 (worst/least function) to 4 (best/most function), in reference to how much the elbow problem interferes with ability to complete the task. A total score is converted to a scale of 0 to 10 (where 10 represents best function). The PAQ can be scored independently outside the full instrument. The total score for the PAQ ranges from 0 to 36, with 0 representing no difficulty in function. Munoz-Mahamud et al<sup>252</sup> reported PAQ scores in 10 patients who underwent plate osteosynthesis for severe

olecranon fractures; however, no data supporting the PAQ's reliability, validity, or responsiveness data were reported.

### Minnesota Rate of Manipulation Test

The Minnesota Rate of Manipulation Test is a performance-based measure that assesses unilateral and bilateral manual dexterity through the use of 5 timed subtests. These subtests include the following: (1) the placing test, (2) the turning test, (3) the displacing test, (4) the 1-hand turning and placing test, and (5) the 2-hand placing and turning test.<sup>253</sup> The subtests are scored by recording the number of seconds required to complete each task, and the overall score is the total time of all subtests. Normative values are available in the Minnesota Rate of Manipulation Test user manual.

Gloss and Wardle<sup>254</sup> used the Minnesota Rate of Manipulation Test subtests with patients with hand impairment when evaluating the reliability and validity of the American Medical Association's *Guides to the Evaluation of Permanent Impairment*. Concurrent validity was supported by correlations with the permanent impairment measure (according to the American Medical Association guide), which ranged from  $r=.49$  to  $r=.60$  for the entire sample. Differences by location of hand impairment and by hand dominance were noted, but statistical tests were not performed. No reliability, responsiveness, or floor/ceiling effects analyses were reported.

### Modified Health Assessment Questionnaire

The Modified Health Assessment Questionnaire (MHAQ) is a self-report questionnaire originally developed to assess functional status in patients who have rheumatic disease. The MHAQ was developed as a shorter version of the Stanford Health Assessment Questionnaire.<sup>255</sup> The MHAQ consists of 8 items (1 item from each of the Health Assessment Questionnaire categories) which include dressing, getting out of bed, lifting a full cup to mouth, walking outdoors on flat ground, wash and dry entire body, bend down to pick up clothes from floor, turn regular faucet on/off, and getting out of a car. Respondents rate the amount of difficulty they have performing the tasks (where 0 is without any difficulty, 1 is some difficulty, 2 is much difficulty, and 3 is unable to do). The total score is obtained by adding scored items together and dividing by the total number of items answered. The total score is between 0 and 3, with higher scores indicating worse function and greater disability. Time to complete is <5 minutes.<sup>256</sup>

Rohde et al<sup>257</sup> used the MHAQ when examining patients with low-energy distal radius fracture and attainment of preinjury HRQOL and global quality of life 1 year after the fracture. No significant difference in MHAQ score was identified between patients with distal radius fractures and uninjured controls at 1 year. No data supporting reliability or validity were reported.

### Musculoskeletal Functional Attachment

The Musculoskeletal Functional Attachment (MFA) is a 100-item self-report questionnaire designed to identify small changes in functioning in patients who have sustained musculoskeletal disorders of the extremities. The 100 items are grouped into 10 categories: self-care (18 items), sleep/rest (6 items), hand/fine motor skills (7 items), mobility (20 items), household work (9 items), employment/work (4 items), leisure/recreation (4 items), family relations (10 items), cognition/thinking (4 items), and emotional adjustment/coping/adaptation (18 items). The patient assesses his or her function by answering yes or no to each

question (yes corresponds to 1 point and no to 0 point). The total score can range from 0 to 100, with higher scores representing increased dysfunction. The full instrument takes approximately 15 minutes to complete.<sup>34</sup> The overall score meets criteria for inclusion in this review because approximately 60% of all items relate to activity performance. The individual domains of housework, self-care, and hand/fine motor skills also met the inclusion criteria for this review.

Goldfarb et al<sup>79</sup> reported a correlation between MFA total score and DASH score ( $r = .82$ ,  $P \leq .01$ ) in patients treated by open reduction and internal fixation for fractures of the forearm, and a negative correlation with flexion of the wrist ( $r = -.51$ ,  $P \leq .05$ ), but not with extension of wrist, pinch strength, or grip strength. The total measure exhibited evidence of responsiveness given that patients scored better 1 year after treatment.<sup>258</sup>

Kreder et al<sup>250</sup> compared closed reduction and casting with closed reduction and external fixation with optional K-wire fixation in patients with distal radius fractures with metaphyseal displacement but without joint incongruity using the upper extremity function domain of the MFA. This domain was not described; however, we assumed that it was the same as the hand/fine motor skills domain. No significant difference was found between casted and external fixator treatment groups. Reliability data of the MFA or any of its subscales were not found.

### Nine-Hole Peg Test

The Nine-Hole Peg Test is a performance-based measure of fine dexterity that involves placing and removing 9 pegs in a pegboard. It is one of the most commonly used tools for assessing dexterity in neurologically impaired populations. The Nine-Hole Peg Test score is the total time in seconds to complete placing and removing all 9 pegs, one at a time. Normative scores are available for men and women and right and left hands.<sup>259,260</sup> Time to administer the Nine-Hole Peg Test is <5 minutes for both hands.<sup>260</sup> Metzger et al<sup>261</sup> reported the Nine-Hole Peg Test scores in unilateral transradial prosthetic device users but did not provide any analyses supporting reliability, validity, or responsiveness of the measure.

### O'Connor Finger Dexterity Test

The O'Connor Finger Dexterity Test is a performance-based psychomotor test that measures dexterity. This assessment involves manipulating and placing small pins (3 at a time) into 100 small holes on a pegboard. Patients are given 3 minutes for each hand, and the number of holes filled correctly is recorded. Gloss and Wardle<sup>254</sup> used the Finger Dexterity Test when examining the American Medical Association's *Guides to the Evaluation of Permanent Impairment* rating schedule for reliability and validity. They reported that the Finger Dexterity Test was significantly correlated with patient ratings of permanent impairment among all subjects ( $r = .53$ ).<sup>254</sup> Test scores for injuries on the dominant/nondominant and impaired/healthy hands were provided, but statistical tests were not used to make comparisons. No reliability, responsiveness, or floor/ceiling analyses were reported.

### Oxford Shoulder Score

The Oxford Shoulder Score (OSS) is a 12-item self-report questionnaire that assesses the outcome of shoulder surgery, excluding surgery for instability. The OSS addresses shoulder problems over the last 4 weeks and includes 4 items about pain (worst pain,

usual pain, pain interference with usual work, and pain at night) and 8 items about daily functions (dressing, use of knife and fork, brushing/comb hair, car transfer, shopping, carrying a tray across the room, bathing, and dressing). The scoring system was modified in 2009.<sup>39</sup> Under this system, each question is scored from 0 to 4, with 4 representing best function (this is the opposite direction from the original method of scoring).<sup>39</sup> A total score is derived by summing the 12 items of the OSS. The total score ranges from 0 to 48, with 48 being the best outcome. The OSS takes approximately 2 minutes to complete.<sup>40</sup>

Seven publications were identified that used the OSS to examine outcomes after conditions, including as rotator cuff tears,<sup>262</sup> shoulder fractures,<sup>157</sup> shoulder dislocations,<sup>263</sup> proximal humeral fractures,<sup>142</sup> and new surgical treatments (percutaneous technique,<sup>264</sup> bracing,<sup>265</sup> plates, etc<sup>139</sup>). van der Water<sup>157</sup> evaluated the test-retest reliability of the OSS using data collected at 12 and 13 weeks of active rehabilitation after a shoulder fracture and reported an ICC of .75. van der Water also conducted a detailed content analysis of the measure and linked items with the *International Classification of Functioning, Disability and Health*.

van der Water examined the concurrent validity of the OSS, reporting significant correlations at 6 or 12 weeks postfracture with the DASH ( $r = -.80$  and  $r = -.85$ ), SSV ( $r = .43$  and  $r = .65$ ), constant ( $r = .53$  and  $r = .79$ ), and UCLA scores ( $r = .77$  and  $r = .83$ ), respectively. Change scores (from 12 to 13wk) were also significantly correlated with the DASH ( $r = -.80$ ), constant ( $r = .64$ ), and UCLA change scores ( $r = .73$ ) (but were not significantly correlated with the SSV change score;  $r = .44$ ).<sup>142</sup>

Shahid et al<sup>139</sup> reported that patients with postoperative complications or dislocation at the time of injury had worse scores than those who did not, but did not report results of statistical testing. Several authors reported that OSSs improved with treatment over time, but they did not report statistical significance of findings.<sup>157,262</sup> van der Water et al<sup>157</sup> reported that among 20 patients with post proximal humeral fracture, none had the highest or the lowest score—providing preliminary, but insufficient evidence, that there may not be floor or ceiling effects in this patient population. They used both anchor-based and distribution-based methods to calculate the minimal clinically important difference, which they reported as 11.4 and 5.1 points, respectively.

### Patient Evaluation Measure

The Patient Evaluation Measure is a self-report questionnaire that consists of 3 sections. The first section consists of 5 questions related to the patient's opinion on the delivery of care. The second section (hand health profile) consists of 10 questions that are related to subjective hand function. The third section consists of 3 questions which address the overall assessment of outcome. The hand health profile meets the inclusion criteria for our review. The symptoms assessed in the hand health profile include feeling, cold intolerance, pain, dexterity, wrist movement, subjective grip strength, daily activities, work, appearance, and a general assessment of wrist and hand function. It is scored on a Likert scale from 1 to 7, and the score is determined as a percentage of the maximum score possible (70 points) and is expressed as a percentage of disability ranging from 0 to 100.<sup>266</sup>

Forward et al<sup>172</sup> investigated the internal consistency and the validity of the Patient Evaluation Measure in a sample of 200 patients 6 to 42 years after a distal radius fracture. They reported strong internal consistency ( $\alpha = .94$ ) and strong concurrent validity with the DASH ( $r = .73$ ). The Patient Evaluation Measure was

found to be weakly correlated with grip strength ( $r = -.18$ ), tip pinch strength ( $r = -.17$ ), and range of motion ( $r = -.27$ ).

Karantana et al<sup>267</sup> compared the functional outcomes of persons with displaced distal radial fractures when treated with a volar locking plate (hypothesized to be an improved treatment method) or with the conventional method of closed reduction and percutaneous wire fixation. Although they found Patient Evaluation Measure scores were 11 points lower (better) in the volar locking plate group at 6 weeks postoperatively, there was no significant difference at 12 weeks or 1 year. No responsiveness or floor/ceiling effect data were reported.

## Patient-Specific Functional Scale

The Patient-Specific Functional Scale is a patient-specific measure that asks persons to identify up to 5 activities that they have difficulty performing because of their condition and then rate the amount of limitation they have in performing these activities on a scale of 0 to 10, with 0 being unable to perform the activity and 10 being able to perform the activity with no problem. Individual items are scored separately. Resnik and Borgia<sup>20,21,23</sup> used the Patient-Specific Functional Scale in 3 publications. The authors found significant differences across levels of amputation with the lowest scores among transradial amputees using conventional prostheses.<sup>23</sup> However, in a separate study, the authors reported no differences in level of device configuration (radial, humeral, or shoulder) in users of the DEKA Arm.<sup>20</sup> They reported that subjects scored better with the DEKA Arm compared with their conventional prostheses. Additionally, they reported an ES of 1.59 after completion of prosthetic training sessions.<sup>21</sup> No floor or ceiling effects were observed when the Patient-Specific Functional Scale score distribution was examined. No data on reliability of the Patient-Specific Functional Scale were found.

## Penn Shoulder Score

The Penn Shoulder Score is a 24-item self-report measure designed to assess shoulder pain and function.<sup>268</sup> The Penn Shoulder Score consists of 3 subscales: pain, satisfaction, and function. A total score can be calculated by summing the 3 subscales (maximum score of 100 indicates high function, low pain, and high satisfaction), or the subscales can be used independently. Only the function subscale was considered eligible for our review. The function subscale consists of 20 items addressing various reaching tasks, combing hair, washing back and opposite shoulder, carrying groceries, opening a door, placing a can of soup on shoulder-height shelf, performing usual sport or hobby, household chores, and ability to work at a regular job. Each question is rated on a 4-category Likert scale for level of difficulty (where 0 is cannot do at all, 1 is much difficulty, 2 is some difficulty, 3 is no difficulty, and x is did not do before injury). The function subscale is scored by totaling the 20 responses with a total score ranging from 0 to 60. If a patient responded that they did not complete some of the activities, the function score is calculated by subtracting 3 points for every item that was not done before the injury from 60 (total possible points of the function subscale). That number is then divided by the raw sum of function items and then multiplied by 60 for a total function subscale score.

Tjoumakaris et al<sup>215</sup> used the Penn Shoulder Score to investigate the difference in outcomes between patients who underwent arthroscopic Bankart repair and open Bankart repair for recurrent

anterior glenohumeral instability. As hypothesized, they found no significant difference in Penn Shoulder Score function subscale groups. No reliability, validity, responsiveness, or floor/ceiling analyses were reported.

## Purdue Pegboard

The Purdue Pegboard is a performance-based measure of dexterity. This assessment involves a series of 4 subtests that consist of placing small pins into holes on a pegboard (right hand, left hand, and both hands) and assembling pins and washers. Each subtest is scored by the number of pins or washers and pins that can be placed on the board in 30 seconds (for pins) and 60 seconds (for pins and washers). Normative data are available for men and women and a variety of age groups.<sup>269-271</sup> The Purdue Pegboard takes <5 minutes to administer.

Kuo et al<sup>272</sup> used the Purdue Pegboard with Taiwanese patients with distal radius fractures to determine whether progressive early digit mobilization resulted in better functional results. Although they reported that scores improved from 1 to 12 weeks after surgery, suggesting responsiveness to change, no statistical tests were reported. No data reliability, validity, or floor/ceiling effect analyses were reported.

## Questionnaire for Bilateral Activities

The Questionnaire for Bilateral Activities is a structured interview assessment tool in which patients are asked to rank 4 activities (tying shoe laces, peeling potatoes, eating with a knife and fork, and cutting a slice of bread) on a 5-point scale.<sup>233</sup> The possible scores are the following: 0 (cannot perform the activity), 1 (can perform the activity with help/aid), 2 (can perform the activity without help, but compensates), 3 (can perform the activity as before the trauma/surgery), and 4 (irrelevant).

Knygsand-Roenhoej<sup>233</sup> used the Questionnaire for Bilateral Activities to compare the effectiveness of a modified manual edema mobilization approach with a traditional edema technique in patients with subacute hand or arm edema after a distal radius fracture. They found a significant difference between the manual edema mobilization and control treatment groups at 3 weeks posttreatment but not at inclusion, 6 weeks, or 9 weeks, indicating a quicker improvement in the manual edema mobilization group.<sup>267</sup> No data on reliability, validity, responsiveness, or floor/ceiling effect analyses were reported.

## Short Musculoskeletal Functional Assessment

The Short Musculoskeletal Functional Assessment (SMFA) is a 46-item self-report measure designed to assess musculoskeletal functional status. The SMFA is based on the 100-item Musculoskeletal Function Assessment. The SMFA includes a 34-item dysfunction index, (sometimes called the function index) and a 12-item bother index. The items included in the dysfunction index are grouped into 4 categories: daily activities (10 items), emotional status (7 items), function of the arm and hand (8 items), and mobility (9 items). Each item is answered using a 5-point response scale, where 1 indicates good function and 5 indicates poor function. The bother index includes 12 items that address functional areas to include recreation and leisure, sleep and rest, work, and family. This section also includes a 5-point response scale, where 1 point is not at all bothered and 5 points is extremely bothered. The scores for the dysfunction index and the bother

index are calculated by summing the responses and then using the following formula to convert the scores to a standardized format ranging from 0 to 100:  $(\text{actual raw score} - \text{lowest possible raw score}) / \text{possible range of raw score} \times 100$ . This formula can also be used to score the individual categories within the dysfunction index. A higher score indicates poorer function. The SMFA can be completed in approximately 10 minutes.<sup>273</sup> The following categories from the dysfunction index meet the inclusion criteria for our study: daily activities and arm and hand function.

Owsley and Gorczyca<sup>186</sup> assessed the SMFA function score in patients with proximal humeral fractures treated with a locking plate and found a significant difference between the dysfunction subscale scores of patients with radiographic evidence of complication (mean score, 15 points) and without evidence of a complication (mean score, 7 points). Ekholm et al<sup>274</sup> investigated the outcome of a nonoperative fracture brace for isolated humeral shaft fractures but found no significant difference between the nonoperative and surgically treated groups in arm and hand function, daily activities, or mobility subscales. No data on reliability or responsiveness of the measure were reported.

## Shoulder, Pain and Disability Index

The Shoulder, Pain and Disability Index (SPADI) is a self-administered questionnaire to measure pain and disability associated with shoulder function. It consists of 13 items which are divided in 2 subscales: pain (5 questions) and function (8 questions: grooming, dressing, reaching, and carrying a heavy object). There are 2 versions of the SPADI: the original version is scored on a VAS,<sup>275</sup> and the second is scored on a numerical rating scale.<sup>276</sup> The later was developed to ease administration and scoring. Subjects are asked to rate their pain or level of disability on an 11-point scale where 0 is no pain or no difficulty and 10 is the worst pain imaginable or so difficult it requires help. The pain scale is scored by summing the responses, dividing by 50, and multiplying by 100. The same is done for the disability scale except the summed responses are divided by 80. The total SPADI score is calculated by averaging the pain and disability subscales. The SPADI takes approximately 5 minutes to administer.<sup>51</sup> The total score and function subscale met criteria for inclusion into our study.

In patients with musculoskeletal upper extremity problems who had not changed during treatment, the total SPADI score (numerical rating scale) was reported to have an ICC of .86, demonstrating excellent test-retest reliability, and a corresponding minimal detectable change (MDC) of 18.1 and minimally important difference of 13.2.<sup>136</sup> Concurrent validity of the total score was supported by significant correlations between the Global Disability Rating and the SPADI total score 3 months after initial clinic visit ( $r = .69$ ) and 6 months after ( $r = .64$ ).<sup>136</sup> Beaton et al,<sup>42</sup> reporting on the concurrent validity of the SPADI functional subscale and the DASH in patients with wrist, hand, or shoulder problems found Pearson and Spearman correlations of  $r = .88$  and  $r = .87$ , respectively, but did not report whether or not these were statistically significant.

Schmitt and Di Fabio<sup>136</sup> reported on responsiveness of the SPADI total score in patients with musculoskeletal upper extremity problems showing an ES of 1.21, SRM of 1.08, and Guyatt Responsiveness Index of 1.53. Responsiveness of the SPADI functional subscale was supported by Beaton's findings<sup>42</sup> of an SRM of .62 between pretreatment baseline and 12 weeks after treatment began. Higher SRMs were reported for patients who rated their problem (SRM = .84) or function (SRM = .86) as having improved. No reports of floor or ceiling effect analyses were found.

## Shoulder Rating Questionnaire

The Shoulder Rating Questionnaire (SRQ) is a 21-item self-report measure designed to assess symptoms of the shoulder.<sup>277</sup> The SRQ includes 6 separately scored domains: global assessment (1 question based on a VAS); pain (4 questions: at rest, over the last month, at night, frequency of severe pain); daily activities (6 questions related to: general shoulder function, donning a shirt, brushing hair, reaching overhead, washing lower back, carrying bag of groceries); recreational and athletic activities (3 questions: limitation of total shoulder function, throwing a ball, limitation with a specific activity); work (5 questions: identification of main type of work [not scored], ability to do work over last month, ability to do work carefully or efficiently over last month, frequency of shortened work day over last month, frequency of change to usual work); and satisfaction (1 question: degree of overall satisfaction with shoulder). At the end of the questionnaire there is a final nongraded question where patients can list 2 areas in which he or she would most like to see improvement. Each of the domains, with the exception of the global assessment domain, consists of multiple-choice questions ranging from 1 (poorest) to 5 (best). Each domain is scored by averaging the scores and multiplying by 2, with possible scores ranging from 2 (poorest) to 10 (best).<sup>278</sup> Each domain is graded separately and is weighted to arrive at the total score.<sup>277</sup> The time to complete the SRQ is approximately 5 to 10 minutes.<sup>278</sup> The total score, a daily activities domain, and the recreational and athletic activities domain meet the criteria for inclusion in our study. However, we only identified 1 study that used the total score and none that used the subdomain scores.

Sosef et al<sup>279</sup> used the total SRQ score when examining a minimally invasive fixation technique for displaced proximal humeral fractures reporting that patients with more fractures had lower SRQ scores than those with fewer fractures. They did not compare scores statistically and did not present data on reliability or responsiveness.

## Simple Shoulder Test

The Simple Shoulder Test (SST) is a 12-item self-report measure that asks people about their ability to tolerate or perform different ADL. This measure is intended to measure general shoulder function. The SST addresses tasks such as ability to perform full-time job functions, lifting a 0.5 and 3.6 kg load, reaching, placing a coin on a shelf, and throwing a ball. The patient indicates his or her ability to complete the activity by circling yes or no for each question. The SST scores range from 0 to 100 (where a higher score indicates a higher level of function) and are reported as the percentage of items to which the subject has answered in the affirmative; however, several studies report the average number of items completed instead.<sup>280</sup> We identified 12 articles that used the SST with patients who had a variety of upper extremity injuries, including humeral fractures and rotator cuff tears.<sup>141,153,163,164,198,206,208,281-285</sup>

In a study of patients with arthroscopic Bankart repairs, Carreira et al<sup>198</sup> found that those with an extension of the labral injury into the superior labrum could perform significantly fewer tasks providing some evidence of known-group validity. However, Virtanen et al<sup>163</sup> found no significant differences between patients with or without complications from surgical treatment of acromioclavicular joint dislocations. Tashjian et al<sup>153</sup> reported the SST was significantly correlated with number of comorbidities for

patients with chronic rotator cuff tears, demonstrating some construct validity. No study examined the SST's correlation with concurrent measures.

Responsiveness of the SST was strongly supported by findings from 5 studies that showed significant improvement in scores after arthroscopic surgical repair,<sup>198,208</sup> endoscopic bursectomy,<sup>206</sup> manipulation and arthroscopic release,<sup>281</sup> and plate osteosynthesis.<sup>164</sup> Castellarin et al<sup>281</sup> reported that patients could complete >8 more SST tasks, on average, after arthroscopic release and immediate rehabilitation treatment. Duckworth et al<sup>284</sup> displayed the distribution of SST scores and noted that 22% of their sample of patients with rotator cuff tears could perform either 1 or none of the tasks and therefore received the lowest scores; because this is below half of the score's SD (3), this distribution does suggest a floor effect. No data on reliability of the SST were reported in any of the studies.

### Sollerman Hand Function Test

The Sollerman Hand Function Test is a performance measure based on 7 of the 8 most common hand grips (pulp pinch, lateral pinch, tripod pinch, 5-finger pinch, diagonal volar grip, transverse volar grip, and spherical volar grip).<sup>286,287</sup> The Sollerman Hand Function Test consists of 20 ADL subtests that involve picking up various items, turning a screwdriver, pouring water, writing, and cutting modeling compound with a knife and fork. Each subtest is scored on a scale from 0 to 4 (where 0 is cannot perform task; 1 is task partially performed within 60s; 2 is task completed with great difficulty within 60s but >40s, or does not use prescribed hand-grip; 3 is task completed with slight difficulty within 40s but >20s, or task completed with slight divergence from prescribed hand-grip; and 4 is task completed within 20s with prescribed hand-grip of normative quality). The time for each subtest is capped at 1 minute, and the test can usually be completed within 20 minutes. The test was originally validated on patients with tetraplegia.<sup>286</sup> Normative values have been established on men and women between 20 and 70 years of age.<sup>287</sup>

Lindqvist et al<sup>103</sup> used the Sollerman Hand Function Test to evaluate outcome of Swedish patients with hand injuries from powered wood splitters, reporting mean scores of 66.5 for the injured hand and 78.3 for the uninjured hand. They also reported a moderate correlation between the Sollerman score of the injured hand and the overall Injury Severity Score ( $r = -.45$ ), but no correlation with the Hand Injury Severity Score. No data on reliability, responsiveness, or floor/ceiling effects were found.

### Tapping Test

The Tapping Test is a performance-based test that measures eye-hand coordination and wrist-finger speed. This test consists of a page with 300 circles, and the subject is asked to place 3 marks in each circle with a pencil as quickly as possible, proceeding across the rows without skipping any of the circles. The subject is allowed 60 seconds to complete as many circles as possible. The test is completed twice, once for each hand.<sup>254</sup>

Gloss and Wardle<sup>254</sup> used the Tapping Test in a study of the reliability and validity of the American Medical Association's *Guides to the Evaluation of Permanent Impairment* rating. The Tapping Test was found to be moderately correlated with permanent impairment ( $r = -.33$ ). No data on reliability, responsiveness, or floor/ceiling analyses were found.

### UEFS from the OPUS

The UEFS from the OPUS was developed as a measure of functional activity performance for use with upper limb adult amputees. UEFS items ask clients to evaluate the ease of performing 23 activities, including self-care and instrumental daily living tasks, using a 5-point scale from 1 (very easy) to 5 (cannot perform). Items include activities varying from washing, buttoning shirt, tying shoelaces, using fork or spoon, and writing name to donning and doffing the prosthesis. The measure is scored by a Rasch rating scale. The original measure was described by Heinemann et al,<sup>288</sup> but no evaluation of the UEFS measurement was reported. A total of 11 articles in our review used the UEFS, but some used modified versions (as subsequently described).<sup>19-21,23,24,193,289-293</sup> Three studies in our review used the unmodified version of the UEFS.<sup>193,289,292</sup> Burger et al<sup>289</sup> performed Rasch scale analysis of the Slovene version of the UEFS in a sample of persons with unilateral upper limb amputation, and determined that the 5 category responses needed to be collapsed to 4 categories. Afterward, all items fit the underlying construct ( $0.6 < \text{MnSq} < 1.4$ ) except 2 misfit items (cut meat with knife and fork and use a hammer and nail). The person-separation reliability was .89, indicating adequate internal consistency; item-separation reliability was .97; and principle component analysis (PCA) of the UEFS supported its unidimensionality. In a later study, Burger et al<sup>193</sup> also reported that the original UEFS was correlated with the ABILHAND-ULA (Spearman  $\rho = .71$ ).

Jarl and Hermansson<sup>292</sup> reported on the translation and linguistic validation of the Swedish version of the OPUS and back translated this version to English to demonstrate linguistic validity with the English OPUS.

### Modified UEFS

The UEFS (modified by Burger et al<sup>289</sup>) resulted from the rating scale analysis of the Slovene language of the measure, in a sample of 61 adult patients with unilateral upper limb amputations. The resulting modified version collapsed 5 item categories into 4, with 2 items misfitting. The modified measure the authors proposed had good structural validity, with a single factor explaining 80% of the variance in scores. PCA revealed only 3% of the unexplained variance from the first factor. Person separation was 2.78, and person-separation reliability was .89.<sup>289</sup> This study also reported that patients with different levels of amputation did not differ significantly in their scores but that patients with transradial amputation who sustained amputations on their nondominant side ( $n = 19$ ) had significantly higher (better) UEFS scores than those with amputations on the dominant side ( $n = 21$ ,  $z = -2.11$ ,  $P = .034$ ). van Gils et al<sup>293</sup> also used the Burger-modified UEFS in a study on the sensibility of the stump in adults with major upper extremity amputation but found no significant difference in the UEFS score between prosthetic users and nonusers. No other validity analyses were reported, and no responsiveness analyses were found for the unmodified UEFS.

### Modified UEFS

The UEFS (modified by Jarl et al<sup>290,291</sup>) was based on a Swedish version of the UEFS, modified by adding additional items, in 2 studies. In the first, they evaluated validity in a sample of 134 adults with various prosthetic and orthotic devices. Six items were

added to the instrument including the following: peel potatoes (or fruit) with a knife/peeler, open a bag of chips, take banknote out of the wallet, take credit card out of wallet, twist a lid off a small drink bottle, and sharpen a pencil. Jarl reported a person-separation index of 3.51 and person-separation reliability of .92. However, PCA of residuals revealed that the modified UEFS explained only 60% of the variance, and unidimensionality was not fully supported. In their second study, Jarl et al<sup>290</sup> analyzed 2-week test-retest scores of the modified UEFS and reported an ICC of .89 and Bland-Altman plots showing agreement. They reported no finding of systematic differences when regressing the differences and averages. The smallest detectable difference was 15 UEFS units.

## Modified UEFS

The UEFS (modified by Resnik et al<sup>23</sup>) is a 22-item version of the UEFS with 1 item removed (related to washing). The scoring of the instrument was recalibrated with Item Response Theory methods. The modified version was used in 5 studies.<sup>19-21,23,24</sup> They evaluated test-retest reliability, known-group validity, and MDC of several measures in a convenience sample of 59 upper prosthetic users testing the DEKA Arm (mean age, 45.4±15.7y) and a reliability sample of 49 users (mean age, 46.2±16.5y).<sup>23</sup> They reported an ICC of .80, an MDC90 of 12.07, and an MDC95 of 14.45, but no significant difference in scores across level of amputation. Resnik reported that the UEFS was weakly but significantly correlated ( $r=-0.2$ ) with the UNB<sup>24</sup> and moderately correlated ( $r=-.44$ ) with the AM-ULA.<sup>19</sup> Resnik also examined outcome measures for responsiveness for training, but the UEFS was only measured at 10 hours of training and final testing and was not responsive in that interval (ES 95% confidence interval included 0). No floor or ceiling effects were observed in their sample.

## UEFS Use of Prosthesis

Even though the UEFS questionnaire directs respondents to indicate whether they usually perform each activity with or without prosthesis, this information is not used in calculating the score. Resnik et al<sup>19</sup> developed a UEFS subscale by calculating the proportion of listed activities that the patient indicates that they ordinarily completed using their prosthesis, and counting the number of items that the prosthesis was used to perform. The UEFS Use of Prosthesis subscale was not correlated with the AM-ULA in a sample of 52 subjects with upper limb amputation. Resnik et al<sup>20</sup> found no significant differences in UEFS Use of Prosthesis scores between configuration level of the DEKA Arm; however, subjects used the DEKA Arm for significantly more UEFS items than their original prosthesis: a trend which persisted across all arm levels.

## Upper Limb Functional Index

The Upper Limb Functional Index is a 25-item self-report measure designed to assess patients with upper extremity dysfunction.<sup>294</sup> Patients are asked to indicate which statement most accurately describes difficulties related to upper limb function (I stay at home most of the time, I change position frequently for comfort, etc), and the total number of difficulties denoted is multiplied by 4. The

Upper Limb Functional Index scores range from 0 (no functional disability) to 100 (severe disability).

In a sample of patients who underwent volar plate fixation for a distal radius fracture, Valdes et al<sup>295</sup> compared the Upper Limb Functional Index scores of patients treated with early range of motion exercises with patients who had range of motion 6 weeks after immobilization, but they found no differences at initiation or discharge from therapy or at 6-month follow-up.

## Western Ontario Rotator Cuff Index

The Western Ontario Rotator Cuff Index (WORC) is a 21-item interviewer-administered self-report measure designed to measure quality of life for patients with rotator cuff disease.<sup>296</sup> The WORC includes 5 subscales: physical symptoms (6 questions), sports and recreation (4 questions), work (4 questions), lifestyle (4 questions), and emotion (3 questions). Each item has a possible score of 0 to 100 (100-mm VAS) and has the same weight. The total WORC score ranges from 0 to 100, with a higher raw score indicating worse function. The raw score can be converted into a percentage score with the following formula:  $(2100 - \text{raw score}) \div (2100 \times 100) = \% \text{ score}$ . In this case, a score of 0% is the worst score possible, and 100% suggests no reduction in health-related quality of life. Each subscale can also be scored separately. We considered the following subscales as eligible for inclusion in this systematic review: work and lifestyle. The total score is not eligible.

Lopes et al<sup>104</sup> reported on the validity and reliability of the Brazilian Portuguese version of the WORC in a sample of 100 patients with rotator cuff disorders and a reliability sample of 50 patients. They reported excellent internal consistency ( $\alpha > .90$  for both of the included subscales), interrater reliability (ICC  $> .95$ , SEM  $\geq 4.5$  for both subscales), and test-retest reliability (ICC  $> .97$ , SEM  $\geq 4.3$  for both subscales). They also estimated the MDC90 to be 12.6 for the lifestyle domain and 10.6 for the work domain.

Wessel et al<sup>297</sup> cross-culturally adapted the WORC for use in a Dutch population and evaluated reliability, agreement, and floor and ceiling effects. They reported that both subscales had strong internal consistency (Cronbach  $\alpha = .85$ ) in their sample of patients with rotator cuff disease. They reported that the lifestyle subscale had a test-retest reliability ICC of .89 and the work subscale had an ICC of .87. Corresponding smallest detectable change was 25.2 and 23.3 for the lifestyle and work subscales, and neither subscale had 15% of responders achieving the lowest or highest possible score.

## Wrist Outcome Measure

The Wrist Outcome Measure is a self-report measure designed to assess ability to perform ADL after a distal radius fracture or other unilateral musculoskeletal disorder.<sup>298</sup> The measure consists of 3 components: a standardized subscale, an individualized subscale, and a demographic component. The standardized subscale assesses an individual's difficulty in performing 25 daily activities before injury and at the time of wrist injury. The 25 activities are grouped into 2 categories: essential (consisting of dressing, grooming, feeding, and money management) and other activities (household tasks, driving, childcare, and leisure tasks). The response options include yes (difficulty completing task), no (no difficulty completing task), and have not tried (do not

normally complete task). The test is scored based on the number of yes responses before and at the time of injury. The total score ranges from 0 to 25, where 0 is no activity limitation and 25 is severe activity limitation. The individualized subscale is completed when the patient experiences difficulty with daily activities that are not listed in the standardized section. Up to 5 activities can be listed, and the score is based on a scale that ranges from 0 to 50 (where 0 is no activity limitation and 50 is severe activity limitation). Both scales were considered eligible for inclusion in our review.

The development article by Bialocerkowski et al<sup>298</sup> on the wrist outcome measure did not include a total score but asked participants whether items were clear and whether the measure fully covered ADL performance. Changes were made as needed, and Bialocerkowski reported that response categories and items were appropriate for a wide cross-section of people with wrist disorders. Bialocerkowski et al<sup>299</sup> later evaluated the concurrent validity and responsiveness of the Wrist Outcome Measure in a sample of 26 individuals with a distal radius or ulnar fracture. Correlations between the standardized and individualized subscales were reported as  $r=.39$ ,  $r=.78$ ,  $r=.66$ , and  $r=.83$  at 8, 12, 18, and 24 weeks postfracture, respectively (significance not

reported). Statistically significant improvement was reported from 8 weeks postfracture to 12, 18, and 24 weeks for both subscales. ESs were 1.71 for the individualized subscale and 1.67 for the standardized subscale.

Abbreviations: ABILHAND-ULA, ABILHAND upper limb amputee; APMC, Assessment of Capacity for Myoelectric Control; ADL, activities of daily living; ASES, American Shoulder and Elbow Surgeons Score; ASES-E, American Shoulder and Elbow Surgeons Elbow Score; BADL, basic activity of daily living; COPM, Canadian Occupational Performance Measure; DIF, differential item functioning; GARS, Groningen Activity Restriction Scale; MDC, minimal detectable change; MFA, Musculoskeletal Functional Attachment; MHAQ, Modified Health Assessment Questionnaire; MnSq, mean-square statistic; OPUS, Orthotics and Prosthetics User Survey; OSS, Oxford Shoulder Score; PAQ, patient-answered questionnaire; SMFA, Short Musculoskeletal Functional Attachment; SPADI, Shoulder, Pain and Disability Index; SRQ, Shoulder Rating Questionnaire; SST, Simple Shoulder Test; SSV, Subjective Shoulder Value; UCLA, University of California Los Angeles Shoulder Score; UEFS, Upper Extremity Functional Status; VAS, visual analog scale; WORC, Western Ontario Rotator Cuff Index.

REVIEW ARTICLE

# Measuring Community Integration in Persons With Limb Trauma and Amputation: A Systematic Review



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## Abstract

**Objectives:** To conduct a systematic review of community integration measures used with populations with limb trauma, amputation, or both, and to evaluate each measure's focus, content, and psychometric properties.

**Data Sources:** Searches of PubMed and CINAHL for the terms *social participation*, *community integration*, *social function*, *outcome assessment*, *wounds and injuries*, and *amputation/rehabilitation*.

**Study Selection:** Included English-language articles with a sample size of  $\geq 20$  adults with limb trauma or amputation. Measures were deemed eligible if they contained a majority of items related to the construct of participation as defined by the *International Classification of Functioning, Disability and Health*.

**Data Extraction:** Data on internal consistency; test-retest, interrater, and intrarater reliability; content, structural, construct, concurrent, and predictive validity; responsiveness; and floor/ceiling effects were extracted from each article and confirmed by a second investigator.

**Data Synthesis:** A total of 156 articles containing 34 measures and 94 subscales were reviewed. Psychometric properties were rated, and an overall score was calculated for each measure. Content of the highest scoring measures was examined. Scant evidence was found regarding the psychometric properties of most measures. Eight scales from 5 instruments had the strongest measurement properties: the Trinity Amputation and Prosthesis Experience (TAPES) social restriction and adjustment to limitation scales; Community Reintegration of Injured Service Members (CRIS) extent of participation and perceived limitations scales; Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) role-physical and social functioning scales; the 136-item Sickness Impact Profile (SIP) psychosocial domain scale; and the World Health Organization Disability Assessment Schedule 2.0 (WHODAS-II) 12-item total score.

**Conclusions:** Eight scales from 5 instruments—the TAPES, CRIS, SF-36, the 136-item SIP, and the WHODAS-II 12-item measure—had the strongest measurement properties.

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Recent interest in studying the impact of limb trauma and amputation<sup>1-4</sup> has been driven, in part, by reports of service members injured in the Global War on Terror. Research has examined a variety of outcomes for persons with combat casualties including postoperative complications, mental health diagnoses and health care utilization, and compared outcomes of persons with limb trauma with and without amputation. Large longitudinal studies of civilians have compared quality of life (QOL) and physical function in persons with amputation and limb

trauma,<sup>5</sup> and used a variety of measures such as walking speed, pain, hospitalizations, and psychological distress.<sup>6-13</sup>

There is increasing recognition of the importance of measuring community integration for those with specific disabilities and conditions.<sup>14-17</sup> Community integration measurement is important to assess treatment effectiveness and track health. However, most prior research has not focused on community integration—the return of individuals to participation in their adult roles.

This review uses the conceptual framework of participation, as described by the *International Classification of Functioning, Disability and Health* (ICF), to define community integration and uses the terms *community integration* and *participation* synonymously. This approach has been endorsed by the Department of Veterans Affairs' Measurement Group on Community Integration.<sup>14</sup>

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General systematic reviews<sup>14,16,18</sup> of measures that assess 1 or more aspects of participation have been published. Some reviews<sup>19,20</sup> focused on participation measurement in specific patient populations. However, there have been no systematic reviews for persons with limb trauma and amputation. Therefore, our purposes were to (1) conduct a systematic review to identify measures assessing aspects of community integration that have been used in the literature with populations with limb trauma, amputation, or both; and (2) evaluate each measure's focus, content, and psychometric properties.

## Methods

### Participation measures

The ICF provides a language and framework to describe human functioning disability. The first component covers 4 levels of functioning: body function, body structure, activities, and participation. The second component covers contextual factors affecting function.<sup>21</sup> The taxonomy for activity and participation includes chapters on learning and applying knowledge, general tasks and demands, communication, mobility, self-care, domestic life, interpersonal relationships, major life areas, and community, social, and civic life.

Although activities and participation are thought to be conceptually distinct, they use a single taxonomy. ICF annex 3 presents 4 options for differentiating between activities and participation. In keeping with prior work,<sup>22</sup> we used the fourth approach: considering items that ask about simple tasks and actions to be activities, and those that ask about complex functional tasks and actions to be participation. Examples of simple tasks include standing, toileting, and bathing, whereas examples of complex tasks include getting around in the community, driving, and shopping.

### Literature search

Initial searches were conducted within PubMed and CINAHL, and included the following terms: *social participation*, *community integration*, *social function*, *outcome assessment*, *wounds and injuries*, *amputation*, and others (supplemental appendix S1, available online only at <http://www.archives-pmr.org/>). All abstracts were independently reviewed by 2 authors. Included articles used a relevant standardized outcome measure, a sample of  $\geq 20$  adults with limb trauma or amputation, were in English, and had an available abstract. Dissertations, book chapters, and

conference proceedings were excluded. When authors disagreed on abstract inclusion, the inclusion decision was made jointly after discussion. When the abstract did not state which measure was used, the full text was reviewed to determine eligibility.

In this review, we included only measures or scales in which most of the items assessed participation. Given that many commonly used measures were developed before the adoption of the ICF, we made judgments about content using a previously described approach, in which we evaluated and compared the content of measures based on linking item content with the ICF activities and participation taxonomy.<sup>22</sup> The first author reviewed each scale before determining whether it met our inclusion criteria. Once the list of eligible measures was identified, searches of PubMed and CINAHL were repeated, adding the names of included measures.

### Data extraction

The full text of articles was reviewed to extract relevant information. A second author reviewed information extracted to ensure accuracy and completeness. When disagreements were discovered, the third author reviewed the full text and resolved any discrepancies. Measurement properties examined included internal consistency, test-retest reliability, interrater reliability, intrarater reliability, content validity, structural validity, construct validity, known-group validity, concurrent validity, predictive validity, responsiveness, minimum detectable change, floor and ceiling effects, and Rasch measurement evaluation (table 1).

### Quality assessment

Each measure's psychometric properties were rated based on aggregate review results using a 4-point scale: excellent (++), adequate (+), poor (−), and unknown (?) (table 2).<sup>28–30</sup> We modified previously used rating criteria<sup>29,31,32</sup> to make them clearer and easier to implement. Notable changes to previous methods are described below.

We incorporated the CanChild's rating requirement of  $\geq 3$  studies with positive findings and strong methodology, for a property to achieve the highest possible rating.<sup>32</sup> We categorized reliability coefficients in keeping with previous methods,<sup>32</sup> but also added person-separation reliability indices generated from Rasch analyses as evidence of internal consistency. Scores  $\geq .90$  were considered excellent, and those  $\geq .80$  but  $< .90$  were considered adequate.<sup>25</sup> For patient-reported measures, intrarater reliability and interrater reliability were automatically scored not applicable because the patient is the only possible reporter.

We established explicit criteria for rating face and content validity. We considered face validity as a component of content validity. To achieve a rating of excellent or adequate, a description of methodology and results of content validity evaluation were required. We used separate categories for criterion and predictive validity, believing these to be distinct. Terwee et al<sup>28</sup> defined both criterion and predictive validity as the presence of strong agreement between a measure of interest and a criterion standard. We, however, defined them as a relationship between a score on the measure and a future event, behavior, or measure,<sup>33</sup> but given the lack of criterion standards in community integration, not necessarily one that has been previously established as a criterion standard.

We separated construct validity from concurrent/discriminant validity and expanded the definition and evaluation criteria for construct validity to include factor analysis (previously included as

#### List of abbreviations:

|           |                                                                     |
|-----------|---------------------------------------------------------------------|
| CRIS      | Community Reintegration of Injured Service Members                  |
| ICF       | International Classification of Functioning, Disability, and Health |
| QOL       | quality of life                                                     |
| SF-36     | Medical Outcomes Study 36-Item Short-Form Health Survey             |
| SIP       | Sickness Impact Profile                                             |
| TAPES     | Trinity Amputation and Prosthesis Experience Scales                 |
| TBI       | traumatic brain injury                                              |
| WHODAS-II | World Health Organization Disability Assessment Scale 2.0           |

**Table 1** Measurement properties evaluated in systematic review

| Psychometric Attribute                         | Methodological Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Reliability</b>                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Internal consistency                           | Internal consistency is a measure based on the correlation between items of a measure. It measures whether separate items are similar enough that they are capturing the same general construct. Typically Cronbach alpha is used to test internal consistency—excellent scores for coefficients are $\geq .80$ , adequate are from $.60$ to $.79$ , and poor are $< .06$ . Person-separation reliability index from Rasch analyses may also be used, where good scores are $\geq .80$ and excellent ones are $\geq .90$ .                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Test-retest reliability                        | Test-retest reliability (or repeatability) is a measure of stability of a test over time, under the same conditions. Test-retest reliability is typically evaluated using ICCs for continuous data or kappa statistics for categorical data. Coefficients of $> .80$ are considered excellent, scores from $.60$ to $.79$ are considered good, and anything $< .60$ is considered poor. Test-retest interval should be stated and be at least several days apart and well justified. Overall sample size should be $\geq 30$ participants (may have smaller subgroups for exploratory analyses). Training of assessors/interviewers and test administration details should be clearly outlined.                                                                                                                                                                                                                                                                                                     |
| Interrater reliability                         | Interrater reliability is the degree of agreement among different raters. Interrater reliability is evaluated using the same metrics as test-retest reliability.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Intrarater reliability                         | Intrarater reliability is the degree of agreement among repeated measurements by a single rater. It is evaluated using the same metrics as test-retest reliability.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Validity</b>                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Face and content validity (scale construction) | Face validity is a subjective determination of how well a measure covers the construct it is meant to measure. Content validity is similar but typically involves an evaluation by experts on whether a measure covers all aspects of the given construct. For face validity, there should be evidence that the test is intuitively meaningful to the tester and patient. For content validity, there should be a description of a formal content-validity evaluation. This would typically involve a description of the literature review process and the stakeholders involved in item generation, item reduction, and final review of content (items and response sets) within the clinical population to which the measure will be applied. For content validation there should be representation from clinicians/experts as well as investigators, and from patients/clients (if a self-report questionnaire).                                                                                 |
| Criterion validity                             | Criterion validity is a measure of good agreement between test scores and scores of current criterion standard. Choice of criterion standard needs to be well substantiated. <sup>20</sup> For most rehabilitation measures, criterion standards are not available, and hence evaluation of criterion validity will not be commonly done.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Predictive validity                            | Predictive validity is a measure's ability to predict outcomes or scores of another measure at a future point in time. Predictive validity is determined by examining the strength of the relationship between test scores and a future event or behavior. Predictive validity can be examined by a variety of statistical methods including correlation and regression.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Construct validity                             | Construct validity is the degree to which a test measures what it claims or purports to be measuring. Construct validity can be demonstrated in several ways including the known-groups method, hypotheses testing, and factor analysis. Known groups validity is used to assess a test's ability to discriminate between groups with a trait or condition of interest known to be related to the measure construct and those without. Use of hypothesis testing with an a priori hypothesis demonstrates that the measure performs as expected. Use of factor analysis, Rasch factor analysis, or principle component analysis reveals the meaningful structure underpinning the construct. For confirmatory factor analysis, the sample size should be adequate ( $\sim 5$ – $10$ subjects per item). Ideally, RMSEA should be $\leq .05$ (adequate if $\leq .08$ ), SRMR should be $\leq .08$ , and other model fit statistics (NFI, NNFI/TLI, CFI, RNI) should be $\geq .95$ . <sup>23,24</sup> |
| Concurrent/discriminant validity               | Concurrent and discriminant validity assess how much a measure correlates with other validated measures of similar or different constructs. Strength and direction of correlations (expressed as $r$ or $rs$ ) should be hypothesized a priori, and results/discussion should include a comment on the results of testing these validity hypotheses and the extent to which these hypotheses were met. For a correlation to be considered large, it should be $> .50$ ; moderate correlations are $0.3$ to $0.5$ , and small correlations are those that are $0.1$ to $< 0.3$ . If an association is tested through regression modeling, concurrent validity can be assessed as the presence of a statistically significant association with variables or constructs hypothesized to be related. For discriminant validity, comparisons with tests of very different concept coefficients should be low (close to $0$ ).                                                                            |

(continued on next page)

**Table 1** (*continued*)

| Psychometric Attribute    | Methodological Requirements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Rasch scaling             | Rasch measurement is used in a family of statistical models to assess the quality of tests and questionnaires, and to construct true interval-scale measures from the raw scores obtained from instruments. Most or all of the following should be specified about measures developed or evaluated using a Rasch measurement approach: the Rasch model selected, ordering of items, item and person fit to the models (including fit statistics), person-separation reliability, 1 or more tests of unidimensionality, and the presence of differential item functioning (DIF or item bias) and approaches to handle. <sup>25</sup> Significant fit statistics $<.05$ or $>1.5$ indicate an item or person misfits model expectation. Mean location values should be close to 0, and the separation index or item separation ratio should be .70 or 1.5, respectively for group use or .85 or 2.5, respectively for individual use. |
| Minimal detectable change | The MDC is a statistical estimate of the smallest change outside of measurement error that can be detected by the measure. This is typically derived from the results of the test-retest reliability work. Typically expressed as the MDC90 or MDC95.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Responsiveness evaluation | Responsiveness is the ability of a measure to detect meaningful change over time. This is done in the context of before-after evaluations of specific interventions or significant event/time period within clinical groups. Look for evaluation of change as determined by statistical approaches (eg, effect size with pooled SD, effect size with baseline SD, standardized response mean, Guyatt's Responsiveness Index, ROC curves). <sup>22,26</sup> Look for evidence of minimal clinically important differences or improvements gleaned from anchor-based methods (eg, external rating of change from clinicians or patients) or consensus approaches (expert or patient ratings of clinical change scenarios). <sup>27</sup>                                                                                                                                                                                              |
| Floor/ceiling effects     | Floor and ceiling effects refer to the lower and upper bounds of a measurement past which the measure cannot be considered accurate or reliable. Generally, these effects occur when a substantial proportion of the test score is at or near these bounds. These effects are evaluated by examining the distribution of the scores and determining the percentage of scores that lie above 90% or below 10%, but they can also be estimable from review of descriptive statistics tables if the mean scores are very high/low and SDs are large. Ideally, there should be fewer than 15% of respondents in these outer ranges. <sup>20,22</sup>                                                                                                                                                                                                                                                                                    |

Abbreviations: CFI, Comparative Fit Index; ICC, intraclass correlation coefficient; MDC, minimum detectable change; NFI, Normed Fit Index; NNFI, Nonnormed Fit Index; RMSEA, root mean square error of approximation; RNI, rate of natural increase; ROC, receiver operating characteristic; SRMR, standardized root mean residual; TLI, Tucker-Lewis Index.

part of internal consistency<sup>28</sup>). We looked for evidence of construct validity gleaned through a variety of methods as shown in [table 2](#).<sup>34</sup> The criteria used for evaluating confirmatory factor analysis, consistent with prior work,<sup>23</sup> are also presented in [table 2](#).

We modified thresholds for strength of correlation required to support concurrent validity. By using Cohen's criteria for evaluating strength of correlation, we interpreted coefficients  $\geq 0.5$  as large, 0.3 to 0.5 as moderate, and  $<0.3$  as small.<sup>24,26</sup>

We expanded on methods of evaluating evidence from Rasch measurement using a previously described approach.<sup>23</sup> A measure met the criteria for an excellent rating if evidence was gleaned from studies with adequate sample size (5–10 subjects per item) and showed excellent structure.<sup>27,35</sup>

Responsiveness was assessed temporally in the context of an intervention or significant event. Evidence of responsiveness was demonstrated by a change in scores after a defined intervention or event. We used criteria described previously by others that evaluation of change should be based on statistical approaches (eg, effect sizes, standardized response means),<sup>29,36</sup> but also acknowledged that an adequate level of responsiveness could be demonstrated by statistically significant findings from paired *t* tests or analyses of variance with no responsiveness statistic calculated. Minimal clinically important differences should be based on either anchor-based methods or consensus approaches.<sup>37</sup>

## Scoring

Three investigators independently assigned scores to each measurement property and met to discuss results. When discrepancies

arose, a consensus score was determined through discussion and re-review of relevant articles. An overall score was calculated by transforming the property-level ratings to numerical scores ( $++=2$ ;  $+ = 1$ ;  $-- = -1$ ;  $? = 0$ ), and summing across all properties. We selected the highest scoring scales with positive evidence of 1 or more aspects of reliability and validity and examined their method of assessment, burden, and content.

## Results

### Literature search

The literature review process is shown in [figure 1](#). We identified a total of 1091 publications. Three hundred thirteen met initial criteria for full review, and 156 met inclusion criteria after full review. Included articles contained data on 34 included outcome measures containing 94 distinct scales ([table 3](#)).

### Measures and published psychometric information

Eight scales from 5 instruments had the strongest measurement properties: the Trinity Amputation and Prosthesis Experience (TAPES) social restriction and adjustment to limitation scales; the Community Reintegration of Injured Service Members (CRIS) extent of participation and perceived limitations scales; the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) role-physical and social functioning scales; the 136-item Sickness Impact Profile (SIP) psychosocial domain; and the World

**Table 2** Scoring criteria for quality assessment of each measure

| Scoring Criteria                                           | Excellent (++)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Adequate (+)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Poor (–)                                                                                                                                                                                                                                                                               | No Evidence           |
|------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Overall ratings of strength of evidence                    | ≥3 separate, well-designed studies with positive results and strong methodology for the specific measurement property as defined below                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 1 to 2 well-designed studies with positive results—any other studies have no more than fair methodology but showed positive results                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 1 or more studies did not strongly support the property or indicated issues and/or were limited by issues in the study design, or a study was not well designed to examine psychometric properties.                                                                                    | No evidence available |
| Reliability*                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                        |                       |
| Internal consistency (test-retest, intrarater, interrater) | Demonstrates adequate to excellent reliability values*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Demonstrates adequate to excellent reliability values.*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Instrument has poor reliability values.*                                                                                                                                                                                                                                               | No evidence available |
| Validity                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                        |                       |
| Face and content                                           | Used judgmental method; the measure is comprehensive and includes items suited to the measurement purpose. Description of a content validity evaluation should be included.                                                                                                                                                                                                                                                                                                                                                                                                                | Used judgmental method; the measure is comprehensive and includes items suited to the measurement purpose. Description of a content validity evaluation should be included.                                                                                                                                                                                                                                                                                                                                                                                                                          | Instrument is not comprehensive and does not address relevant content areas. Content validity evaluation not described.                                                                                                                                                                | No evidence available |
| Criterion validity                                         | Demonstrates adequate agreement with a criterion or criterion standard                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Demonstrates adequate agreement with a criterion or criterion standard                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Demonstrates inadequate agreement with a criterion or criterion standard measure                                                                                                                                                                                                       | No evidence available |
| Predictive validity                                        | Presence of a statistically significant relationship between test scores and future important event, behavior, or measure                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Presence of a statistically significant relationship between test scores and future important event, behavior, or measure                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | No evidence of a statistically significant relationship between test scores and future important event, behavior, or measure                                                                                                                                                           | No evidence available |
| Construct                                                  | At least 1 of the following criteria must be met:<br>1. Statistically significant results for known-group analyses<br>2. Results of a priori hypothesis testing support the construct.<br>3. Factor analysis (exploratory and confirmatory), Rasch factor analysis, or principle component analysis was conducted and supports the structural validity of the scale.<br>4. For confirmatory factor analysis, has adequate sample (~5–10 subjects per item) and shows excellent structure as gauged by SRMR≤.08, RMSEA≤.05 as well as CFI, RNI≥.90 NFI or NNFI (TLI) ≥.95. <sup>27,35</sup> | At least 1 of the following criteria must be met:<br>1. Statistically significant results for known-group analyses or hypothesis tests established a priori<br>2. Results of a priori hypothesis testing. support the construct<br>3. Factor analysis (exploratory and confirmatory) or principle component analysis was conducted and supports the structural validity of the scale.<br>4. For confirmatory factor analysis, has adequate sample (~5–10 subjects per item) and shows acceptable structure as gauged by SRMR≤.08 or RMSEA≤.05 or CFI, RNI≥.90, NFI or NNFI (TLI) ≥.95. <sup>35</sup> | No statistically significant results for known-group analyses or no hypothesis tests established a priori. Factor analyses or principle component analyses were not conducted or were conducted, but there was an unacceptably small sample size or inadequate findings for model fit. | No evidence available |

(continued on next page)

Table 2 (continued)

| Scoring Criteria            | Excellent (++)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Adequate (+)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Poor (–)                                                                                                                                                                                                                                                                                                                                                                       | No Evidence           |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| Concurrent and discriminant | Exhibits strong correlation ( $\geq 0.5$ ) with most measures considered related, or low correlation (close to zero) when testing for differing constructs (discriminant validity) <sup>24,26</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Exhibits moderate correlation ( $\geq 0.3$ ) with most measures considered related, or low correlation (close to zero) when testing for differing constructs (discriminant validity)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Exhibits only weak correlation ( $< 0.3$ ) with concurrent measures, or a statistically significant association in a regression model with variables or constructs hypothesized to be related, and shows fair or greater correlations when testing for differing constructs (discriminant validity)                                                                            | No evidence available |
| Rasch scaling               | Rasch model and ordering of response categories specified, items and persons fit to model, reliability high enough for individual use with person separation $\geq .85$ (or item separation ratio $\geq 2.5$ ), and mean location values close to 0. Differential item functioning should be evaluated. Significant fit statistics are between .05 and 1.5.                                                                                                                                                                                                                                                                                                                                                                                    | Rasch model and ordering of response categories specified, items and persons mostly fit to model, reliability high enough for group use with person separation $\geq .75$ (or item separation ratio $\geq 1.5$ ), and mean location values close to 0. Differential item functioning should be evaluated. Significant fit statistics are between .05 and 1.5.                                                                                                                                                                                                                                                                                                                                                | Rasch model or item scoring not clearly specified, few item and persons fit to model, low reliability with person separation $< .75$ (or item separation ratio $< 1.5$ ), and mean location values not close to 0. No evaluation of differential item functioning. Significant fit statistics are $< .05$ or $> 1.5$ , indicating an item or person misfits model expectation. | No evidence available |
| Minimal detectable change   | Data shown on MDC 90% or 95%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Data shown on MDC 90% or 95%.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Not applicable                                                                                                                                                                                                                                                                                                                                                                 | No evidence available |
| Responsiveness              | At least 1 of the following criteria must be met:<br>1. Strong hypothesized relationships between changes in the measure and other measures of change on the same attribute (anchor-based methods or consensus approaches, etc)<br>2. Evidence of responsiveness as determined by statistical approaches such as effect size with pooled SD, effect size with baseline SD, standardized response mean, Guyatt's Responsiveness Index, ROC curves with confidence intervals that do not cross zero <sup>37</sup><br>3. Data available on MCID or MCII from anchor-based methods<br>4. Responsiveness tested by <i>t</i> test or ANOVA. However, if <u>no</u> articles use above responsiveness statistics, an excellent rating is not possible. | Responsiveness only tested by <i>t</i> test or ANOVA with no responsiveness statistics calculated (regardless of number of articles).<br>OR At least 1 of the following criteria must be met:<br>1. Strong hypothesized relationships between changes in the measure and other measures of change on the same attribute (anchor-based methods or consensus approaches, etc)<br>2. Evidence of responsiveness as determined by statistical approaches such as effect size with pooled SD, effect size with baseline SD, standardized response mean, Guyatt's Responsiveness Index, ROC curves with confidence intervals that do not cross zero<br>3. Data available on MCID or MCII from anchor-based methods | No statistically significant evidence of responsiveness as determined by any approach described                                                                                                                                                                                                                                                                                | No evidence available |
| Floor and ceiling effects   | Evaluation of score distribution does not reveal a floor or ceiling effect, defined as $< 15\%$ of the sample with scores $> 90\%$ or $< 10\%$ .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Evaluation of score distribution does not reveal a floor or ceiling effect, defined as $< 15\%$ of the sample with scores $> 90\%$ or $< 10\%$ .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Evidence of a floor and/or ceiling effect, defined as $\geq 15\%$ of population reported in the top or bottom 10% of scale range                                                                                                                                                                                                                                               | No evidence available |

Abbreviations: ANOVA, analysis of variance; CFI, Comparative Fit Index; MCID, minimal clinically important difference; MCII, minimal clinically important improvement; MDC, minimum detectable change; NFI, Normed Fit Index; NNFI, Nonnormed Fit Index; RMSEA, root mean square error of approximation; RNI, rate of natural increase; ROC, receiver operating characteristic; SRMR, standardized root mean residual; TLI, Tucker-Lewis Index.

\* Guidelines for reliability coefficient: excellent:  $\geq .80$ ; adequate:  $.60-.79$ ; poor:  $< .60$ . For Rasch person-separation reliability, excellent scores are  $\geq .90$  and adequate scores are  $\geq .80$ .

Health Organization Disability Assessment Scale 2.0 (WHODAS-II) total overall score. Table 4 shows the content analysis results. These measures and the research supporting their measurement properties are described below, with similar details for measures not rated most highly in supplemental appendix S2 (available online only at <http://www.archives-pmr.org/>).

### Trinity Amputation and Prosthesis Experience Scales

The TAPES assesses adjustment to a prosthesis, demands of wearing a prosthesis, and sources of maladjustment. It contains 9 scales across 3 domains: psychosocial adjustment; activity restriction; and prosthetic satisfaction. Within psychosocial adjustment, we considered the adjustment to limitation scale consistent with community integration; and within activity restriction, we considered the social restriction scale consistent.

The 5-item adjustment to limitation scale assesses restrictions ensuing from having an artificial limb. Each item is rated on a 5-point Likert scale (“strongly disagree” to “strongly agree”). Examples of items include, “Having an artificial limb interferes with the ability to do my work,” and “Having an artificial limb limits the amount of work that I can do.” The 4-item social restriction scale addresses limitations in social activities. Each item is coded on a 3-point scale (“yes, limited a lot” to “no, not limited at all”). The items are centered on a global question, “Does having an artificial limb limit you in any of the following activities? If so, how much?” Examples include “maintaining friendships,” and “working on hobbies.”

Nine studies<sup>38-46</sup> used the included TAPES scales with patients with amputation. Initial psychometric evaluation was reported in a sample of 104 predominantly male amputees (mean age  $\pm$  SD, 45 $\pm$ 19y) from Ireland, 52% with below-the-knee amputation and 42% with above-the-knee amputation.<sup>39</sup> Factor analysis was used to identify the 9 TAPES subscales. Internal consistency of the adjustment scales ranged from .86 to .89.<sup>43</sup>

Predictive validity was examined with multiple regression exploring the relationship between the scales and hours of prosthetic use. Adjustment to limitation accounted for 13% of the variance.<sup>39</sup> Several studies<sup>40,42</sup> reported evidence supporting concurrent and discriminant validity. For example, the social restriction scale was moderately and negatively correlated with the

physical ( $r = -.65$ ), psychological ( $r = -.56$ ), social ( $r = -.39$ ), and environmental ( $r = -.52$ ) domains of the World Health Organization Quality of Life Scale—Brief Version.<sup>40</sup> The adjustment to limitations and social restriction scales were negatively correlated with the Hospital Anxiety and Depression Scale ( $r = -.44$  and  $-.39$ , respectively) and the Amputation Body Image Scale ( $r = -.45$  and  $-.44$ , respectively).<sup>42</sup>

A later study examining structural validity recommended that special scoring be used for persons with upper limb amputation.<sup>43</sup>

The adjustment to limitation scales discriminated between those who experienced phantom limb pain and those who did not.<sup>39</sup> Other studies examined relationships between TAPES scales and prosthetic experience,<sup>40</sup> physical activity,<sup>47</sup> coping, phantom and residual limb pain,<sup>44</sup> depression and anxiety,<sup>42</sup> and hope and social support.<sup>48</sup>

The TAPES was translated, and psychometric studies were performed with Turkish<sup>49</sup> and Persian versions.<sup>38</sup> Test-retest reliability and construct validity of the Turkish version were confirmed, although some scales were combined into composite scales. Acceptable test-retest reliability was demonstrated, and factor analysis confirmed structural validity for all scales except social activity.

### Community Reintegration of Service Members

The CRIS is a self-report measure with 3 scales, designed for use with service members.<sup>22</sup> Items cover 9 ICF chapters of activity and participation. Extent of participation asks respondents to indicate how often they experience or participate in specific activities. Examples include, “In the past 2 weeks: How often did you take care of what you needed to do where you lived?” or “How often did you exercise or do light to moderate physical activity (such as walking) for at least 30 minutes?” Items are coded on a 7-point frequency scale (“never” to “more than once per day,” or “not at all” to “always”). Perceived limitations asks respondents to indicate perceived limitations in participation. Examples include, “In the past 2 weeks: I was limited in going places like going to work, going out to a store, or for a walk,” or “I was limited in engaging in social gatherings.” Responses are coded on a 7-point agreement scale (“completely disagree” to “completely agree”). Lastly, satisfaction with participation asks

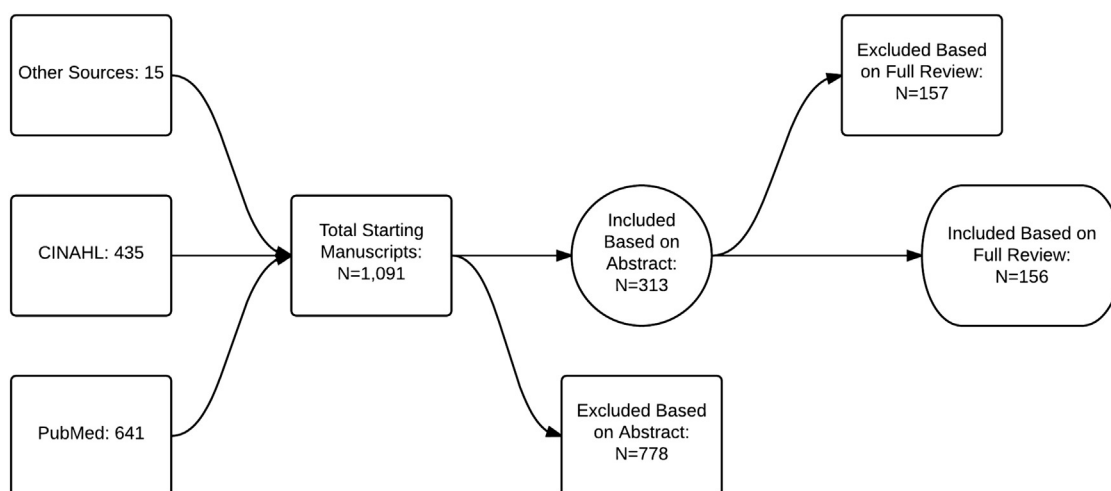


Fig 1 Summary of literature review.

**Table 3** Quality ratings for assessment measures

| Measure                                             | Reliability:<br>Internal<br>consistency | Reliability:<br>Test-Retest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | MDC | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score |
|-----------------------------------------------------|-----------------------------------------|--------------------------------------------|-------------------------------------------|-----------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|-----|----------------|---------------------------------|------------------|
| AIMS-modified                                       |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Household activity                                  | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Social activity                                     | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| AQOL                                                |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                 | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | —                                       | ?                | ?   | ?              | ?                               | —1               |
| CIQ                                                 |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                 | +                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | —                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Home integration                                    | +                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | —                     | —                                       | ?                | ?   | ?              | ?                               | —1               |
| Productivity                                        | —                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | —                     | +                                       | ?                | ?   | ?              | ?                               | —1               |
| Social integration                                  | —                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | —                     | +                                       | ?                | ?   | ?              | ?                               | —1               |
| CIQ modified                                        |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                 | +                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | —                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Home integration                                    | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | —                                       | ?                | ?   | ?              | ?                               | 0                |
| Productivity                                        | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | ?              | ?                               | 2                |
| Social integration                                  | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | ?              | ?                               | 2                |
| CRIS                                                |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Extent of participation                             | ?                                       | +                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +   | +              | +                               | 6                |
| Perceived limitations                               | ?                                       | +                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +   | +              | +                               | 6                |
| Satisfaction with participation                     | ?                                       | +                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | ?                | +   | +              | —                               | 4                |
| CHART                                               |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Occupation                                          | ?                                       | ?                                          | +                                         | ?                                       | ?                               | ?                     | ?                      | ?                     | —                                       | ?                | ?   | —              | ?                               | —1               |
| Social integration                                  | ?                                       | ?                                          | —                                         | ?                                       | ?                               | ?                     | ?                      | +                     | —                                       | ?                | ?   | —              | ?                               | —2               |
| Effects after amputation or limb-sparing surgery    |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Interpersonal and social functioning and self Image | +                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | +                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| FAI                                                 |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                 | +                                       | +                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ++                                      | —                | ?   | ?              | ?                               | 4                |
| FAI Modified (Miller)                               |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                 | +                                       | +                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | ?              | ?                               | 4                |
| FAI Modified (Chern) 10-Item Revised FAI            |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                 | +                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | +                | ?   | +              | ?                               |                  |

(continued on next page)

Table 3 (continued)

| Measure                                                      | Reliability:<br>Internal<br>consistency | Reliability:<br>Test-Retest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | MDC | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score |
|--------------------------------------------------------------|-----------------------------------------|--------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|-----|----------------|---------------------------------|------------------|
| DSF-84                                                       |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Daily activities                                             | +                                       | ?                                          | +                                         | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 3                |
| Performance components                                       | +                                       | ?                                          | +                                         | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 3                |
| Social participation                                         | +                                       | ?                                          | +                                         | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 3                |
| ICF Measure of Participation and Activities (IMPACT-S)       |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                          | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | ?              | ?                               | 4                |
| Participation subtotal score                                 | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | —                     | +                                       | ?                | ?   | ?              | ?                               | 2                |
| Activities subtotal score                                    | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | —                     | +                                       | ?                | ?   | ?              | ?                               | 2                |
| Communication                                                | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Community life                                               | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Domestic life                                                | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| General tasks                                                | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Interpersonal                                                | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Knowledge                                                    | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Major life areas                                             | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Self-care                                                    | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| IES                                                          |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                          | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | +              | ?                               | 3                |
| Inclusion                                                    | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | +              | ?                               | 3                |
| IES (Revised)                                                |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                                          | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | ?              | ?                               | 2                |
| Inclusion                                                    | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| LEAIQ                                                        |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Change for work status (ChW)/reduced capacity for work (CaW) | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| Decreased contact (Co)                                       | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| Decreased pleasure from leisure time (PL)                    | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |

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Table 3 (continued)

| Measure                          | Reliability:<br>Internal<br>consistency | Reliability:<br>Test-Retest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | MDC | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score |
|----------------------------------|-----------------------------------------|--------------------------------------------|-------------------------------------------|-----------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|-----|----------------|---------------------------------|------------------|
| LHS                              |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score              | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 1                |
| MAP                              |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Barriers and<br>challenges       | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Participation                    | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Life-H Short Form 3.1            |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Community life                   | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| Employment                       | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| Housing                          | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| Mobility<br>restriction          | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| Personal care                    | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| Recreation and<br>pastimes       | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| Communication                    | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| Interpersonal<br>relationships   | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | —              | ?                               | —1               |
| Responsibility                   | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | +              | ?                               | 1                |
| MOS 36                           |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Role-emotional                   | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ++                    | —                                       | ?                | ?   | +              | —                               | 1                |
| Role-physical                    | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | +                      | ++                    | —                                       | ?                | ?   | +              | —                               | 2                |
| Social functioning               | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ++                    | ?                                       | ?                | ?   | +              | —                               | 2                |
| NHP                              |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Social isolation                 | ?                                       | +                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Emotional<br>reactions           | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 1                |
| PAIS                             |                                         |                                            |                                           |                                         |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score              | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| Domestic<br>environment          | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| Extended family<br>relationships | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| Sexual<br>relationships          | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| Social<br>environment            | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |
| Vocational<br>environment        | ?                                       | ?                                          | NA                                        | NA                                      | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 1                |

(continued on next page)

Table 3 (continued)

| Measure                                  | Reliability:<br>Internal<br>consistency | Reliability:<br>Test-Retest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | MDC | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score |
|------------------------------------------|-----------------------------------------|--------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|-----|----------------|---------------------------------|------------------|
| RAND-36                                  |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Role-emotional                           | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | —                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Role-physical                            | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ++                    | ?                                       | ?                | ?   | ?              | ?                               | 3                |
| Social functioning                       | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | +              | ?                               | 3                |
| SF-12                                    |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Role-emotional                           | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 2                |
| Role-physical                            | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 2                |
| Social functioning                       | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | —                     | ?                                       | ?                | ?   | ?              | ?                               | —1               |
| SF-36                                    |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Role-emotional                           | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ++                    | +                                       | ?                | ?   | +              | —                               | 4                |
| Role-physical                            | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | +                      | ++                    | ++                                      | ?                | ?   | ++             | —                               | 7                |
| Social functioning                       | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | +                      | ++                    | ++                                      | ?                | ?   | ++             | —                               | 7                |
| VR-36                                    |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Role-emotional                           | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | +              | ?                               | 2                |
| Role-physical                            | ?                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | +   | +              | —                               | 3                |
| Social functioning                       | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | +              | ?                               | 2                |
| SIP                                      |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                      | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | +                      | +                     | +                                       | ?                | ?   | +              | ?                               | 4                |
| Alertness behavior                       | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | —                     | ?                                       | ?                | ?   | +              | ?                               | 0                |
| Communication                            | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | —                     | ?                                       | ?                | ?   | —              | ?                               | —2               |
| Mobility                                 | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | —                     | ?                                       | ?                | ?   | +              | ?                               | 0                |
| Social interaction                       | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | +              | ?                               | 3                |
| Psychosocial domain                      | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | +                      | ++                    | +                                       | ?                | ?   | +              | ?                               | 5                |
| Work                                     | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | +              | ?                               | 3                |
| Home management                          | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | +              | ?                               | 3                |
| Recreation and pastimes                  | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | +              | ?                               | 3                |
| SIP68                                    |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score                      | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Emotional stability                      | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Mobility range                           | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Psychological autonomy and communication | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Social behavior                          | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |

(continued on next page)

**Table 3** (continued)

| Measure                        | Reliability:<br>Internal<br>consistency | Reliability:<br>Test-Retest<br>Reliability | Reliability:<br>Interrater<br>Reliability | Reliability:<br>Intrarater<br>Reliability | Face and<br>Content<br>Validity | Criterion<br>Validity | Predictive<br>Validity | Construct<br>Validity | Concurrent/<br>Discriminant<br>Validity | Rasch<br>Scaling | MDC | Responsiveness | Floor and<br>Ceiling<br>Effects | Overall<br>Score |
|--------------------------------|-----------------------------------------|--------------------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------------|------------------|-----|----------------|---------------------------------|------------------|
| Tegner Activity Scale          |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score            | ?                                       | ?                                          |                                           |                                           | ?                               | ?                     | ?                      | ?                     | —                                       | ?                | ?   | ?              | ?                               | —1               |
| TAPES                          |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Adjustment to<br>limitation    | +                                       | +                                          | NA                                        | NA                                        | +                               | ?                     | ?                      | ++                    | ++                                      | ?                | +   | ?              | +                               | 8                |
| Social restriction             | +                                       | +                                          | NA                                        | NA                                        | +                               | ?                     | ?                      | +                     | ++                                      | ?                | +   | ?              | +                               | 8                |
| TAPES Modified                 |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Adjustment to<br>limitation    | ?                                       | +                                          | NA                                        | NA                                        | +                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Social restriction             | ?                                       | +                                          | NA                                        | NA                                        | +                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| TAPES Revised                  |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Adjustment to<br>limitation    | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | +                | ?   | ?              | ?                               | 3                |
| TAPES Upper <sup>183,184</sup> |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Adjustment to<br>limitation    | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | +                                       | ?                | ?   | ?              | ?                               | 3                |
| Social restriction             | +                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | +                     | ?                                       | ?                | ?   | ?              | ?                               | 2                |
| WHODAS-II 36 item              |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score            | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 1                |
| Cognition                      | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 1                |
| Getting along                  | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 1                |
| Life activities                | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 1                |
| Participation                  | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | +                                       | ?                | ?   | ?              | ?                               | 1                |
| WHODAS-II 12 item              |                                         |                                            |                                           |                                           |                                 |                       |                        |                       |                                         |                  |     |                |                                 |                  |
| Total overall score            | +                                       | +                                          | NA                                        | NA                                        | ?                               | ?                     | +                      | +                     | +                                       | ?                | ?   | +              | —                               | 5                |
| Cognition                      | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Getting along                  | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Life activities:<br>home       | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Life activities:<br>work       | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |
| Participation                  | ?                                       | ?                                          | NA                                        | NA                                        | ?                               | ?                     | ?                      | ?                     | ?                                       | ?                | ?   | ?              | ?                               | 0                |

NOTE. In order to calculate a total score, ++=2; +=1; --=-1; ?=0; NA=0 (scale of -13 to 26). Overall score was calculated as the unweighted average of measurement properties.

Abbreviations: AIMS, Arthritis Impact Measurement Scale; AQOL, Assessment of Quality of Life; CHART, Craig Handicap Assessment and Reporting Technique; CIQ, Community Integration Questionnaire; DSF-84, Functional and Social Performance Checklist; FAI, Frenchay Activities Index; IES, Impact of Events Scale; LEAIQ, Late Effects of Accidental Injury Questionnaire; LHS, London Handicap Scale; Life-H, Measures of Life Habits; MAP, Measure of Activity and Participation; MDC, minimum detectable change; MOS-36, Medical Outcomes Study; NA, not applicable; NHP, Nottingham Health Profile; PAIS, Psychosocial Adjustment to Illness Scale; RAND-36, RAND 36-Item Short-Form Health Survey; SF-12, Short-Form 12; VR-36, Veterans SF-36 Health Status Questionnaire.

respondents to indicate the degree of satisfaction with different aspects of community integration. Examples include, "In the past 2 weeks: How satisfied are you with your ability to prepare meals?" or "How satisfied were you with how you took care of what you needed to do where you lived?" Responses are coded on a 7-point scale ("very unhappy" to "very happy"). Higher scores indicate better community integration.

The CRIS was used in a study of 68 patients (mean age  $\pm$  SD, 27.1 $\pm$ 5.6y; 94.1% men) with severe limb trauma. Thirty-seven subjects had major limb amputations.<sup>50</sup> Test-retest reliabilities (intraclass correlation coefficients) for all scales were .90 to .91. Minimal detectable change scores were estimated at 90% and 95% confidence. Concurrent validation found strong relationships between CRIS scales and measures of QOL, and SF-36 role functioning, social functioning, and role-physical emotional scales. The effect size and standardized response mean of CRIS scales was small after 3 months of rehabilitation, but equal to or greater than all measures used for concurrent validation. Together these findings suggest that CRIS scales are reliable and valid for use in a population with severe limb trauma including amputation.

### Medical Outcomes Study 36-Item Short-Form Health Survey

The SF-36 is a generic measure of health-related QOL. It can be scored as 8 separate scales and 2 summary measures: the physical component summary and the mental component summary. Items within role-physical, role-emotional, and social functioning scales assess the construct of community integration. Examples of role-physical items include, "Cut down on the amount of time you spent on work or other activities," or "Accomplished less than you would like." Examples of role-emotional items include, "Cut down the amount of time you spent on work or other activities," or "Didn't do work or other activities as carefully as usual." Examples of social functioning items include, "During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?" or "During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc)?"

We found 63 articles<sup>38,51-111</sup> that used the included SF-36 scales. Studies were conducted in several countries and included samples of persons with orthopedic trauma, other, and amputation.<sup>76</sup> Collectively, findings provided excellent evidence of construct validity. For example, amputees who had sustained other major bodily injuries were reported to have lower scores on all scales as compared with amputees without other injury.<sup>53</sup> Vietnam veterans with amputation were reported to have lower scores as compared with age-matched controls.<sup>56</sup> Veterans with amputation were reported to have lower scores for the 3 scales compared with population norms.<sup>87</sup> Two studies reported lower scores of social functioning and role-physical for patients with ankle<sup>106</sup> or heel<sup>95</sup> fracture as compared with population norms, but comparable scores of the role-emotional scale. Significantly worse role-physical scores were reported in patients with acute injury compared with chronic injury, with both groups scoring significantly worse than general population norms.<sup>110</sup> Patients with below-the-knee amputation were reported to have higher role-physical scores as compared with diabetic patients with ulceration,<sup>58</sup> and unilateral amputees were reported to have better role-emotional and role-physical scores than bilateral amputees.<sup>51</sup> Both lower and upper limb amputees were reported to have better scores on all 3 scales as compared with patients from pain

clinics.<sup>59</sup> All 3 scales were found to be negatively correlated with number of comorbidities.<sup>61</sup>

Ten studies<sup>38,52,60,72,83,84,87,89,103,110</sup> contained evidence supporting concurrent validity of the SF-36. The role-physical scale was moderately correlated with the Health Assessment Questionnaire.<sup>60</sup> The social functioning scale was also correlated with the General Health Questionnaire score ( $r = -.39$ ) 6 months after an emergency department visit,<sup>89</sup> and with the Prosthetic Evaluation Questionnaire in persons with lower limb amputation ( $r = .59$ ).<sup>87</sup> The role-emotional and social functioning scales were correlated with the Roland-Morris Disability Questionnaire ( $r = -.74$  and  $-.69$ , respectively) in patients with lower limb amputation.<sup>72</sup> Correlations (.26–.61) between the role-physical and social functioning scales and all 3 scales of the Questionnaire for Transfemoral Amputees were reported.<sup>83</sup> The role-emotional scale was moderately correlated with the Questionnaire for Transfemoral Amputees prosthetic mobility, problem, and global scales, but not the prosthetic use scale.<sup>83</sup> Quality of life (EuroQol-6D) was correlated with role-emotional ( $r = -.55$ ), role-physical ( $r = -.47$ ), and social functioning ( $r = -.59$ ) scales. Significant correlations (weak to moderate) with the TAPES adjustment to limitations, social restriction, functional satisfaction, activity restriction, and social adjustment scales were also reported.<sup>38</sup> Lastly, all 3 scales were significantly correlated with the International Knee Documentation Committee Subjective Knee Form: role-emotional ( $r = .24$ ), social functioning ( $r = .41$ ), and role-physical scales ( $r = .50$ ).<sup>103</sup>

Evidence of predictive validity was found in several studies. Subjects with lower role-physical scores had a statistically higher hazard of extended lost work time.<sup>60</sup> Social functioning scores at 6 weeks after injury were a significant predictor of return to work 6 months after injury.<sup>64</sup> Internal consistency was supported by Cronbach alpha values of .84 to .95 for all 3 scales.<sup>62</sup>

Evidence supporting responsiveness was reported in 10 studies.<sup>54,55,77,79,93,94,102,105,106,110</sup> For example, significantly worse scores in the 3 scales were reported after traumatic injury, and significant improvement after 8 months in the role-physical and social functioning scales.<sup>54</sup> Similarly, higher scores 1 year after orthopedic injury compared with preinjury scores were reported for the role-emotional, role-physical, and social functioning scales.<sup>94</sup> Statistically significant improvement was found in all 3 scales 9 months after ankle surgery as compared with preoperative scores.<sup>102</sup> Improvement in all 3 scales between 6 months and 1 year after injury, and improvement in scores between 4 and 20 months after injury were reported.<sup>55,106</sup> Significant improvement in the role-physical and social functioning, but not in the role-emotional scale was reported in trauma patients followed up for 1 to 6 months after hospital discharge.<sup>77</sup> Conversely, a separate study<sup>93</sup> of patients with traffic injuries showed a significant increase in only the role-emotional scale from 1 to 6 weeks post-injury. Finally, the role-physical scale improved significantly from pretreatment to 1 and 2 years in persons with above-the-knee amputation after osseointegration.<sup>79</sup>

Two studies of treatment of anterior cruciate ligament injuries provided further evidence for responsiveness of the role-physical scale, but reported no significant changes over time for the role-emotional and social functioning scales, suggesting that these 2 scales were less responsive to physical rehabilitation as compared with the role-physical.

Floor/ceiling effects were reported in 2 studies. Among prosthesis-wearing subjects with below-the-knee, through-knee, or

**Table 4** Content analysis of top-rated participation measures

| Measure | Scale                    | How Assessed    |                      |                       |                      |             |        |              |
|---------|--------------------------|-----------------|----------------------|-----------------------|----------------------|-------------|--------|--------------|
|         |                          | Burden<br>(min) | Amount/<br>Frequency | Assistance/<br>Device | Difficulty/<br>Speed | Limitations | Impact | Satisfaction |
| TAPES   | Social restriction       | 2–5             |                      |                       |                      | x           |        |              |
| TAPES   | Adjustment to limitation | 2–5             | x                    |                       |                      | x           |        | x            |
| CRIS    | Extent of participation  | 10              | x                    |                       |                      |             |        |              |
| CRIS    | Perceived limitations    | 10              |                      |                       |                      | x           |        | x            |
| SF-36   | Role-emotional           | <2              | x                    |                       |                      |             | x      |              |
| SF-36   | Role-physical            | <2              | x                    |                       |                      |             | x      |              |
| SF-36   | Social function          | <2              | x                    |                       |                      |             | x      |              |
| SIP     | Psychosocial domain      | 18              | x                    | x                     | x                    | x           | x      |              |

above-the-knee amputations, 34%, 21%, and 1% had the worst possible scores on the role-physical, role-emotional, and social functioning scales, respectively, and 21%, 39%, and 28% had the best possible scores, respectively.<sup>38</sup> In contrast, another study<sup>63</sup> of persons with combat-related below-the-knee amputation found no evidence of floor or ceiling effects (<20% with worst/best scores).

### Sickness Impact Profile

The SIP is a generic 136-item instrument assessing 12 areas: ambulation, mobility, body care and movement, social interaction, alertness behavior, emotional behavior, communication, sleep and rest, recreation and pastimes, eating, work, and home management. The categories may be scored separately or as a total score. Additionally, 2-dimension scores can be calculated. Ambulation, mobility, and body care and movement can be summed to form a physical domain score, and social interaction, alertness behavior, emotional behavior, and communication can form a psychosocial domain score. The remaining 5 scales are scored separately. All items are reported dichotomously. Respondents indicate areas that apply to them “today.” We considered the psychosocial domain and scales of mobility, alertness behavior, communication, social interaction, work, recreation and pastimes, and home management to be consistent with the construct of community integration. Item examples include the following: for mobility, “I stay within one room”; for alertness behavior, “I do not keep my attention on any activity for long”; for communication, “I am having trouble writing or typing”; for social interaction, “I stay alone much of the time”; for work, “I am doing part of my job at home”; for recreation and pastimes, “I am going out for entertainment less often”; and for home management, “I am not doing heavy work around the house.”

We found 27 studies that used the SIP in our target population.<sup>6-9,71,112-134</sup> Studies were conducted in the United States, Scotland, the Netherlands, and Canada. Many articles reported on findings from the Lower Extremity Assessment Project study that included samples of persons with severe limb-threatening injuries who were recruited from level 1 trauma centers; other samples included persons with leg or foot fractures, and/or amputation. Collectively, these studies provide good evidence on validity and responsiveness of the SIP, although no data on reliability.

In terms of known-group validity, persons in motor vehicle collisions treated in tertiary trauma centers had significantly worse psychosocial and total SIP scores as compared with persons with other injuries.<sup>125</sup> Patients from the intensive care unit or patients with high Injury Severity Scores had worse psychosocial scores.<sup>125</sup> Longer hospital stay was significantly associated with

worse psychosocial scores.<sup>125</sup> Four of the SIP scales (physical domain, work, recreation and pastimes, home management) were significantly worse for trauma patients as compared with population norms even 24 months after reconstruction surgery.<sup>132</sup> Operation Enduring Freedom/Operation Iraqi Freedom veterans with histories of blast exposure and traumatic brain injury (TBI) with loss of consciousness had significantly more psychosocial dysfunction than the TBI group without loss of consciousness and the no-TBI group.<sup>130</sup>

Evidence of concurrent and discriminant validity was provided in several studies. The SIP social integration scale had a strong negative correlation with the Prosthetic Evaluation Questionnaire social burden scale ( $r = -.52$ ).<sup>71</sup> The QOL of severely injured trauma survivors was moderately negatively correlated with the SIP total score and QOL ( $r = -.497$ ).<sup>115</sup> Studies examining the relationship between several lower-extremity injury severity scoring systems (Mangled Extremity Severity Score; Limb Salvage Index; Predictive Salvage Index; Nerve Injury, Ischemia, Soft-Tissue Injury, Skeletal Injury, Shock, and Age score; Hannover Fracture Scale-98; SIP psychosocial domain score) found only weak and nonsignificant correlations.<sup>9</sup> The SIP total scores and the SIP subscales of home management, work, and recreation and pastimes were weakly correlated with impairment measures such as range of motion and strength,<sup>120</sup> a finding that we interpreted as evidence of discriminant validity.

Responsiveness of the SIP was supported by several studies measuring functional disability before and after injury. Patients with lower limb fracture had significantly better pretrauma SIP total scores and psychosocial domain scores as compared with 6-month posttrauma scores.<sup>116</sup> Among patients with musculoskeletal injuries from an orthopedic trauma unit, significant deterioration was noted from preinjury baseline to 2 months for relevant SIP scales; however, only SIP total score, alertness behavior, and work scales were significantly worse at 6 months after injury.<sup>127</sup> Patients with limb reconstruction and amputation had significantly worse scores 6 months after injury compared with preinjury.<sup>119</sup> SIP psychosocial scores were significantly higher 7 years after injury compared with 2 years after injury.<sup>120</sup> In contrast, another study<sup>124</sup> found that the SIP total score and psychosocial domain scores were elevated (worse function) 3 months after serious trauma compared with preinjury baseline, but did not find the differences to be statistically significant. Collectively these studies provide good evidence on validity and responsiveness of the SIP, although no reliability or floor/ceiling analyses were found.

**Table 4** *Continued*

| Learning/<br>Cognitive | General<br>Tasks | Aspect of Activities and Participation |               |          |               |                     |           |                      | Other    |            |
|------------------------|------------------|----------------------------------------|---------------|----------|---------------|---------------------|-----------|----------------------|----------|------------|
|                        |                  | Communication                          | Domestic Life | Mobility | Interpersonal | Major Life<br>Areas | Self-Care | Com/<br>Social/Civic | Autonomy | Adjustment |
|                        |                  |                                        |               |          |               | x                   |           | x                    |          |            |
|                        |                  |                                        |               |          | x             | x                   |           |                      | x        | x          |
| x                      | x                | x                                      | x             | x        | x             | x                   | x         | x                    |          |            |
| x                      | x                | x                                      | x             | x        | x             | x                   | x         | x                    |          |            |
|                        |                  |                                        |               |          |               | x                   |           |                      |          |            |
|                        |                  |                                        |               |          |               | x                   |           |                      |          |            |
|                        |                  |                                        |               |          | x             |                     |           | x                    |          |            |
| x                      | x                | x                                      | x             | x        | x             | x                   | x         | x                    | x        |            |

**World Health Organization Disability Assessment Schedule 2.0**

WHODAS-II is a 12-item generic measure assessing functioning in 6 domains: cognition, mobility, self-care, getting along, life activities, and participation in society. We determined that the total overall score was consistent with the construct of community integration, as were the cognition, getting along, life activities (home and work), and participation domain scores.

Psychometrics of the WHODAS-II and its scales have been studied in other populations; however, we did not find similar studies in samples with amputation or limb trauma. We found 8 studies<sup>104,135-141</sup> that used the WHODAS-II with persons with amputation and limb trauma, amputation, and fall-related extremity injury who were from Ireland, New Zealand, Maori, China, Ghana, India, Mexico, the Russian Federation, and South Africa. Two studies<sup>136,141</sup> examined internal consistency of the total WHODAS-II scores, reporting internal consistency (Cronbach  $\alpha$ ) ranging from .75 to .87. Intrarater (test-retest) reliability was reported as an intraclass correlation coefficient of .468, indicating that 47% of the variance was attributable to participants.

Evidence of construct validity was provided in several articles. Scores of hospitalized injured persons were compared with those of persons not hospitalized. The hospitalized group scored  $\geq 10$  on the WHODAS-II after 1 year, and those with a body mass index  $>30$  were at an increased risk of disability at 1 year.<sup>138</sup> Subjects with severe traffic-related injuries scored significantly worse than those with moderate or minor injuries ( $P=.000$ ) for both working and nonworking populations.<sup>104</sup> There were also significant differences reported by injury level in scores of cognition, life activities, and participation, but not in the domain of getting along.<sup>104</sup>

Several studies compared WHODAS-II of injured persons from different regions and populations. A New Zealand study<sup>137</sup> of persons injured in automobile collisions found Pacific participants significantly more likely to have greater disability than non-Pacific participants. Another study<sup>138</sup> reported that injured Maori patients, a group known to have greater health disparities, had greater disability as compared with non-Maori patients. A study<sup>140</sup> conducted in a nationally representative sample from China, Ghana, India, Mexico, the Russian Federation, and South Africa reported that those with a fall-related injury, older age groups, and the presence of 2 or more chronic conditions had worse disability scores as compared to those without. Evidence of concurrent validity was provided in several articles. The WHODAS-II total score was significantly, weakly to moderately associated with the Flexible Goal Adjustment,<sup>136</sup> the ICF Measure of Participation and Activities,<sup>139</sup> and Tenacious Goal Pursuit.<sup>136</sup>

Studies<sup>136,141</sup> that followed up individuals with lower limb amputation from admission to rehabilitation, 6 weeks, 6 months, and 15 months postdischarge reported no differences between time points, suggesting that the WHODAS-II was not responsive to change resulting from rehabilitation. One study<sup>136</sup> suggested a large ceiling effect in that the entire sample scored above the 95th percentile of normative values.

Another study<sup>135</sup> used WHODAS-II individual items, rather than scales, when examining barriers, participation restriction, and functioning of persons with a major limb amputation, and compared participation restrictions of upper limb and lower limb amputees.

**Discussion**

We identified 36 measures containing 94 scales. Eight scales had the strongest measurement properties: the TAPES social restriction and adjustment to limitation scales; the CRIS extent of participation and perceived limitations scales; the SF-36 role-physical and social functioning scales; the SIP psychosocial domain scale; and the WHODAS-II 12-item total overall score. The SF-36, SIP, and WHODAS-II are generic measures, while TAPES is an amputation-specific measure. The CRIS is a measure that was developed for and validated with veterans and has yet to be tested in civilians.

Because quantity of evidence, not only quality, was a consideration in ranking, it is not surprising that 3 of the most widely used measures—the SF-36, TAPES, and SIP—were among the highest rated measures. Under our criteria, no property could receive an excellent score unless there were at least 3 sources of evidence for that property.

Another important consideration is the presence of conflicting and contradictory evidence across studies. There were numerous instances where we found 1 or more articles that provided strong evidence in support of a particular property, but other articles that provided weak or negative evidence. We assessed each instance individually, considering aspects of research methodology such as sample characteristics and size, and methodological rigor to reach consensus about the rating of the overall evidence supported for that property.

There are few measures of community integration developed using the ICF framework. Scales in the SIP and the CRIS were the most comprehensive in terms of the aspects of community integration assessed. Many measures in this review were developed to

assess constructs other than (or in addition to) community integration. Our review focused on scales within these measures that addressed areas of community integration.

Several measures in our review were variants of other measures. The SF-36, SF-36V (veterans), MOS-36, and RAND-36 were evaluated as separate entities because of their subtle differences in scoring (eg, TAPES and TAPES Modified) or item phrasing (SF-36, SF-36V), and because they may have differing public use restrictions. We recognize that this means that some very closely related measures had little evidence regarding their measurement properties, affecting their rankings.

## Study limitations

Our results should be interpreted in the context of several limitations. First, we calculated overall scores without applying weights to any property, although we did consider several approaches. Law<sup>32</sup> suggested combining all properties related to reliability into 1 group and validity into another. Terwee,<sup>28</sup> however, argued that content validity, test-retest reliability, construct validity, and responsiveness should carry the most weight. Terwee also recognized the difficulty of executing this and did not recommend using a composite. Wright<sup>29</sup> presented a composite summary score, but did not explain her weighting methodology. In contrast, Johnston and Graves<sup>142</sup> stressed the importance of capturing relevant information of all types when possible. Weighting overall scores could result in differing final scores and interpretation. Findings from detailed scoring should be considered when identifying a measure for a particular purpose or population to ensure that it meets those needs.

Second, our findings can be considered accurate as of March 2016. With more published literature and a larger body of evidence, the overall and scale ratings of included measures may change.

Third, although we believe our systematic review was exhaustive, it is possible that some studies were overlooked. Lastly, our findings regarding strength of evidence on measurement properties are specific to the application of that instrument to persons with limb trauma and/or amputations, and they should not be interpreted as generalizable beyond this group.

## Conclusions

Our review identified 34 measures containing 94 scales used in the literature to measure aspects of community integration in persons with traumatic limb injury or amputation. Eight scales from 5 instruments—the TAPES, CRIS, SF-36, the 136-item SIP, and the WHODAS-II 12-item measure—had the strongest measurement properties.

## Keywords

Amputation; Community integration; Disability evaluation; Rehabilitation; Social adjustment

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## Supplemental Appendix S1 Search Terms

### PubMed

#### Search #1

(Social Participation OR Social Involvement OR Community Involvement OR Community Integration OR Social Behavior OR Social Functioning OR Social Adjustment OR Adjustment Disorders OR Adaptation OR Role Function OR Employment OR Rehabilitation, Vocational [Mesh]) AND (Questionnaires OR Outcome Assessment OR Outcome Measurement OR Disability Assessment OR Disability Evaluation OR Psychosocial Outcomes OR Observer Variation[Mesh]) AND “Wounds and Injuries” AND hasabstract[text] AND “humans”[MeSH Terms] AND (Classical Article[ptyp] OR Clinical Trial[ptyp] OR Journal Article[ptyp] OR Randomized Controlled Trial[ptyp]) AND English[lang] AND (“aged, 80 and over”[MeSH Terms] OR “adult”[MeSH Terms] OR “adult”[MeSH Terms:noexp] OR “aged”[MeSH Terms] OR (“middle aged”[MeSH Terms] OR “aged”[MeSH Terms]) OR “middle aged”[MeSH Terms] OR “young adult”[MeSH Terms]) NOT Practice Guideline[ptyp] NOT Case Reports[ptyp] NOT “blood vessel prosthesis”[MeSH Terms] NOT transplantation NOT organ NOT stents NOT vascular NOT “arthroplasty”[MeSH Terms]\

#### Search #2

(Social Participation OR Social Involvement OR Community Involvement OR Community Integration OR Social Behavior OR Social Functioning OR Social Adjustment OR Adjustment Disorders OR Adaptation OR Role Function OR Employment OR Rehabilitation, Vocational [Mesh]) AND (Questionnaires OR Outcome Assessment OR Outcome Measurement OR Disability Assessment OR Disability Evaluation OR Psychosocial Outcomes OR Observer Variation[Mesh]) AND (“Amputation”[Majr] OR “Amputees”[Majr] OR “Artificial Limb” OR “Artificial Limbs” OR “Amputation/Rehabilitation” OR “Disabled Person” OR “Amputation Methods”) AND hasabstract[text] AND “humans”[MeSH Terms] AND (Classical Article[ptyp] OR Clinical Trial [ptyp] OR Journal Article[ptyp] OR Randomized Controlled Trial [ptyp]) AND English[lang] AND (“aged, 80 and over”[MeSH Terms] OR “adult”[MeSH Terms] OR “adult”[MeSH Terms:noexp] OR “aged”[MeSH Terms] OR (“middle aged”[MeSH Terms] OR “aged”[MeSH Terms]) OR “middle aged”[MeSH Terms] OR “young adult”[MeSH Terms]) NOT Practice Guideline [ptyp] NOT Case Reports[ptyp] NOT “blood vessel prosthesis”[MeSH Terms] NOT transplantation NOT organ NOT stents NOT vascular NOT “arthroplasty”[MeSH Terms]\

#### Search #3

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Injuries” AND hasabstract[text] AND “humans”[MeSH Terms] AND (Classical Article[ptyp] OR Clinical Trial[ptyp] OR Journal Article[ptyp] OR Randomized Controlled Trial[ptyp]) AND English[lang] AND (“aged, 80 and over”[MeSH Terms] OR “adult”[MeSH Terms] OR “adult”[MeSH Terms:noexp] OR “aged”[MeSH Terms] OR (“middle aged”[MeSH Terms] OR “aged”[MeSH Terms]) OR “middle aged”[MeSH Terms] OR “young adult”[MeSH Terms]) NOT Practice Guideline[ptyp] NOT Case Reports[ptyp] NOT “blood vessel prosthesis”[MeSH Terms] NOT transplantation NOT organ NOT stents NOT vascular NOT “arthroplasty”[MeSH Terms]\

#### Search #4

(Social Participation OR Social Involvement OR Community Involvement OR Community Integration OR Social Behavior OR Social Functioning OR Social Adjustment OR Adjustment Disorders OR Adaptation OR Role Function OR Employment OR Rehabilitation, Vocational OR Health Status OR Quality of Life [Mesh]) AND (Questionnaires OR “Outcome Assessment” OR Outcome Measurement OR Disability Assessment OR Disability Evaluation OR Psychosocial Outcomes OR Observer Variation OR Health Surveys or Psychometrics[Mesh]) AND “leg injuries” AND hasabstract[text] AND “humans”[MeSH Terms] AND (Classical Article[ptyp] OR Clinical Trial[ptyp] OR Journal Article[ptyp] OR Randomized Controlled Trial[ptyp]) AND English[lang] AND (“aged, 80 and over”[MeSH Terms] OR “adult”[MeSH Terms] OR “adult”[MeSH Terms:noexp] OR “aged”[MeSH Terms] OR (“middle aged”[MeSH Terms] OR “aged”[MeSH Terms]) OR “middle aged”[MeSH Terms] OR “young adult”[MeSH Terms]) NOT Practice Guideline[ptyp] NOT Case Reports[ptyp] NOT “blood vessel prosthesis”[MeSH Terms] NOT transplantation NOT organ NOT stents NOT vascular NOT “arthroplasty”[MeSH Terms]

### CINAHL

#### Search #1

(Social Participation OR Social Involvement OR Community Involvement OR Community Integration OR Social Behavior OR Social Functioning OR Social Adjustment OR Adjustment Disorders OR Adaptation OR Role Function OR Employment OR Rehabilitation Vocational) AND (Questionnaires OR Outcome Assessment OR Outcome Measurement OR Disability Assessment OR Disability Evaluation OR Psychosocial Outcomes OR Observer Variation) AND (“Amputation” OR “Amputees” OR “Artificial limb” OR “Artificial limbs” OR Amputation Rehabilitation OR Amputees Rehabilitation) NOT PT Case Study NOT PT Practice Guideline NOT Blood Vessel Prosthesis NOT Transplantation NOT Organ NOT Stents NOT Arthroplasty

#### Search #2

(Social Participation OR Social Involvement OR Community Involvement OR Community Integration OR Social Behavior OR Social Functioning OR Social Adjustment OR Adjustment Disorders OR Adaptation OR Role Function OR Employment OR Rehabilitation Vocational) AND (Questionnaires OR Outcome Assessment OR Outcome Measurement OR Disability Assessment OR Disability Evaluation OR Psychosocial Outcomes OR

Observer Variation) AND ("Wounds and Injuries" OR Orthopaedic) NOT PT Case Study NOT PT Practice Guideline NOT Blood Vessel Prosthesis NOT Transplantation NOT Organ NOT Stents NOT Arthroplasty

### Search #3

(Social Participation OR Social Involvement OR Community Involvement OR Community Integration OR Social Behavior OR Social Functioning OR Social Adjustment OR Adjustment Disorders OR Adaptation OR Role Function OR Employment OR Rehabilitation Vocational OR Health Status OR Quality of Life) AND (Questionnaires OR Outcome Assessment OR Outcome Measurement OR Disability Assessment OR Disability Evaluation OR Psychosocial Outcomes OR Observer Variation OR Health Surveys OR Psychometrics) AND (Blast Injuries) NOT PT Case Study NOT PT Practice Guideline NOT Blood Vessel Prosthesis NOT Transplantation NOT Organ NOT Stents NOT Arthroplasty

### Search #4

(Social Participation OR Social Involvement OR Community Involvement OR Community Integration OR Social Behavior OR Social Functioning OR Social Adjustment OR Adjustment Disorders OR Adaptation OR Role Function OR Employment OR Rehabilitation Vocational OR Health Status OR Quality of Life) AND (Questionnaires OR Outcome Assessment OR Outcome Measurement OR Disability Assessment OR Disability Evaluation OR Psychosocial Outcomes OR Observer Variation OR Health Surveys OR Psychometrics) AND (Leg Injuries) NOT PT Case Study NOT PT Practice Guideline NOT Blood Vessel Prosthesis NOT Transplantation NOT Organ NOT Stents NOT Arthroplasty

**Limiters for all CINHAL searches:** Abstract Available; Human; Language: English; Publication Type: Clinical Trial, Journal Article, Randomized Controlled Trial, Research; Age Groups: All Adult

**Search modes:** Boolean/Phrase

## Supplemental Appendix S2 Additional Measures Identified in the Systematic Review, But Not Rated Highest

### Arthritis Impact Measurement Scale Modified

The Arthritis Impact Measurement Scale (AIMS) is a 45-item self-report instrument that includes 9 subscales measuring mobility, physical activity, dexterity, household activity, social activity, activities of daily living, pain, depression, and anxiety. We considered 2 of the subscales to be measures of participation: household activity and social activity. The AIMS can be administered in 15 minutes. Each item is scored using a 5-point Likert scale, with zero representing better health status and higher numbers representing greater disability. The total score for each subscale is calculated by summing the items in the scale. Lerner used the household activity and social activity subscales in a study on the impact of chronic refractory osteomyelitis, posttraumatic long-bone fracture nonunion, and amputation on psychological adjustment and functional impairment,<sup>143</sup> modifying the wording so that "arthritis" was removed from all questions. Their sample included 20 persons with amputation. Lerner reported on

differences between groups of patients but did not conduct any further analyses to add to the literature on the psychometric properties of the AIMS instrument.

### Community Integration Questionnaire and Community Integration Questionnaire Modified

The original Community Integration Questionnaire (CIQ) is a 15-item, condition-specific self-report measure of participation in adults with physical disabilities. It was originally developed for use with persons with TBI. The CIQ consists of 3 subscales assessing home integration, social integration, and productivity. Each subscale can be scored independently, and a total score can be calculated. The basis for scoring is primarily frequency of performing activities or roles, with secondary weight given to whether or not activities are done jointly with others, and the nature of those other persons. Most items are scored on a 3-point scale from 0 to 2, with 1 item scored from 0 to 4 and 1 item scored from 0 to 5. Higher scores indicate a greater degree of community integration.

Prior authors reported on the reliability and validity of the original CIQ in other populations, notably those with TBI. We found only 1 article that used the CIQ to study persons with amputation.<sup>144</sup> Hirsh investigated the psychometric properties of the CIQ in a sample of 751 persons with physical disabilities, of whom 158 were persons with limb loss (95% lower limb).<sup>144</sup> They reported internal consistency (using data from the entire sample) for the scales as follows: summary score  $\alpha = .75$ ; home integration  $\alpha = .84$ ; social integration  $\alpha = .51$ ; and productive activities  $\alpha = .45$ . These findings suggest that the social integration and productive activities subscales may not be unidimensional. Hirsch then conducted factor analyses, which confirmed that modification to scale structure and score should be made. Concurrent validation showed weak but statistically significant correlations with measures of general health and mental health for the original CIQ.

Hirsch then explored a modified scoring method for the CIQ based on the results of exploratory and confirmatory factor analyses.<sup>144</sup> All CIQ items were retained, but the items comprising 2 of the scales, home integration and social integration, were modified. The modified scoring method led to better correlations between general health and mental health, providing stronger evidence of concurrent validity. Based on these results, the modified scoring of the CIQ was recommended, and the addition of new items to the productive activities subscale was suggested.

### Craig Handicap Assessment and Reporting Technique

The original Craig Handicap Assessment and Reporting Technique (CHART) was a 27-item, interviewer-administered self-report measure that includes 5 subscales assessing physical independence, mobility, occupation, social integration, and economic self-sufficiency. The revised CHART includes 32 items and a new subscale assessing orientation. Each of the CHART subscales has a maximum score of 100 points and considered the level of performance of an average nondisabled person. Although the CHART was initially developed for persons with spinal cord injuries, it has been used for decades in studies of persons with a range of physical and

cognitive disabilities. The social integration subscale consists of 6 questions about extent of participation in, and maintenance of, customary social relationships. The occupational functioning subscale consists of 7 questions about extent of participation in occupational activities customary to a person's sex, age, and culture. All CHART subscales measure quantity of engagement—that is, hours of work or productive activity and number of friends or business associates—but do not assess perceived limitations or satisfaction with the amount of participation.

Three studies of amputees used the CHART.<sup>50,145,146</sup> All used the social integration subscale, while only 2 used the occupational functioning subscale.<sup>145,146</sup> Cusick examined the level of agreement between 938 patients (many of whom had amputations) and their proxies, while Resnik (2011) used the CHART to examine the convergent validity of the CRIS in service members with severe limb trauma.<sup>50</sup> Cusick reported that person and proxy agreement intraclass correlation coefficients (ICCs) were .61 and .73, respectively.<sup>145</sup> Resnik found weak but significant correlations between the CRIS and the occupation subscale, but not with the social integration subscale.<sup>50</sup>

Preliminary evidence suggests that these 2 CHART subscales were not responsive to change in amputees undergoing comprehensive rehabilitation. Resnik reported that the effect size for persons undergoing 3 months of outpatient rehabilitation at the Center for the Intrepid was nonsignificant (.06 and .09), and far smaller than other measures such as the CRIS, the QOL scale, and the SF-36 role-physical scale, which showed weak effects.<sup>50</sup> No correlation was observed between the occupational functioning subscale and the CRIS, suggesting that these 2 scales measure different constructs. A weak correlation between the social integration scale and the CRIS satisfaction with participation scale was observed ( $R = .26$ ), also suggesting that these scales measure different but related constructs.<sup>50</sup>

Lobello compared a sample of 34 injured participants with a maximum CHART social integration score of 100 with a matched set of 34 subjects who scored  $\leq 50$  and found a significant difference between the social integration groups on the Life Satisfaction Index and the Family Satisfaction Scale using analyses of covariance.<sup>146</sup> Reliability and internal consistency of the CHART subscales in an extremity-injured population have not been examined.

## Effects after amputation or limb-sparing surgery

Two subscales (taken from the 7-item interpersonal and social functioning and the 12-item work performance or employment functional areas) were considered in this review after content analysis of the self-administered 104-item full questionnaire that also covers educational status, functional limitations, pain intensity, emotional distress, rehabilitation experience, and general satisfaction. Hudson designed this questionnaire for their study on patients after amputation or limb-sparing surgery for pediatric bone tumors. Items for the interpersonal and social functioning subscale were scored on a 4-point scale, and a higher composite (based on average of all 7 items) score represents a greater degree of impact on social functioning after amputation or limb-sparing surgery.<sup>147</sup> Items on the work performance or employment subscale were scored as “yes” or “no” if subjects indicated some form of interference resulting from their amputation or limb-sparing surgery.

Hudson reported that the interpersonal/social functioning subscale had high internal consistency (Cronbach  $\alpha = .84$ ) and found Spearman correlation coefficients of .40 with the functional limitation subscale of the effects after amputation or limb sparing surgery scale, .44 with the pain interference subscale, .55 with the emotional distress subscale, and .70 with the self-image subscale.<sup>147</sup> Internal consistency analysis was only shown with a subset of 9 of the 12 items in this subscale.

The interpersonal/social functioning subscale was also a significant independent predictor ( $\beta = .49$ ,  $P = .0002$ ) of the emotional distress functional area. No significant difference was found between the amputation and the limb-sparing groups. There were no analyses performed to support the validity of the work performance or employment subscale, and the internal consistency statistic (Cronbach  $\alpha = .73$ ) was calculated with only 9 of the total 12 subscale items.<sup>147</sup> No other study reviewed has used this measure.

## Frenchay Activities Index and Frenchay Activities Index Modified

The Frenchay Activities Index (FAI) is a generic, 15-item self-report measure of participation. Items reflect the frequency with which each item or activity is undertaken over the past 3 or 6 months (depending on the nature of the activity). Each item is assigned a score of 1 to 4, where 1 is indicative of the lowest level of activity and 4 is indicative of the highest. Items cover 3 areas: domestic chores, leisure/work, and outdoor activities. A total score is calculated by summing the responses.

Three articles used the FAI (and 1 used a modified version of the FAI) to study amputees.<sup>48,148-150</sup> Asano used the FAI to examine factors associated with QOL in a sample of 415 unilateral lower limb amputees (27% above knee and 73% below knee).<sup>148</sup> They reported that FAI scores were a significant predictor of QOL scores, confirming the importance of participation QOL. Hou examined the impact of return-to-work status on health-related QOL in a 2-year follow-up study of 966 persons with traumatic limb injuries. They reported that FAI scores influenced health-related QOL and explained its relationship with return to work.<sup>151</sup> Hou found significantly higher scores in the FAI for those who did return to work. Datta used the FAI to measure social activities in a sample of 41 persons with bilateral lower limb amputation and to examine the impact of prosthesis use on FAI scores at follow-up (which occurred a minimum of 21mo later).<sup>149</sup> They reported no difference in FAI scores between prosthetic users and nonusers. However, they did note that bilateral amputees who used prostheses at follow-up had greater independence in activities of daily living, but that the scores of the FAI were not improved, suggesting that the FAI measures a different construct than activities of daily living. Reliability and internal consistency of the original FAI in an amputee population have not been examined.

Miller added 3 additional items to the FAI to modify it in a study of the relationship between a history of falls, balance confidence, mobility, and social function. They reported an internal consistency of the modified measure of .87; however, their report did not specify the precise items that were added.<sup>48</sup>

## Functional and Social Performance Checklist

The Functional and Social Performance Checklist (DSF-84) is an 84-item checklist developed by Monteiro, based on the ICF item

bank, for use with individuals with lower limb amputations.<sup>152</sup> The final validated instrument contains 5 domains, 3 of which we considered to be consistent with the construct of participation: daily activities, performance components, and social participation. Each domain has its own scale ranging from 0 to 100, calculated by summing responses, dividing by the maximum score, and multiplying by 100. High scores indicated better performance. Monteiro implemented the checklist with 138 individuals with unilateral lower limb amputation.<sup>152</sup> Internal consistency ranged from .71 to .89, and interrater reliability ICCs between 4 assessors indicated excellent replicability (all ICCs > .91). Intrarater reliability ICCs also indicated excellent correlation ( $P < .0001$ ); however, ICC values were not reported. Monteiro also found that amputees who played soccer had significantly higher scores than those who did not, suggesting known-group validity. No other validity, responsiveness, or floor/ceiling analyses have been conducted.

## Impact of Events Scale

The Impact of Events Scale (IES) is a self-report measure of distress resulting from trauma. There are 16 items in total across 2 domains: intrusion and avoidance. Respondents describe their level of distress resulting from the trauma while completing activities during the past 7 days. Each subscale contributes its own additive score, and a total score can be calculated as well. We considered the total score as well as the intrusion subscale score as consistent with the construct of participation. Anderson used the IES in their study on psychosocial states after traffic injury and intervention by social workers; however, there was no statistical difference in IES between the intervention and control groups.<sup>153</sup> Group differences were found by sex where 32% of women reported high levels (>20) of intrusion compared with 14% of men ( $P < .001$ ). No other validity analyses using the IES were reported. No reliability, responsiveness, or floor/ceiling analyses were reported in samples of people with a history of limb trauma and/or amputation.

## Late Effects of Accidental Injury Questionnaire

The Late Effects of Accidental Injury Questionnaire (LEAIQ) is a self-report measure designed by Malt that assesses 5 areas of biological, psychological, and social effects of traumatic injuries.<sup>154</sup> We considered 3 individual item subscales of LEAIQ to be constructs consistent with participation: reduced pleasure/leisure activities, decreased contact, and deceased work capacity. In their biopsychosocial follow-up study of 551 accidentally injured adults, Malt reported correlations of .28 between reduced pleasure and deceased work capacity, .56 between reduced pleasure and decreased contact, and .21 between deceased work capacity and decreased contact.<sup>155</sup>

A psychiatric resident classified patients on the LEAIQ outcomes in order to assess how far LEAIQ findings corresponded to clinic assessments.<sup>155</sup> For predicting surgeon-evaluated minor reductions of physical function, decreased contact had poor sensitivity (40%) and 77% positive prediction power (PPP). For predicting psychiatric-evaluated minor reduction or change of leisure activities, reduced pleasure had 86% sensitivity and 25% PPP. Finally, for detecting major reduction in work capacity

according to a global evaluation of outcome by the psychiatrist, the deceased work capacity subscale had 70% sensitivity and 70% PPP. All 3 subscales had high negative prediction power and specificity.

The method for scoring the LEAIQ is not clearly described and, to date, only preliminary validity and reliability findings on the LEAIQ have been reported. No reports of responsiveness or floor/ceiling analyses were found.

## London Handicap Scale

The London Handicap Scale (LHS) is a 6-item, condition-specific self-report instrument designed to assess the effect of chronic disorders on a person's functional ability. The LHS includes single items covering the following dimensions: mobility, orientation, physical independence, occupation, social integration, and economic self-sufficiency. Each question asks respondents to choose which of the 6 descriptions is nearest to their own situation. A total score is calculated based on these responses. A single study of amputees by Fischer used the LHS and provided some evidence of concurrent validity.<sup>156</sup> They studied return to work of 100 amputees and reported that the LHS was significantly correlated with the Employment Questionnaire. No other psychometric analyses were found.

## Measure of Activity and Participation module

The Measure of Activity and Participation (MAP) is a section of the National Physical and Sensory Disability Database in Ireland and uses the World Health Organization's ICF as a guiding framework. It includes 3 scales: barriers and challenges, participation, and the WHODAS-II (described below). The barriers and challenges section of the MAP highlights the social environmental factors that potentially serve to exclude or restrict participation. There are 9 total items in the barriers and challenges subscale. The participation section identifies the extent to which an individual's participation has been restricted in 13 life areas such as education, employment, socializing, shopping, and family life. Gallagher used the MAP tools in a descriptive study of the barriers, participation restriction, and functioning levels experienced by 148 people with a major limb amputation in Ireland.<sup>135</sup> The actual instruments used were not available for our review (except the WHODAS-II; see below), and the article did not report on any psychometric analyses of these measures.

## Measures of Life Habits (Life-H)

The Measures of Life Habits (Life-H) questionnaire is a condition-specific, 77-item self-report instrument that evaluates social participation of persons with disabilities. The Life-H covers 12 categories: nutrition, fitness, personal care, communication, housing, mobility, responsibility, interpersonal relationships, community life, education, employment, and recreation. The measure is based on 2 specific elements: the degree of difficulty in carrying out life habits in a person's actual environment accomplished with no difficulty, with difficulty, with substitution, or not accomplished; and the type of assistance required to carry out the habits (no help, technical assistance or adaptation, human

assistance). The question is phrased as follows: “For each of the following life habits, indicate (1) how the person generally accomplishes it, and (2) the type of assistance required to accomplish it.” A score may be obtained for each item, each category (mean of items), the mean of the daily activities categories, the mean of the social roles categories, and finally, the mean of all items or categories (total score). Zidarov used the Life-H to assess participation in a sample of 19 persons with amputation<sup>157</sup> and reported that there were significant improvements in scores from admission to inpatient rehabilitation to 3 months after in all the scales except interpersonal relationships, suggesting that this measure may be responsive to change in this population. Thus, there is preliminary evidence suggesting responsiveness of these scales. No other studies were found that examined reliability, internal consistency, or validity in an amputee population.

## Medical Outcomes Study (MOS-36)

The Medical Outcomes Study (MOS-36) is composed of the same items as the RAND-36 and the SF-36 and is scored via the same 8 subscales: physical functioning, bodily pain, role limitations attributable to physical health problems (role-physical), role limitations attributable to personal or emotional problems (role-emotional), emotional well-being, social functioning, energy/fatigue, and general health perceptions. We considered 3 of the scales to be consistent with the construct of participation: role limitation attributable to physical health problems, role limitations attributable to personal or emotional problems, and social functioning.

The primary difference between the MOS-36 and the RAND-36 is in the scoring algorithm of the general health and pain subscales. The scale was formally called the MOS Short Form-36 but now is often called the SF-36 for short. However, the MOS-36 differs from the proprietary version of the SF-36 owned by Quality Metric (see below).

We found 9 articles that used the MOS-36, which included Dutch, Norwegian, Persian, and Sudanese versions.<sup>125,158-167</sup> Collectively, these studies provide good evidence of the known-group validity of the MOS-36. For instance, Abdelgadir compared the health-related QOL of diabetic amputees with that of nondiabetic amputees and reported that amputees scored lower on role-physical and role-emotional subscales as compared with nonamputees.<sup>160</sup> Several studies found significantly lower scores among patients with amputation or activity restriction compared with controls. Abdelgadir showed a significant negative correlation between the Sense of Coherence Scale (a measure of coping for diabetic subjects with lower limb amputation) and the role-physical subscale.<sup>160</sup> Sampalis demonstrated that an Injury Severity Score >25 was associated with better role-emotional scores.<sup>125</sup> Taghipour found that both role-emotional and role-physical subscales were correlated with the Barthel Index, which measures the ability to perform activities of daily living and mobility.<sup>158</sup> Taghipour also found that optimism, low depression, low Injury Severity Score, and not requiring intensive care unit treatment were significantly associated with the 3 subscales. Tate reported a significant association between social functioning and QOL in a cross-sectional study of 136 rehabilitation patients and 72 cancer patients (as measured by Functional Living Index—Cancer).<sup>164</sup>

Responsiveness of the MOS-36 is well documented. Kopjar found significant improvements in all 3 subscales at 24 and 28 weeks compared with 6 to 10 weeks after injury,<sup>161</sup> and Toien found significantly increased scores 3 to 12 months post-emergency department/intensive care unit compared with

beforehand for role-physical and social functioning scales.<sup>165</sup> Ceiling effects were noted in Kopjar’s study for those with no activity restriction, and major floor effects with some ceiling effects were present in those with activity restriction.

## RAND-36

RAND developed the SF-36 as part of the Medical Outcomes Study. The measure includes 8 health subscales: physical functioning, bodily pain, role limitations attributable to physical health problems (role-physical), role limitations attributable to personal or emotional problems (role-emotional), emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item to indicate perceived change in health. We considered 3 of the scales to be consistent with the construct of participation: role limitation attributable to physical health problems, role limitations attributable to personal or emotional problems, and social functioning. The items on the MOS-36, SF-36, and RAND 36-Item Healthy Survey 1.0 are the same; however, the scoring method is different for 2 scales. Higher scores indicate more favorable health. Items within each of the scales are averaged to create the scale score. Scale scores represent the average for all items in the scale that the respondent answered. The RAND-36 is available in an unrestricted public version ([www.sf-36.org/faq/generalinfo.aspx](http://www.sf-36.org/faq/generalinfo.aspx)).

Five studies used the RAND-36 in studies of amputees,<sup>166,168-171</sup> and 4 of them used the Dutch version. ENREF\_107 Schoppen described the employment of persons in the Netherlands with lower limb amputation and compared working and nonworking amputees to a reference population.<sup>166</sup> In a later article, Schoppen studied job satisfaction and health experience of workers with and without amputation.<sup>168</sup> Van der Schans studied health-related QOL and its determinants in lower limb amputees in the Netherlands,<sup>169</sup> while Van der Sluis compared job experience and health of workers with upper and lower limb amputation.<sup>170</sup> Schoppen reported that patients with amputation and with previous work who were no longer working had significantly lower scores of social function, role-physical, and role-emotional as compared with a reference population as well as amputees who were currently working.<sup>168</sup> Schoppen’s study also found that only the role-physical subscale differed significantly between amputees and controls. Van der Schans reported that amputees with phantom pain scored significantly lower on the role-emotional scale than amputees without phantom pain.<sup>169</sup> Van der Sluis reported that lower limb amputees had worse scores on the role-physical scale as compared with controls.<sup>170</sup> Finally, McCutcheon reported Cronbach alpha values of .77, .86, and .96 for the role-emotional, role-physical, and social function subscales, respectively.<sup>171</sup> They also found that subjects with bowel resection scored significantly (40 points) better on the role-physical subscale than subjects with amputation.<sup>171</sup> Together these studies support the construct validity of the RAND-36 scales. No studies of responsiveness of the RAND-36 in persons with limb trauma or amputation were identified. Also, few reliability analyses and no responsiveness or floor/ceiling analyses were found specifically on the RAND-36.

## Short-Form 12

The Short-Form 12 (SF-12) is a shorter version of the SF-36 Health Survey (described below), designed to reproduce the Physical Component Summary and the Mental Component

Summary scores. The 8 subscales for this instrument are the same as the subscales for the MOS-36 but with only 1 or 2 questions per subscale. Scoring of individual items is identical to that for the SF-36 Health Survey. Each scale is transformed to a 0-to-100 scale, with higher scores indicating better health. Quality Metric updated the scoring for the SF-12 to the SF-12 v2, enabling calculation of the subscales and norm-based scoring. Thus the SF-12 v2 measure is available with a fee (<http://www.qualitymetric.com/WhatWeDo/SFHealthSurveys/SF12v2HealthSurvey/tabid/186/Default.aspx>). We considered 3 of the scales to be consistent with the construct of participation: role limitation attributable to physical health problems, role limitations attributable to personal or emotional problems, and social functioning.

Hart used the SF-12 in a study designed to develop a comprehensive outcomes tool to assess health status, client satisfaction, and prosthetists' perception of function for clients with lower extremity prosthetics needs, and provided strong evidence of internal consistency and validity.<sup>172</sup> Hart reported acceptable internal consistency for the 2-item role-physical and role-emotional scales ( $\alpha=.71-.84$ ) and showed that Physical Component Summary scores of the sample were 1.3 SDs below normal, that role-physical scores and Physical Component Summary were better for below-the-knee amputees as compared with above-the-knee amputees, and that younger patients demonstrated greater improvement in role-emotional and role-physical scores after prosthetic fitting.

## Veterans SF-36 Health Status Questionnaire

Veterans SF-36 Health Status Questionnaire (VR-36) was adapted from the MOS SF-36. Modifications were made to role items, where response choices that were originally dichotomized as yes/no were changed to 5-point ordinal choices. Otherwise, the items in the VR-36 (also called the SF-36V) are identical, as are the subscales and component summary scales. We considered 3 of the scales to be consistent with the construct of participation: role limitation attributable to physical health problems, role limitations attributable to personal or emotional problems, and social functioning. Algebraic scoring is relatively simple but cannot be done by the clinician. The VR-36 is freely available to the VA.

A single article supported the concurrent validity of the VR-36 in a population of lower limb amputees.<sup>50</sup> Resnik reported that the correlation between the role-emotional and social functioning scale and CRIS subscales was moderate (.36–.54), and correlations with the role-physical were slightly weaker ( $R=.33-.36$ ). There is limited evidence on responsiveness to change with rehabilitation. Effect sizes were negligible for the social functioning scale (.03), followed by the role-emotional scale (.10). Effect size of the role-physical scale was small (.36). A separate article examined the test-retest reliability and minimal detectable change of the role-physical scale, reporting ICCs for test retest as .80 for role-physical and a minimum detectable change at the 90% confidence level of 26.3 points.<sup>50</sup>

## Nottingham Health Profile

The Nottingham Health Profile (NHP) is a generic self-report measure that can be administered in person or by mail. The NHP consists of 38 questions covering 6 categories of perceived

distress: energy level, pain, emotional reactions, sleep, social isolation, and mobility. We considered the social isolation scale to be consistent with the construct of participation in interpersonal relationships because it assesses areas such as perceived loneliness and close relationships. A low NHP score signifies a high QOL. Respondents must answer “yes” or “no,” scored respectively as 1 and 0. Series of weights are used to score each category from 0 to 100. A low NHP score signifies lower perceived distress and therefore a high QOL.

Demet studied the reliability of the NHP in subjects with major amputation of 1 or more limbs.<sup>173</sup> Their sample included 542 amputees, 254 of whom responded to the questionnaire on 2 occasions. They reported an ICC for the social isolation scale of .64, indicating marginal acceptability. In a later article, Demet evaluated factors related to health-related QOL for 539 persons with limb amputation.<sup>167</sup> They reported that younger age and traumatic (vs dysvascular) amputation were related to better scores on the social isolation scale of the NHP, while being female was associated with greater social isolation, providing some evidence of validity. Topuz used the NHP to help validate a Turkish version of the TAPES psychosocial adjustment scale but found no significant correlation.<sup>49</sup> No studies reported on the responsiveness of the NHP.

## Psychosocial Adjustment to Illness Scale

The Psychosocial Adjustment to Illness Scale (PAIS) is a generic, 46-item, multiple domain, semistructured interview designed to assess the quality of a patient's psychosocial adjustment to a current medical illness or the sequelae of a previous illness. With slight variations in format, the PAIS may also be used to measure the nature of spouses', parents', or other relatives' adjustment to the index patient's illness, or their perceptions of the patient's adjustment to his/her own illness. The PAIS and PAIS-SR (Self-Report) measure psychosocial adjustment to illness in terms of 7 primary domains of adjustment: health care orientation, vocational environment, domestic environment, sexual relationships, extended family relationships, social environment, and psychological distress. Vocational environment, domestic environment, and extended family relationships were considered consistent with the construct of participation after content analysis.

Lerner used the spouse version of the PAIS to study the psychosocial adjustment of persons with chronic refractory osteomyelitis, posttraumatic long-bone fracture nonunion, and amputation on psychological adjustment and functional impairment.<sup>143</sup> They reported that the presence of pain had a significant detrimental effect on spousal PAIS scales. However, they did not report on the measurement characteristics of the scale.

Carrington used the PAIS to compare QOL between diabetic people with either chronic foot ulceration or lower limb amputation and diabetic controls and found both the diabetic ulcer and the amputation subjects had significantly poorer psychosocial adjustment than the diabetic controls.<sup>174</sup> No other psychometric analyses were found for the PAIS.

## Trinity Amputation and Prosthesis Experience Scales Modified

The TAPES itself was described in the main text of the article. The TAPES has been translated into several languages, and psychometric studies have been performed on the Turkish<sup>49</sup> and Persian

versions.<sup>38</sup> Topuz confirmed the test-retest reliability and construct validity of the Turkish version, although it appears that they used a modified scoring method that combined the 3 adjustment subscales into a composite adjustment scale, and also combined the 3 activity restriction subscales into a composite activity restriction scale.<sup>49</sup>

## Trinity Amputation and Prosthesis Experience Scales—Revised

In 2010, Gallagher reported on a Rasch analysis of the TAPES instrument using data from a sample of 498 persons.<sup>41</sup> Models suggested that a revision to the TAPES scale structure should be made, leading to the development of the TAPES-R. The single study reporting on the TAPES-R was performed by Gallagher and reported in 2010.<sup>41</sup>

The TAPES-R includes 33 items and consists of 3 psychosocial adjustment subscales, a single activity scale, and 3 prosthetic satisfaction subscales. Social adjustment is a 5-item subscale that assesses the influence of the artificial limb in social situations, encompassing ease of talking about the limb and dealing with the reactions of people to it. Adjustment to limitation is a 5-item scale that assesses restriction ensuing from having an artificial limb. General adjustment consists of 5 items that reflect the extent of adjustment to, and acceptance of, an artificial limb. Aesthetic satisfaction is a 4-item scale assessing satisfaction with the appearance of the prosthesis. Weight satisfaction is a single-item scale assessing satisfaction with weight of the prosthesis. Functional satisfaction consists of 5 items reflecting satisfaction with the functionality of the prosthesis. Within Psychosocial Adjustment, we considered the adjustment to limitation subscale consistent with participation; and within Activity Restriction, we considered the social restriction subscale consistent with participation. We did not consider any subscales in satisfaction with prosthesis consistent with the participation construct. Gallaher et al performed a Rasch analysis of the TAPES in a robust sample of 498 people. Their models led to the suggested revisions to create the TAPES-R scales and scoring.<sup>41</sup>

## Trinity Amputation and Prosthesis Experience Scales—Upper

The TAPES Upper was developed for people with an upper limb amputation, after analyses on the TAPES found that users of lower and upper limb prosthetics assess experience and needs differently. The TAPES Upper has a different factor structure than the TAPES with 2 additional subscales added, one in the adjustment domain (optimal adjustment) and one in the activity restriction domain (occupational restriction). The TAPES Upper has 4 psychosocial adjustment scales: general adjustment (3 items), social adjustment (4 items), adjustment to limitation (5 items), and the optimal adjustment scale (2 items), reflecting the development of an optimistic outlook and the positive appraisal of life in spite of the trauma associated with amputation and the use of an artificial limb. There are 4 activity restriction scales: athletic activity restriction (3 items), reflecting the limitation of activities that involve more dynamic physical effort (eg, sport and recreation, and running for a bus); social restriction, which addresses limitation of social activities such as visiting friends and working on hobbies; mobility restriction (5 items), which addresses physical

function and mobility; and a new occupational restriction (2-item) scale relating to restrictions in occupational performance.

The TAPES Upper has a single satisfaction scale consisting of 10 items reflecting satisfaction with the appearance of the prosthesis, satisfaction with the weight of the prosthesis, and satisfaction with the functionality of the prosthesis. Within psychosocial adjustment, we considered the adjustment to limitation subscale consistent with participation; and within activity restriction, we considered the social restriction subscale consistent with participation. We did not consider any subscales in satisfaction with prosthesis consistent with the participation construct.

A single study of 101 persons with upper limb amputation examined the factor structure of the TAPES and recommended the revised scoring.<sup>175</sup> Desmond reported that the internal consistency of the revised scales ranged from .72 to .94.<sup>175</sup> In a later study, Desmond used the TAPES Upper to study the contribution of coping strategies to psychosocial adjustment after upper limb amputation and found similarly high internal consistency.<sup>176</sup> Significant moderate correlations were found between TAPES subscales in both studies, and the later study identified significant negative correlations with the avoidance subscale of the Coping Strategy Indicator.

## World Health Organization Disability Assessment Schedule 2.0

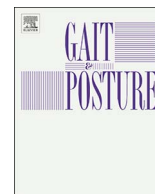
WHODAS-II is a 12-item generic measure grounded in the conceptual framework of the ICF and captures an individual's level of functioning in 6 major life domains: cognition (understanding and communication); mobility (ability to move and get around); self-care (ability to attend to personal hygiene, dressing and eating, and to live alone); getting along (ability to interact with other people); life activities (ability to carry out responsibilities at home, work, and school); and participation in society (ability to engage in community, civil, and recreational activities).

WHODAS-II produces domain-specific scores for 6 different functioning domains—cognition, mobility, self-care, getting along, life activities (household and work), and participation—or an overall summary score including all 6 subscales. After content analysis of the WHODAS-II, we determined that only the total overall score was consistent with the construct of participation. Psychometrics of the WHODAS-II have been studied extensively; however, we did not find any articles that specifically looked at measurement properties of any of the WHODAS-II subscales in an amputee and/or limb trauma sample.

We found 3 studies that used the WHODAS-II.<sup>135,137,141</sup> Mauiliu used the WHODAS-II in their study of persons with injuries from automobile collisions in New Zealand and found Pacific participants were significantly more likely to have greater overall disability than non-Pacific participants.<sup>137</sup> Coffey studied individuals with lower limb amputation at 3 time points: admission to rehabilitation, 6 weeks postdischarge, and 6 months postdischarge.<sup>141</sup> They examined WHODAS-II internal consistency (Cronbach  $\alpha = .82$ ) at 6 months postdischarge and found that the total score was significantly associated with the Flexible Goal Adjustment Scale ( $B = -.31$ ,  $P < .05$ ).<sup>141</sup> However, no significant differences were found between time points, suggesting that the WHODAS-II was not responsive to change resulting from rehabilitation. They also reported ceiling effects in their sample in that the entire sample scored above the 95th percentile of the disability scale's range.

Gallagher investigated the barriers, participation restriction, and functioning levels experienced by Irish persons with a major limb amputation using secondary data from the National Physical and Sensory Disability Database in Ireland, and compared participation restrictions of upper limb and lower limb

amputees.<sup>135</sup> They reported individual items for the WHODAS-II rather than scores of each subscale. They found that lower limb amputees had more difficulties joining in community activities. There were no differences between upper and lower limb amputees on any other of the WHODAS-II domains.



## Full length article

How humans use visual optic flow to regulate stepping during walking<sup>☆</sup>Mandy M. Salinas<sup>a</sup>, Jason M. Wilken<sup>b</sup>, Jonathan B. Dingwell<sup>a,\*</sup><sup>a</sup> Department of Kinesiology & Health Education, University of Texas, Austin, TX 78712, USA<sup>b</sup> Center for the Intrepid, Brooke Army Medical Center, JBSA Ft. Sam Houston, TX, USA

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## ABSTRACT

Humans use visual optic flow to regulate average walking speed. Among many possible strategies available, healthy humans walking on motorized treadmills allow fluctuations in stride length ( $L_n$ ) and stride time ( $T_n$ ) to persist across multiple consecutive strides, but rapidly correct deviations in stride speed ( $S_n = L_n/T_n$ ) at each successive stride,  $n$ . Several experiments verified this stepping strategy when participants walked with no optic flow. This study determined how removing or systematically altering optic flow influenced peoples' stride-to-stride stepping control strategies. Participants walked on a treadmill with a virtual reality (VR) scene projected onto a 3 m tall, 180° semi-cylindrical screen in front of the treadmill. Five conditions were tested: blank screen ("BLANK"), static scene ("STATIC"), or moving scene with optic flow speed slower than ("SLOW"), matched to ("MATCH"), or faster than ("FAST") walking speed. Participants took shorter and faster strides and demonstrated increased stepping variability during the BLANK condition compared to the other conditions. Thus, when visual information was removed, individuals appeared to walk more cautiously. Optic flow influenced both how quickly humans corrected stride speed deviations and how successful they were at enacting this strategy to try to maintain approximately constant speed at each stride. These results were consistent with Weber's law: healthy adults more-rapidly corrected stride speed deviations in a no optic flow condition (the lower intensity stimuli) compared to contexts with non-zero optic flow. These results demonstrate how the temporal characteristics of optic flow influence ability to correct speed fluctuations during walking.

## 1. Introduction

During forward motion, spatiotemporal information is projected onto the retina by the objects and surfaces in our environment. The relative motions between ourselves and these external objects and surfaces produce visual optic flow. These optic flow patterns are used to guide locomotion. Uniquely, however, our movements through our environment also alter the optic flow pattern [1]. Visual optic flow plays a central role in human balance and locomotor control particularly during navigation in complex environments [2] and provides a continuous stream of information used to distinguish steering direction [3,4], and ground distance traveled [5]. Therefore, to gain a better understanding of navigation in complex environments, it is essential to investigate how visual optic flow influences how humans regulate walking.

When walking on a treadmill in a static environment that provides no optic flow, young healthy adults naturally try to maintain approximately constant stride speed ( $S_n$ ) at each successive stride,  $n$  [6–8]. They do this by explicitly exploiting the inherent redundancy between

stride length ( $L_n$ ) and stride time ( $T_n$ ). Participants allow deviations in  $L_n$  and  $T_n$  relative to their mean values to persist across multiple consecutive strides, while rapidly correcting any deviations in  $S_n$ . Humans adopt this active speed correction in spite of there being many other very different, but equally feasible stepping strategies available to them [6,7]. These findings were independently verified in other studies [9,10]. Considering it is well-documented that humans use optic flow to regulate the speed of locomotion [11–15], particularly in the short-term [16], this study explored how systematically manipulating optic flow would impact (if at all) how healthy adults modified their stride-to-stride stepping strategies (especially active speed correction) during treadmill walking.

To truly gain insight to the impact of these systematic manipulations during walking, we consider how humans perceive change in a given stimulus. When walking overground, small stride-to-stride changes in walking speed [17] induce small changes in the nominal optic flow rate. Conversely, when walking on most treadmills, the nominal optic flow rate will be approximately zero, so any small change in walking speed (relative to the treadmill belt speed) will immediately induce some non-

<sup>☆</sup> The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of Brooke Army Medical Center, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, Department of Defense or the U.S. Government.

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zero optic flow that will indicate the person is now moving relative to their surrounding environment. This suggests that it may be easier for humans to adopt active speed correction in such contexts, given their natural reliance on visual optic flow. Indeed, Weber's law states that humans' ability to detect small changes in sensation intensity depend on the original intensity [19]: the greater the original intensity, the harder it is to detect small changes. In walking, any small change in speed that might occur on any given stride would induce a corresponding change in optic flow. Weber's law implies that these would be easier to detect when the nominal optic flow was zero (no optic flow), and should scale as the relative rate of optic flow is varied. Here, we hypothesized that participants would more-rapidly correct stride speed deviations in a no optic flow context compared to contexts with non-zero optic flow and these stride-speed corrections would scale as relative optic flow speed was varied, consistent with Weber's Law. Additionally, if visual information (optic flow, motion parallax) is removed, by introducing a completely uniform stimulus, this creates a sensory deprivation known as the Ganzfeld effect [22]. We hypothesized that introducing such a stimulus would affect stride-to-stride regulation of walking in a significant manner.

This study therefore determined how humans altered stride-to-stride control of their stepping movements when optic flow was removed and/or systematically manipulated in a virtual environment. By removing and systematically manipulating optic flow within the same treadmill context, this study sought to demonstrate that any differences found in stride-to-stride stepping control strategies would be due to these particular experimental manipulations. We hypothesized that: (1) when walking with static visual information but no optic flow, participants would tightly regulate stride-to-stride fluctuations in speed ( $S_n$ ), consistent with previous findings during treadmill walking [6,8–10], (2) when walking with non-zero optic flow, participants would regulate fluctuations in  $S_n$  less tightly and in a manner consistent with Weber's law, and (3) that removal of visual information altogether (both moving and static) would significantly disrupt stride-to-stride regulation of walking, as observed in the "Ganzfeld effect" [18].

## 2. Methods

Twenty healthy young adults (10 Female /10 Male,  $25.7 \pm 4.7$  years) participated. All participants were screened to ensure they had no prior history of lower limb injuries, surgeries, or cardiovascular, respiratory, neurological, musculoskeletal or visual conditions that might have affected their gait. This study was approved by Institutional Review Board at The University of Texas at Austin and all participants provided written informed consent prior to participation.

All participants walked on an instrumented "V-Gait" treadmill (Motekforce Link, Amsterdam, Netherlands; Fig. 1A) while wearing a safety harness (Petzl, Crolles, France). The V-Gait system consists of an instrumented dual-belt treadmill (1 m  $\times$  2 m) and a VR scene projected onto a 3 m tall 180° semi-cylindrical screen in front of the treadmill (Fig. 1A). An integrated 10-camera Vicon motion capture system (Oxford Metrics, Oxford, UK) was used to record movement kinematics.

For all trials, the treadmill was set to operate a constant belt speed, non-dimensionally scaled to each participant's own leg length,  $v_w = \sqrt{Fr \cdot g \cdot l}$ , where  $Fr = 0.16$  is the Froude number,  $g = 9.81 \text{ m/s}^2$ , and  $l$  is leg length in meters, measured from the greater trochanter to the floor [8,19,20].

Participants completed a 5-min warm-up followed by two 5-min trials at each of five experimental conditions: blank screen ("BLANK":  $v_{flow} = 0$ ), static VR scene ("STATIC":  $v_{flow} = 0$ ), optic flow speed slower than walking speed ("SLOW":  $v_{flow} = \frac{1}{3} \times v_w$ ), optic flow speed matched to walking speed ("MATCH":  $v_{flow} = v_w$ ), and optic flow speed faster than walking speed ("FAST":  $v_{flow} = 3 \times v_w$ ). Experimental conditions were presented in random order to each participant, with presentation order balanced across participants.

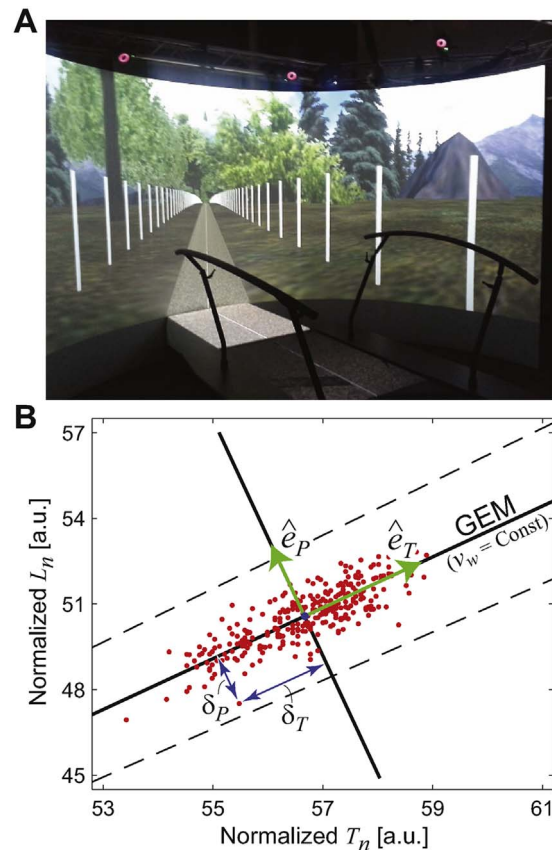


Fig. 1. Walking Environment and Task Goal Definition.

(A) Photograph of the V-Gait system (Motekforce Link, Amsterdam, Netherlands) used. The V-Gait consisted of an instrumented dual-belt treadmill and virtual reality (VR) scene projected onto a 180° screen in front of the treadmill. The VR scene depicted a path through a forest with mountains in the background and was used for 4 of the 5 experimental conditions. The virtual path was lined with white posts spaced every 3 m to increase motion parallax [3,23]. In the 5<sup>th</sup> BLANK condition, this scene was not displayed, and instead only a pure white screen was projected. (B) Schematic of the Goal Equivalent Manifold (GEM) for Constant-Speed Walking. Example stride time ( $T_n$ ) and stride length ( $L_n$ ) data, where each dot represents an individual stride  $n$ . The solid diagonal line represents all the combinations of  $[T_n, L_n]$  that achieve the exact same treadmill belt speed  $v_w$ . This line defines the constant-speed GEM. Orthonormal basis vectors  $[\hat{e}_T, \hat{e}_P]$  were defined, aligned tangent to and perpendicular to the GEM, respectively. Time series of  $L_n$  and  $T_n$  were transformed into  $\delta_T$  and  $\delta_P$  time series of deviations in the  $\hat{e}_T$  and  $\hat{e}_P$  directions, respectively, relative to the preferred operating point,  $[T^*, L^*]$  (POP).

Participants were instructed only to "walk and look straight ahead." Participants did not hold onto the treadmill handrails during any walking trial. During the "BLANK" condition, to keep participants' focus on the screen and to minimize looking down at their feet, participants wore goggles (Uvex, Smithfield, RI), modified to block the lower most portion of their visual field of view. Full frontal and peripheral vision remained unobstructed.

Kinematic data were recorded at 120 Hz using a previously validated whole-body 57-marker set [21]. However, for the analyses conducted here, we used marker data from only the feet and pelvis. Raw kinematic data were processed using Vicon Nexus software (Oxford Metrics, Oxford, UK). Additional data reduction and analyses were performed using MATLAB (MathWorks, Inc., Natick, MA).

The primary objective of walking is to move a finite distance in a finite time. Thus, the variables stride length ( $L_n$ ), stride time ( $T_n$ ) were chosen as the primary variables of interest. Individual heel strikes were determined by finding the local maxima of the distances between the pelvis and heel markers in the anterior-posterior direction [22]. A stride was defined as the period between a right heel strike to the next right heel strike. Stride length ( $L_n$ ) was calculated as the anterior-posterior displacement between two consecutive right heel strikes and using the

heel marker data. Stride time ( $T_n$ ) was calculated as the time between two consecutive right heel strikes. These data were used to extract time series of stride lengths ( $L_n$ ), stride times ( $T_n$ ), from which time series of stride speeds were then also computed ( $S_n = L_n/T_n$ ).

In the task of walking on a treadmill at constant belt speed,  $v_w$ , the primary requirement is to not walk off the treadmill [6]. There are many combination of  $L_n$  and  $T_n$  that satisfy this inequality and will successfully accomplish this task, expressed as follows:

$$-\frac{L_{TM}}{2} < \sum_{n=1}^N (L_n - v_w T_n) < +\frac{L_{TM}}{2}, \quad (1)$$

where  $L_{TM}$  is the length of the treadmill and  $v_w$  is the treadmill belt speed. Although there are many strategies to achieve this [6,7], one simple strategy is to try to maintain constant speed at each stride, and can be mathematically written as the following goal function:

$$L_n - v_w T_n = 0 \rightarrow \frac{L_n}{T_n} = v_w, \quad (2)$$

This goal function is one possible movement strategy and can be depicted as a diagonal line representing all the potential  $L_n$  and  $T_n$  combinations that would yield constant belt speed  $v_w$  (Fig. 1B). This line represents the goal equivalent manifold (GEM). We then used the procedures developed in [6] to decompose these data into two new variables, tangent to ( $\delta_T$ ) and perpendicular to ( $\delta_P$ ) the speed GEM. First,  $T_n$  and  $L_n$  were normalized to unit variance by dividing by their own standard deviations. Then, a preferred operating point (POP) was defined as  $[T^*, L^*] = [\bar{T}, \bar{L}]$ , and the new coordinate system was centered at this point,  $T'_n = T_n - T^*$  and  $L'_n = L_n - L^*$ . Lastly, the following coordinate transformation was performed to acquire deviations tangent ( $\delta_T$ ) and perpendicular to the speed GEM ( $\delta_P$ ) (Fig. 1B).

$$\begin{bmatrix} \delta_T \\ \delta_P \end{bmatrix} = \frac{1}{\sqrt{1 + v_w^2}} \begin{bmatrix} 1 & v_w \\ -v_w & 1 \end{bmatrix} \begin{bmatrix} T'_n \\ L'_n \end{bmatrix}, \quad (3)$$

As tangent deviations do not affect walking speed, they are considered “goal-irrelevant”. Alternatively, perpendicular deviations ( $\delta_P$ ) directly affect walking speed, and are thus considered “goal-relevant” (Fig. 1B).

Considering the primary task requirement, the time series of absolute position ( $P_n$ ) on the treadmill at each stride  $n$  was also examined and determined from  $L_n$  and  $T_n$ , as follows:

$$P_n = \sum_{k=1}^n (\Delta P_k) = \sum_{k=1}^n (L_k - v_w T_k). \quad (4)$$

This measure was computed from the stepping variables ( $L_n$ ,  $T_n$ ) to analyze  $P_n$  deviations on a stride-to-stride basis and to be consistent with the other time series stepping variables.

For each trial, we computed means and standard deviations ( $\sigma$ ) for each of these time series ( $T_n$ ,  $L_n$ ,  $S_n$ ,  $P_n$ ,  $\delta_T$ ,  $\delta_P$ ). We also used Detrended Fluctuation Analysis (DFA) [23–26] to quantify the stride-to-stride fluctuation dynamics and to determine the extent of control for each variable, as we did previously [6]. DFA scaling exponents,  $\alpha$ , quantify the statistical persistence or anti-persistence in a scalar time series, independent of the magnitude of variability. Scaling exponents  $\alpha > 1/2$  indicate statistical persistence: deviations in one direction are more likely to be followed by deviations in the same direction. Scaling exponents  $\alpha < 1/2$  imply anti-persistence: deviations in one direction are more likely to be followed by deviations in the opposite direction (reversals). Scaling exponents  $\alpha = 1/2$  indicate no correlation: all deviations are equally likely to be followed by deviations in either direction. In the context of control, variables that are not tightly controlled generally exhibit strong statistical persistence ( $\alpha > 1/2$ ), while variables that are tightly controlled generally exhibit either uncorrelated or anti-persistent fluctuations ( $\alpha \leq 1/2$ ) [6,7,27]. Thus, while standard deviations ( $\sigma$ ) captured the average magnitude of fluctuations in these time series, these DFA exponents ( $\alpha$ ) captured

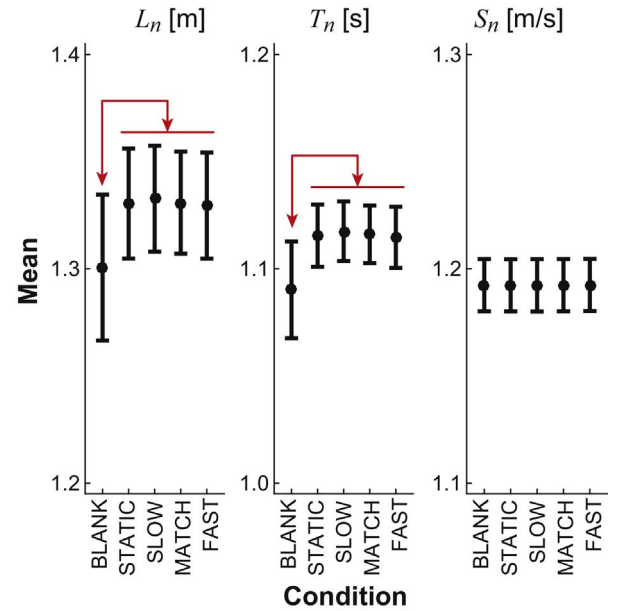


Fig. 2. Means of Stride Parameters.

Stride lengths ( $L_n$ ), stride times ( $T_n$ ), and stride speeds ( $S_n = L_n/T_n$ ). In each sub-plot, data shown are for the five different optic flow conditions: blank screen (BLANK), static VR scene (STATIC), or VR scene with optic flow speed either slower than (SLOW), matched to (MATCH), or faster than (FAST) walking speed. Error bars represent between-participant  $\pm 95\%$  confidence intervals. Red arrows/lines indicate statistically significant differences between conditions. In the BLANK condition, participants adopted shorter stride lengths ( $L_n$ ) and faster stride times ( $T_n$ ) compared to all other experimental conditions (STATIC, SLOW, MATCH, and FAST).

how quickly participants actively corrected these fluctuations on subsequent strides (i.e. stride-to-stride strategy).

Two-factor (Subject  $\times$  Condition) repeated measures analyses of variance (ANOVA) tested for statistically significant differences of means, standard deviations, and DFA  $\alpha$  exponents of stride variables ( $T_n$ ,  $L_n$ ,  $S_n$ ), absolute treadmill position ( $P_n$ ), and deviations relative to the speed GEM ( $\delta_T$ ,  $\delta_P$ ) across the five experimental conditions. Tukey post-hoc analyses assessed differences between experimental conditions. Results were considered statistically significant if  $p < 0.05$ . All statistical analyses were performed using SPSS (SPSS Inc., Chicago, IL).

### 3. Results

Mean values of  $L_n$  ( $F_{(4,76)} = 7.546$ ;  $p < 0.05$ ) and  $T_n$  ( $F_{(4,76)} = 7.306$ ;  $p < 0.05$ ) differed significantly across conditions. Post-hoc analyses indicated that participants adopted, on average, significantly shorter ( $p < 0.05$ ) and faster ( $p < 0.05$ ) strides in BLANK compared to the other four conditions (Fig. 2). By construction, mean values of  $S_n$  did not differ across conditions ( $F_{(4,76)} = 0.744$ ;  $p = 0.565$ , Fig. 2).

Standard deviations of  $L_n$  ( $F_{(4,76)} = 23.670$ ;  $p < 0.05$ ),  $T_n$  ( $F_{(4,76)} = 7.238$ ;  $p < 0.05$ ), and  $S_n$  ( $F_{(4,76)} = 23.613$ ;  $p < 0.05$ ) differed significantly across conditions. Participants exhibited significantly increased variability ( $\sigma$ ) for all three stride parameters ( $p < 0.05$ ) during BLANK compared to the other conditions (Fig. 3A–C). Significantly increased  $L_n$  variability was observed in FAST compared to STATIC and SLOW, whereas FAST elicited greater  $T_n$  variability compared to STATIC. Additionally, greater  $S_n$  variability was exhibited in MATCH and FAST compared to STATIC, and in FAST condition compared to SLOW (Fig. 3C).

For all experimental conditions, participants exhibited stride-to-stride statistical persistence (i.e.  $\alpha > 1/2$ ) in both  $L_n$  and  $T_n$  (Fig. 3D and E). Participants exhibited stride-to-stride statistical anti-persistence (i.e.  $\alpha < 1/2$ ) in  $S_n$  across all conditions (Fig. 3F). DFA  $\alpha$ 's of  $L_n$

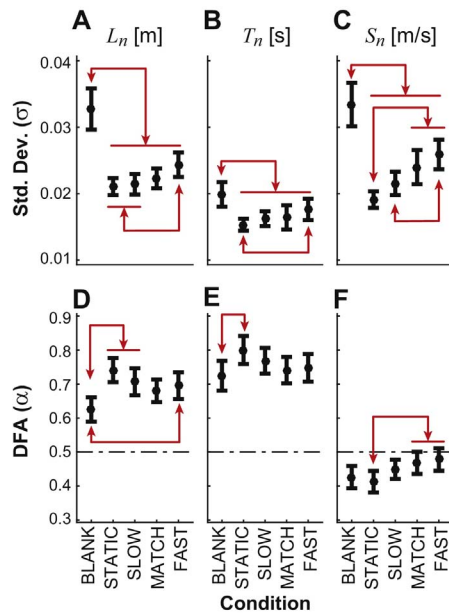


Fig. 3. Variability ( $\sigma$ ) and Statistical Persistence ( $\alpha$ ) of Stride Parameters.

(A–C) Variability (within-trial standard deviations:  $\sigma$ ) for stride lengths ( $L_n$ ), times ( $T_n$ ), and speeds ( $S_n$ ) during each of the five conditions (BLANK, STATIC, SLOW, MATCH, and FAST). (D and F) DFA scaling exponents ( $\alpha$ ) for  $L_n$ ,  $T_n$ , and  $S_n$  during all conditions. Error bars represent between-participant  $\pm$  95% confidence intervals. Red arrows/lines indicate statistically significant differences between individual conditions. During the BLANK condition, increased variability was observed for all three stride parameters (A–C) compared to all other experimental conditions (STATIC, SLOW, MATCH, and FAST). Across all conditions, participants exhibited stride-to-stride statistical persistence (i.e.  $\alpha > 0.5$ ) in both (D) stride lengths ( $L_n$ ) and (E) stride times ( $T_n$ ), suggesting that deviations were not immediately corrected on consecutive strides. F) Conversely, participants exhibited stride-to-stride statistical anti-persistence (i.e.  $\alpha < 0.5$ ) for stride speeds ( $S_n$ ), suggesting these deviations were more tightly controlled. Additionally, participants exhibited significantly more statistical anti-persistence (i.e., more negative  $\alpha$ ) for  $S_n$  in STATIC compared to FAST and MATCH.

( $F_{(4,76)} = 5.323$ ;  $p < 0.05$ ),  $T_n$  ( $F_{(4,76)} = 2.020$ ;  $p < 0.05$ ), and  $S_n$  ( $F_{(4,76)} = 2.692$ ;  $p < 0.05$ ) differed significantly across conditions ( $p < 0.05$ ). In the BLANK condition, participants exhibited significantly less statistical persistence in  $L_n$ , compared to the STATIC, SLOW and FAST conditions ( $p < 0.05$ , Fig. 3D); and significantly greater statistical persistence in  $T_n$  compared to STATIC ( $p < 0.05$ , Fig. 3E). For  $S_n$ , participants exhibited significantly greater statistical anti-persistence in FAST and MATCH compared to STATIC ( $p < 0.05$ , Fig. 3F).

Fig. 4 shows GEM plots and time series for 1 typical trial for each of 3 conditions. Distributions of  $[T_n, L_n]$  (Fig. 4A) demonstrated greater variance along and relatively less variance perpendicular to the speed GEM in all experimental conditions. Notably, in BLANK, this participant exhibited qualitatively more variance in *all* directions (Fig. 4A). In STATIC compared to MATCH, this participant exhibited more variance along and less variance perpendicular to the speed GEM compared to MATCH (Fig. 4A). Corresponding time series data of  $\delta_T$  fluctuations exhibited larger amplitudes than  $\delta_P$  fluctuations across all conditions (Fig. 4B). Fluctuations in  $P_n$  were also sustained across multiple strides, with the magnitudes of these fluctuations generally larger in BLANK compared to the other four conditions (Fig. 4C; only BLANK, STATIC and MATCH shown).

These qualitative observations (Fig. 4) were confirmed by our quantitative analyses (Fig. 5). Standard deviations of  $\delta_T$  ( $F_{(4,76)} = 7.848$ ;  $p < 0.05$ ),  $\delta_P$  ( $F_{(4,76)} = 7.557$ ;  $p < 0.05$ ), and  $P_n$  ( $F_{(4,76)} = 9.695$ ;  $p < 0.05$ ) differed significantly across conditions. Participants exhibited greater variability ( $\sigma$ ) for  $\delta_T$  than for  $\delta_P$  deviations across all conditions (Fig. 5A and B), as expected [6]. Participants also exhibited significantly greater ( $p < 0.05$ ) variability of  $\delta_T$  deviations

and significantly decreased variability of  $\delta_P$  deviations (Fig. 5A and B) in STATIC compared to the other four conditions ( $p < 0.05$ ; Fig. 5A and B). Variability ( $\sigma$ ) of  $P_n$  was lowest in STATIC compared to the other four conditions ( $p < 0.05$ , Fig. 5C).

Participants exhibited greater statistical persistence for  $\delta_T$  than for  $\delta_P$  fluctuations across all conditions (Fig. 5D and E). No significant differences were found in statistical persistence for  $\delta_T$  ( $F_{(4,76)} = 1.445$ ;  $p = 0.227$ , Fig. 5D). However, the statistical anti-persistence of  $\delta_P$  ( $F_{(4,76)} = 2.590$ ;  $p < 0.05$ , Fig. 5E) differed significantly across conditions. Participants exhibited significantly greater statistical anti-persistence in  $\delta_P$  for FAST and MATCH compared to STATIC ( $p < 0.05$ , Fig. 5E). Stride-to-stride fluctuations in  $P_n$  exhibited very strong statistical persistence that did not differ across conditions ( $F_{(4,76)} = 2.075$ ;  $p = 0.092$ , Fig. 5F).

For several of the reported measures, the Subject  $\times$  Condition interactions were also statistically significant ( $p < 0.05$ ). However, while the data showed that individual participants exhibited different changes in their responses across conditions, these differences were not systematic and do not detract from the overall trends due to the main effect of Condition.

#### 4. Discussion

Systematic manipulation of relative optic flow speed or removal of optic flow during treadmill walking significantly altered both how *quickly* parameter fluctuations were actively corrected (DFA scaling exponents,  $\alpha$ ) and how *successful* participants were at correcting these fluctuations (standard deviations,  $\sigma$ ).

Consistent with previous studies [6,8–10], across all conditions, participants *rapidly* corrected deviations in  $S_n$  (as indicated by  $\alpha < 0.5$ , Fig. 3F) to try and maintain approximately constant stride speed at each new stride. However, when walking with static visual information but *zero* optic flow (STATIC) compared to the non-zero optic flow conditions (MATCH and FAST), participants exhibited significantly greater active correction (smaller DFA  $\alpha$ ) of  $S_n$ . These results support our hypothesis that participants would more-rapidly correct stride speed deviations in a zero optic flow context compared to non-zero optic flow contexts. This suggests that small deviations in  $S_n$  induced corresponding changes in optic flow that were easier to detect (as indicated by greater active speed correction) when the nominal optic flow was zero (Fig. 3F), consistent with Weber's law. Moreover, although our analysis focused on how each stride affected subsequent strides and participants were not able to vary their average walking speed (as it was fixed), our results remain consistent with past work [11–15] that documented significant effects of optic flow modulations on average walking speed. Our results further identified changes in stride-to-stride stepping strategies, and specifically active error correction. These findings provide deeper insights into how the temporal characteristics of optic flow influence walking.

Further, participants exhibited significantly less  $S_n$  variability (Fig. 3C), and  $\delta_P$  variability (Fig. 5B), in STATIC compared to the non-zero optic flow conditions (MATCH and FAST). Thus, participants were more *successful* at implementing their strategy to maintain constant speed at each stride during the zero optic flow condition (STATIC), again consistent with Weber's law. Notably, participants also exhibited more variance tangent ( $\sigma(\delta_T)$ ) to the speed GEM in STATIC compared to all the non-zero optic flow conditions (SLOW, MATCH and FAST; Fig. 5A). This indicates that, on average, participants were better able to exploit the speed GEM during the *no* optic flow condition compared to the non-zero optic flow conditions.

Removing visual information (BLANK condition) led participants to appear to walk more cautiously: they took shorter and faster steps (Fig. 2). However, participants' level of stride-to-stride control during BLANK did not differ from the other four conditions for either  $S_n$  (Fig. 3F),  $\delta_T$ ,  $\delta_P$  (Fig. 5D and E), or  $P_n$  (Fig. 5F). Conversely, stride-to-stride fluctuations for  $L_n$  and  $T_n$  were significantly less persistent for

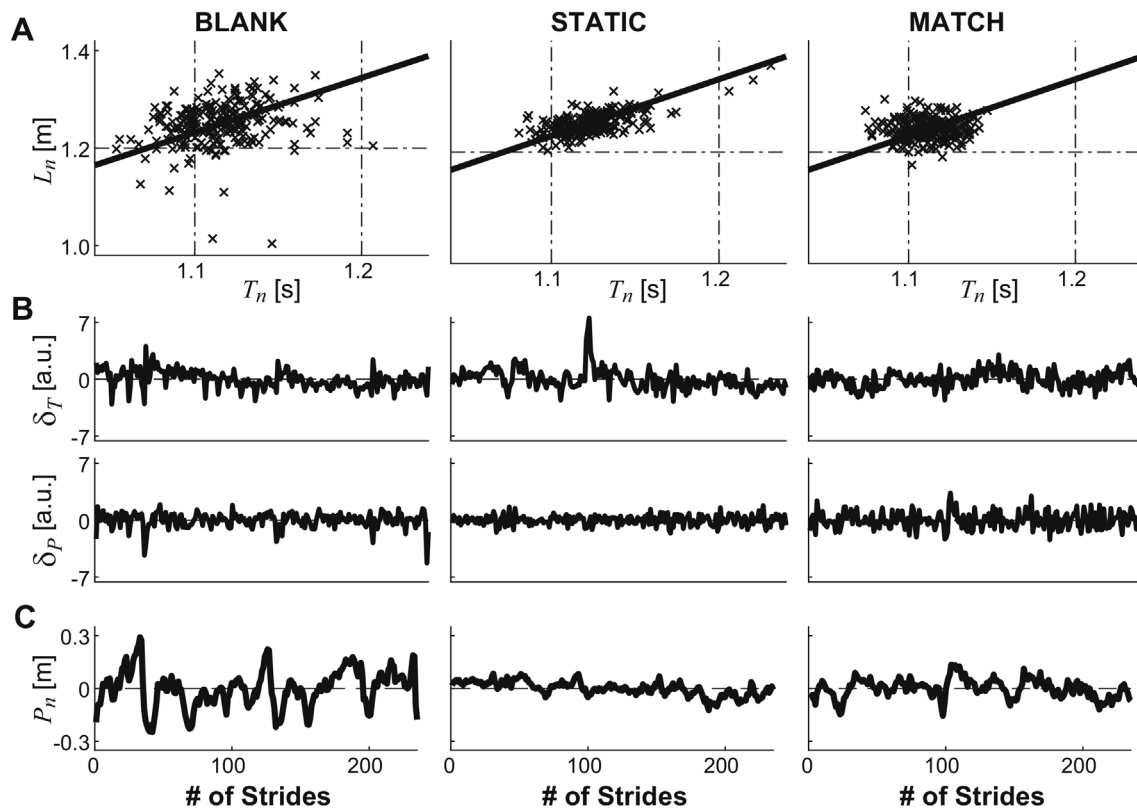


Fig. 4. Example GEM Plots and Time Series Data for a Typical Participant.

(A) Example  $[T_n, L_n]$  data from a typical participant for the BLANK, STATIC, and MATCH conditions. Each individual symbol ('x') represents an individual stride  $n$ . The solid diagonal line represents the speed GEM ( $v_w = 1.12$  m/s, see Fig. 1B). (B) Time series of  $\delta_T$  and  $\delta_P$  deviations for the data shown in (A). Qualitatively,  $\delta_T$  deviations exhibit larger amplitudes compared to  $\delta_P$  deviations across these experimental conditions. Additionally, the STATIC condition appears to have smaller and larger amplitudes of  $\delta_P$  and  $\delta_T$  deviations, respectively, compared to the MATCH condition. (C) Time series data of absolute treadmill position  $P_n$  for the data shown in (A–B). Qualitatively, this participant exhibited substantial deviations in absolute position that were sustained across multiple strides and suggests very strong statistical persistence. Additionally, the magnitude of this “drift” was larger in the BLANK condition compared to the STATIC and MATCH conditions.

BLANK compared to STATIC. Thus, while participants still generally employed the strategy to maintain stride speed ( $S_n$ , or equivalently  $\delta_P$ ), *how* they achieved this (i.e., by correcting  $L_n$  &  $T_n$  deviations relative to their mean values) was significantly altered, as indicated by increased active stride-to-stride correction (Fig. 3D and E). This made them, on average, less successful at maintaining constant speed over the long term (Fig. 3C). Further, participants also exhibited significantly greater variability for both stepping movements (Fig. 3A–C) and position on the treadmill (Fig. 5C) in BLANK compared to the optic flow conditions. Participants did wear goggles to block the lower visual field only in this BLANK condition. Visual information from the lower visual field can be important, particularly when walking over terrain that is irregular or unpredictable [28]. Here, however, participants walked on a continuous flat surface and were instructed to look straight ahead at a very large screen. Likewise, humans elicit all available visual information from their fields of view to control locomotion [29]. Thus, we anticipate that having participants wear these goggles likely had little effect and did not contribute to the substantial stepping differences observed in the BLANK condition compared to the other conditions.

Trying to maintain speed is only one of *many* possible strategies that can successfully achieve treadmill walking [6]. For example, one valid alternative might be to try to stay in the same position on the treadmill. Maintaining either constant-speed or constant-position leads to the same *average* speed and position. However, these stride-to-stride control strategies predict very different fluctuation *dynamics* (i.e., standard deviations ( $\sigma$ ) and DFA ( $\alpha$ ) exponents) for both speed ( $S_n$ ) and position ( $P_n$ ) [7]. In the present study, across all conditions, participants did not tightly regulate ( $\alpha > 1/2$ )  $P_n$  deviations. Instead, healthy participants exhibited deviations in  $P_n$  that were sustained across multiple strides

(Fig. 4C), indicating very weak regulation of position [7]. However,  $P_n$  variability was lowest in the STATIC condition, increased as optic flow speed increased, and was greatest in BLANK when all visual references were removed (Fig. 5C). While participants did not change how they *regulated* these fluctuations from stride to stride (Fig. 5F), the variability data demonstrate optic flow affected how effective they were at maintaining position. Although healthy adults choose to maintain constant stride speed at each stride and not constant position, decreased absolute treadmill position variability suggests participants were better able (on average, Fig. 5C) to detect small treadmill position changes during the STATIC condition compared to the other four conditions, again in a manner consistent with Weber’s law. Both the speed and position effects indicate that the temporal characteristics of optic flow significantly influence the ability of healthy adults to detect and regulate these small stepping fluctuations.

Optic flow influenced both how *quickly* humans corrected stride speed deviations and how *successful* they were at minimizing stride speed and treadmill position variability. These findings provide greater understanding of how experimental optic flow modulations may or may not influence stride-to-stride stepping strategies.

#### Conflict of interest statement

The authors declare that there are no conflicts of interest associated with this work.

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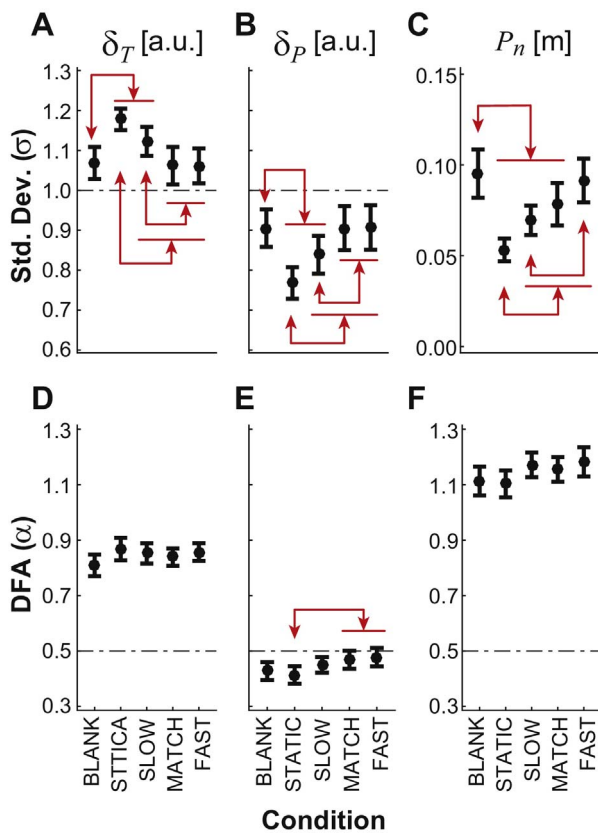


**Fig. 5.** Variability ( $\sigma$ ) and Statistical Persistence ( $\alpha$ ) of both  $\delta_T$  and  $\delta_P$  deviations and Absolute Treadmill Position ( $P_n$ ).

(A–C) Within-trial stride-to-stride variability (standard deviations:  $\sigma$ ) exhibited during each experimental condition (BLANK, STATIC, SLOW, MATCH, FAST). (D and F) DFA scaling exponents ( $\alpha$ ) exhibited during each condition. Error bars represent between-participant  $\pm$  95% confidence intervals. Red arrows/lines indicate statistically significant differences between conditions. Participants exhibited greater variability (A) along the GEM ( $\delta_T$ ) than (B) perpendicular to the GEM ( $\delta_P$ ) across all five experimental conditions. Further, a decrease in variability of  $\delta_P$  deviations and an increase in the variability of  $\delta_T$  deviations was observed in STATIC compared to the other four conditions (BLANK, SLOW, MATCH, and FAST). Participants exhibited greater statistical persistence for (D)  $\delta_T$  than for (E)  $\delta_P$  across all five conditions. Participants' absolute positions on the treadmill ( $P_n$ ) exhibited (C) greater variability in BLANK compared to STATIC, SLOW, and MATCH, and (F) very strong statistical persistence across all conditions; indicating these deviations in absolute position were not tightly controlled.

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# Musculoskeletal Injury Incidence In Deployed Navy Active Duty Service Members (ADSM) Reporting Musculoskeletal Injuries Aboard Two United States Air Craft Carriers



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## Background

Musculoskeletal injuries (MSI) pose a significant problem for ADSM. In a 2004 study conducted on two deployed United States Navy Aircraft Carriers (carriers), Herbert and Pasque found that MSI comprised 40% to 43% of all sick call visits during combat-related deployment with upper extremities comprising the highest incidence. MSI may compromise work readiness. These injuries sustained during deployment comprise 54% of limited duty (LIMDU) assignments and are the main reason for separation and long-term disability. No current data exists on the most common MSI sustained during deployment on non-combat related tours.

## Methods

As part of a larger quasi-experimental non-randomized study data on MSI sustained aboard two naval aircraft carriers was collected. Subjects presenting to the carrier physical therapy (PT) clinic completed a baseline questionnaire during an initial evaluation. Data collected included the MSI for which participants were seeking care in addition to other MSI comorbidities. To ensure accurate diagnoses researchers confirmed the self-reported MSI by conducting PT note analysis. MSI diagnoses were further categorized by the joint involved.

## Results

A total of 195 subjects completed baseline questionnaires. Low Back Pain (LBP) (n=51) had the highest incidence followed by shoulder pain (n=50), knee (n=30), mid-back (n=14), arm/hand (n=14), neck (n=13) ankle (n=12), hip (n=6) and other (n=5). Of those reporting MSI more than half of the sample stated they had a MSI comorbidity (n=108, 55%). The most frequently reported comorbidity was mid-back (n=31) followed by, shoulder (n=28), LBP (n=27), knee (n=23), neck (n=19), ankle/foot (n=17), hip (n=10), other (n=8) and arm/hand (n=7). Of the full sample 44.2% (n=87) reported no comorbidities, 36.5 % (n=72) reported one comorbidity, 11.2% (n=22) reported two comorbidities, and 8.1% (n=16) had three or more comorbidities.

## Conclusion

This analysis found that back and shoulder disorders were most prevalent in non-combat deployed Navy ADSM. Knee injuries were also common. This is in contrast to previous findings in combat deployed Navy personnel that found a higher frequency of complaints in the upper and lower extremities. Of interest is also the finding that more than half of the participants reported a MSI comorbidity, which, in previous studies of civilians, is associated with poor outcomes. In order to identify best injury prevention strategies and inform policy makers it is crucial that MSI diagnoses and rates among deployed navy ADSM are accurate and current. Additional studies should be conducted to confirm these findings and to explore the discrepancy in findings between combat and non-combat deployed members.

### Disclaimer

The views expressed in this article are those of the author(s) and do not necessarily reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

### Ethics statement

Research data derived from an approved Naval Medical Center, Portsmouth, VA IRB [IACUC] protocol. NMCP.2014.0058

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# Mechanism of Injury for Musculoskeletal Injuries in Active Duty Service Members (ADSM) reporting to Physical Therapy aboard two naval aircraft carriers.



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## Background

Musculoskeletal injuries (MSI) pose a significant problem for ADSM and are the main reason for separation and long-term disability. Injuries occurring during deployment are an added burden due to limited physical therapy personnel and the demanding nature of the work environment. Research conducted within other branches of the military identified sports/exercise and intensive training as common mechanisms of injury (MOI). Two older studies that looked at ADSM aboard non-combat deployed aircraft carriers between 1993 and 2001 found “struck by object/aircraft” had the highest MOI incidence category. There have been no recent studies in this population that have looked at the main causes of MSI. Current and valid statistics on MOIs are crucial when determining injury prevention strategies and policy changes. Reductions in preventable MSIs have the potential to reduce health care utilization and long-term disability within this population ensuring a combat-ready force. This study reports on the feasibility of training Navy PTs to implement PBPT during deployment on an Aircraft Carrier. It is part of a larger study supported by the Office of the Assistant Secretary of Defense for Health Affairs through the CDMRP, Award No. W81XWH-14-2-0146.

## Methods

As part of a larger quasi-experimental study we reviewed study subject’s clinical notes to identify the MOI as reported by the patient during their initial PT evaluation. All MOI categories were formed using the CDC non-fatal injury definitions, prior studies that reported MOIs within the military population and investigator team decision categories based on subject answers. MOI’s were extracted and initially categorized into “pre-deployment injuries” and “during deployment injuries”. “During deployment injuries” were further broken down into work-related insidious onset, work-related specific MOIs or sports/exercise related. Work-related specific MOIs consisted of falls/slips/trips, lifting/carrying, pulling/pushing object, struck by object, manipulation of object, sudden movement and injury by other person (unintentional).

## Results

A total of 198 subjects completed an initial PT evaluation. 10.6% (n=21) reported their injury was due to an accident incurred prior to deployment. 88.9% (n=176) of reported MSIs occurred during the deployment period. One subject’s MOI was unknown. In the full sample, insidious onset MOI comprised (n=92, 46.5%) and specific MOI comprised (n=84, 42.4%). Work-related specific MOIs consisted of falls/slips/trips (n=15, 7.6%), lifting/carrying (n=15, 7.6%), pulling/pushing object (n=8, 4%), struck by object (n=4, 2%), manipulation of object (n=1, 0.5%), sudden movement (n=1, .5%), injury by other person unintentional (n=1, 0.5%), and awkward working position (n=1, 0.5%). Sports/Exercise related MOI’s during deployment were report by nearly 20% of the sample (n=38).

## Conclusion

Although almost half of the ADSM reporting to PT had injuries with an insidious onset, a large number of injuries reported were work related and have the potential to be reduced through work and exercise injury prevention education. Falls and lifting comprised two thirds of specific MOIs. Proper lifting techniques should be reinforced and the work environment should be evaluated to reduce falls/slips. Also, with close to 20% of injuries caused by sports participation in the deployed environment it is critical that ADSM are educated in proper exercise safety techniques during recreational time on deployments.

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## INTRODUCTION

- Approximately 34% of all casualties in Afghanistan and Iraq experienced injuries to the extremities, with over 1600 individuals surviving with an amputation of at least one extremity.
- Standardizing the collection of outcome measures at Military Treatment Facilities (MTFs) and Veterans Administration (VA) hospitals could help to ensure consistent care across sites/organizations, timely progression through the rehabilitation process, and allow effective tracking as Service Members transition back to their units, the VA, or the civilian sector.
- Purpose:** Determine the test-retest reliability of an “Extremity Trauma Toolbox” of outcome measures that is intended to provide a comprehensive assessment of physical, psychosocial, and quality of life in Service Members and Veterans with extremity trauma.

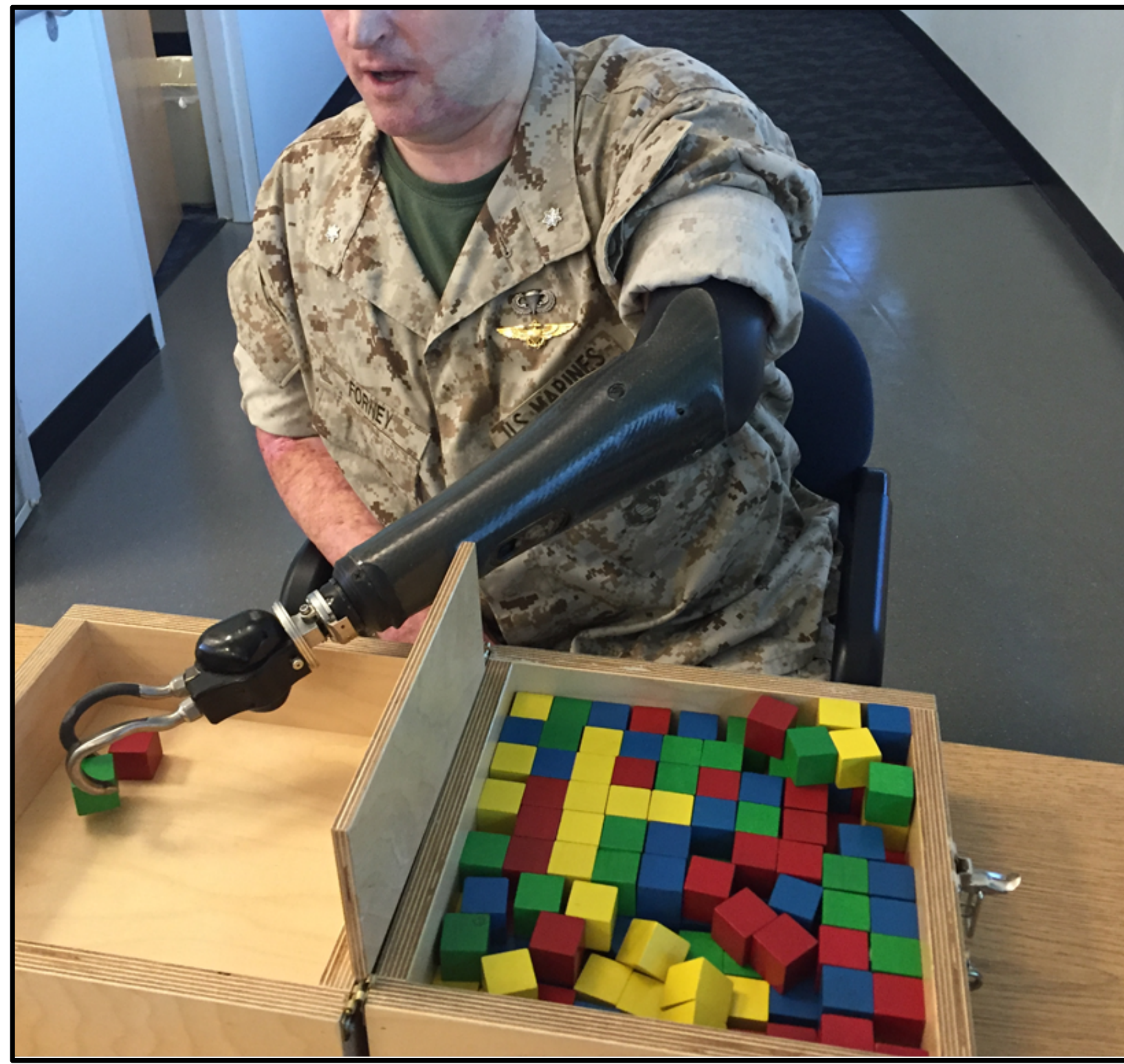


**Figure 1.** Service Member completing Box & Block Test, a performance measure.

## METHODS

- Participants:** Those with upper extremity (UE) or lower extremity (LE) traumatic injuries and/or major limb amputation were enrolled from the San Antonio Military Medical Center, Naval Medical Center San Diego, Walter Reed National Military Medical Center, and James A. Haley VA in Tampa, Florida.
- Measures:** Separate measures administered for UE and LE injuries; supplemental measures given for amputation or specific function; quality of life and community reintegration measures completed by both UE and LE participants (Figure 2).
- Design:** Prospective, repeated-measures study. Participants completed all tests two times with within 14 days.
- Analysis:** Reliability evaluated using interclass correlation coefficient (ICC); ICC values > 0.75 considered “excellent,” 0.40-0.74 “fair to good,” and < 0.40 “poor.” Minimal Detectable Change (MDC) calculated using the retest assessment data, as an indicator of the smallest amount of meaningful score change based on 95% confidence interval.

## OUTCOME MEASURES

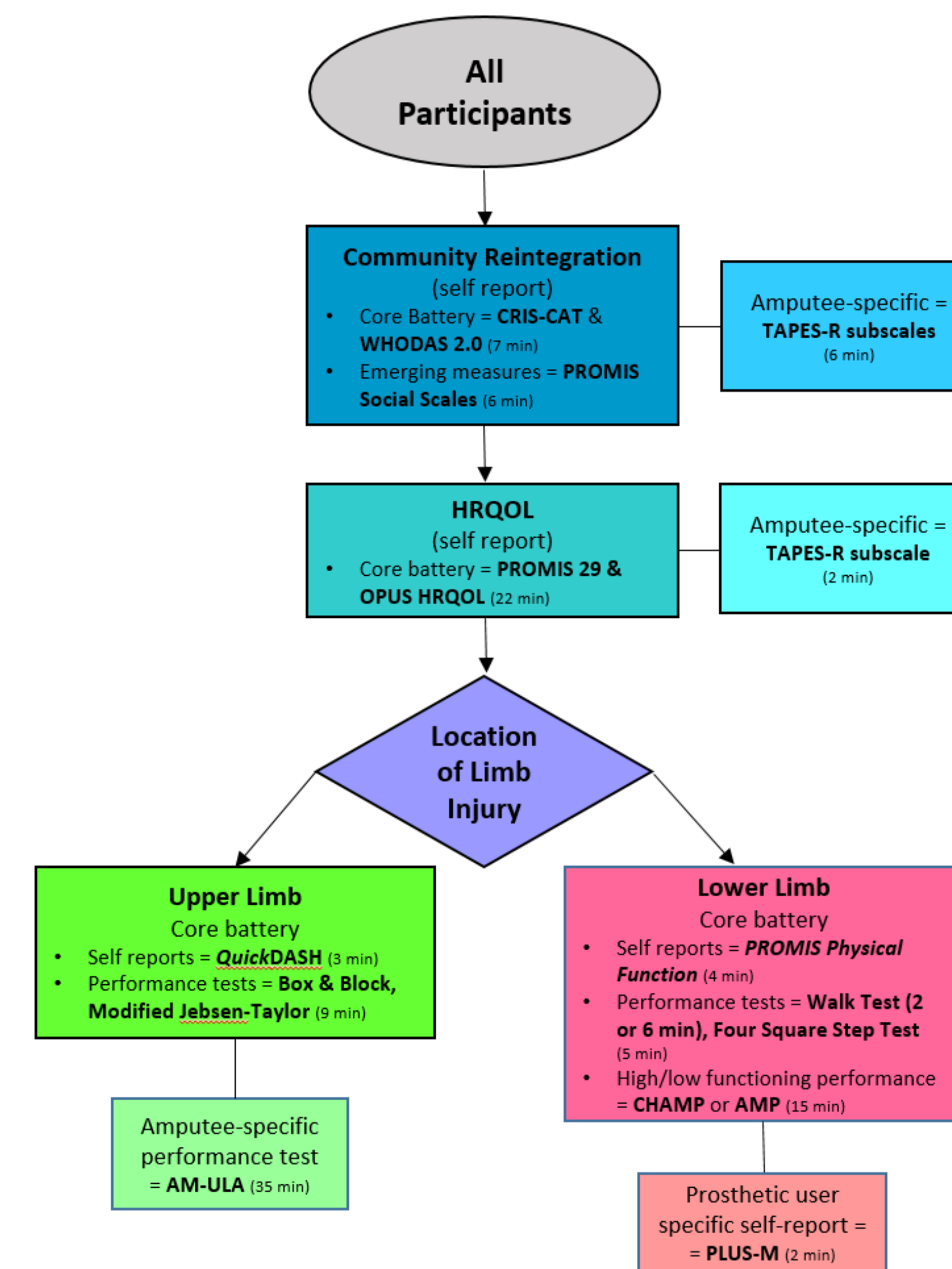


**Figure 2.** Components of the Extremity Trauma Toolbox. Data are reported for UE Surveys and Performance Measures and LE Surveys only.

## RESULTS

- Fifty-nine individuals (47 UE, 12 LE) were enrolled in the study and completed the Toolbox measures (n = 54 men, age 35.0 ± 9.8 years, 39% Active Duty).
- MDC values are provided below as an indication of the smallest, statistically meaningful score change on each measure for this population.

### Performance-Based Assessments

| Instrument                | MDC   |
|---------------------------|-------|
| Box & Block               | 18.64 |
| MJTHFT: Light Objects     | 0.42  |
| MJTHFT: Heavy Objects     | 0.40  |
| MJTHFT: Stacking Checkers | 0.40  |

### Reintegration/Function

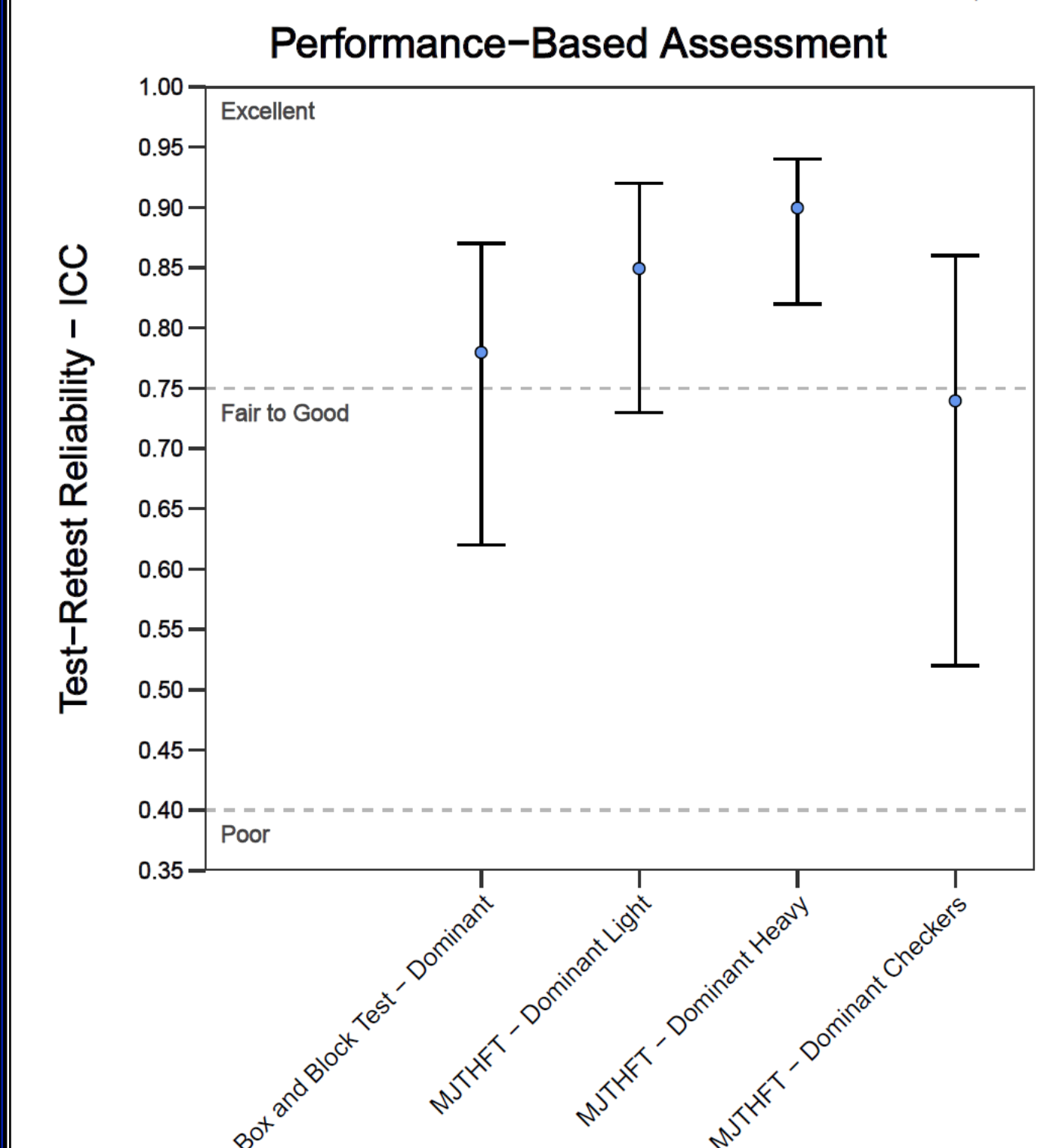
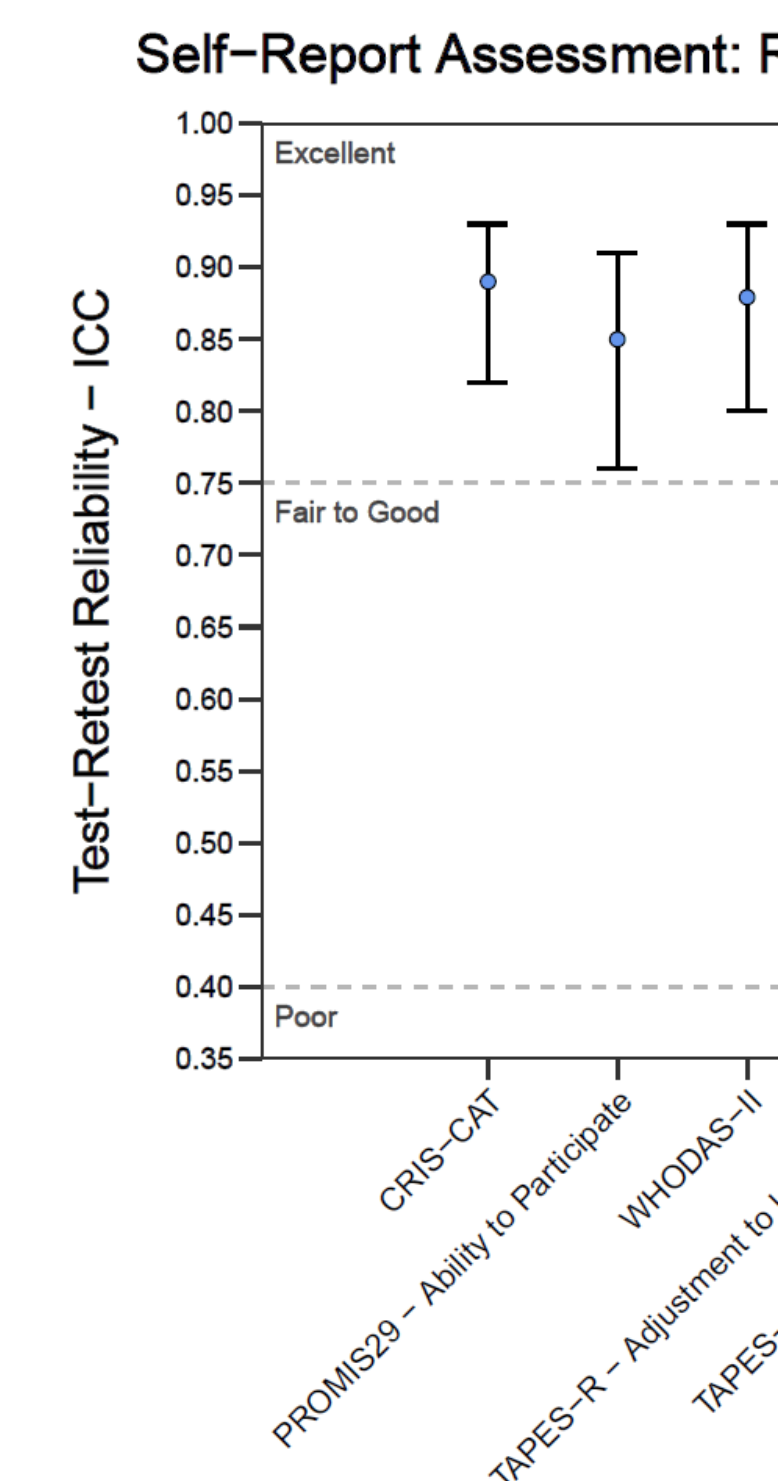
| Instrument                         | MDC   |
|------------------------------------|-------|
| CRIS-CAT                           | 8.04  |
| PROMIS 29: Ability to Participate  | 8.39  |
| WHODAS-II                          | 6.80  |
| TAPES-R: Adjustment to Limitations | 1.33  |
| TAPES-R: Social Adjustment         | 0.66  |
| PROMIS 29: Physical Function       | 8.38  |
| QuickDASH                          | 17.96 |

### Health-Related Quality of Life

| Instrument                   | MDC   |
|------------------------------|-------|
| OPUS HRQOL                   | 11.71 |
| PROMIS 29: Anxiety           | 10.48 |
| PROMIS 29: Depression        | 9.87  |
| PROMIS 29: Fatigue           | 9.72  |
| PROMIS 29: Pain Interference | 7.93  |
| PROMIS 29: Sleep             | 9.18  |
| TAPES-R: General Adjustment  | 0.72  |

## RESULTS

- Mean values did not differ between se  
measures demonstrated excellent test



## CONCLU

- Preliminary results demonstrate that t  
excellent test-retest reliability.
- Further effort is warranted to examine  
used to guide clinical practice, and a  
administrators and providers in m  
continuity of care between sites,  
reintegrating Service Members and Ve

### Acknowled

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A. Haley Veterans' Hospital, the Naval Medical C  
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Purpose of this Research:

- Limb trauma is a common cause of injury for military service members on and off the battlefield
- These injuries can lead to amputation or limb preservation surgeries, and represent a significant source of disability
- Currently there is no standard process for evaluation and monitoring of rehabilitation progress for this population



- This project sought to develop a comprehensive **Toolbox** of assessments to capture and track outcomes and establish Common Data Elements
- Focused on primary domains of community reintegration, quality of life (QOL), and upper and lower limb functioning and limitations

Measure Selection:

- Collaboration of researchers, clinicians, and leadership at Department of Defense (DoD), Department of Veterans Affairs (VA), and civilian/academic sites.
- Rigorous systematic review of the literature using Medline, PubMed, and CINAHL.
  - Reviewed 12,984 articles.
  - Identified 204 potential measures for consideration.
- Then, held two expert consensus meetings.
  - Interactive, virtual meetings with participants across the U.S.
  - Participants were 58 expert stakeholders from across the DoD, VA, and academic research settings.
  - Presentation of the evidence for well-supported measures as well as “emerging measures.”
  - Solicited direct input from experts and gathered feedback.
  - Criteria considered included psychometric characteristics, history of use with orthopedic trauma populations, and burden for examiners and patients.
- Selected 18 measures for the **Extremity Trauma Toolbox**:
  - Separate measure sets for upper- and lower-limb injuries.
  - Supplemental measures for in-depth evaluation (e.g., amputation-specific or higher/lower levels of physical ability).
  - Quality of Life and Community Reintegration measures are applicable to both upper- and lower-limb injuries.

Component Parts of Extremity Trauma

| Upper Limb Battery                                                                  |                                                                                                                         | Lower Limb Battery                          |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| Function/Activity                                                                   |                                                                                                                         |                                             |
| core performance                                                                    | Box and Block Test (3 min.)                                                                                             | Timed Walk Test (2 min.)                    |
|                                                                                     | Modified Jebsen-Taylor Hand Function Test (M-JTHFT) (6 min.)                                                            | Four Square Step Test (2 min.)              |
|                                                                                     | Subtests: Stacking Checkers;                                                                                            |                                             |
|                                                                                     | Lifting large, lightweight objects;                                                                                     |                                             |
|                                                                                     | Lifting large, heavy objects                                                                                            |                                             |
| core self-report                                                                    | Quick Disabilities of the Arm, Shoulder and Hand (QuickDASH) (3 min.)                                                   |                                             |
| PROMIS Physical Function item banks: Physical Function; Mobility; Pain Interference |                                                                                                                         |                                             |
| high-functioning performance*                                                       |                                                                                                                         | Comprehensive High Functioning Arm (CHFA)   |
| low-functioning performance*                                                        |                                                                                                                         | Amputee Mobility Predictor (AMP)            |
| amputee-specific performance*                                                       | Activities Measure for Upper Limb Amputees (AM-ULA) (35 min.)*                                                          |                                             |
| prosthetic user-specific self-report*                                               |                                                                                                                         | Prosthetic Limb Users' Questionnaire (PLUQ) |
| Community Reintegration                                                             |                                                                                                                         |                                             |
| coreself-report                                                                     | Community Reintegration of Injured Service Members (CRIS), Perceived Limitations of Activities Scale (PLAS)             |                                             |
|                                                                                     | World Health Organization Disability Assessment Schedule 2.0 (WHODAS-2.0), 12-Item Short-Form Health Survey (SF-12)     |                                             |
| emerging measures self-report                                                       | PROMIS Scales: Ability to Participate in Social Roles and Activities; Satisfaction with Social Roles and Activities     |                                             |
| amputee-specific self-report*                                                       | Trinity Amputation and Prosthetics Experience Scale, Revised (TAPES-R), Social Adjustment and Satisfaction Scale (SASS) |                                             |
| HRQOL                                                                               |                                                                                                                         |                                             |
| core self-report                                                                    | PROMIS 29-Item Health Profile (PROMIS-29) (14 min.)                                                                     |                                             |
|                                                                                     | Orthotics and Prosthetics Users' Survey (OPUS), HRQOL m                                                                 |                                             |
| amputee-specific self-report*                                                       | TAPES-R General Adjustment subscale (2 min.)*                                                                           |                                             |
| Total Time                                                                          |                                                                                                                         |                                             |
| core measures                                                                       | Performance – 9 min.                                                                                                    | Performance – 11 min.                       |
|                                                                                     | Self-report – 34 min.                                                                                                   | Self-report – 31 min.                       |
| supplemental                                                                        | Performance – 35 min.                                                                                                   | Performance – 15 min.                       |
|                                                                                     | Self-report – 8 min.                                                                                                    | Self-report – 8 min.                        |

Core measure \*Supplemental measure

Pilot Study & Next Steps:

- After measure selection, standardized administration procedures were developed, including equipment, instructions, scoring rubrics.
- Training materials were developed for teaching the standardized administration to users from various backgrounds (e.g., researchers, clinical therapists, etc.).
- Formal training was conducted and then pilot data gathered from a sample of 59 participants from across the country (n = 59).
- Results document acceptability and feasibility of the Extremity Trauma Toolbox.
- **Next Steps:**
  - Derive clinically relevant cut scores for the Extremity Trauma Toolbox.
  - Evaluate and confirm the validity and reliability of the Extremity Trauma Toolbox with a military service member sample with heterogeneous etiologies of upper and lower extremity trauma.
  - Develop integrated dissemination activities and platforms for implementation in DoD, VAs, and civilian settings.

Acknowledgements:

- All research presented here complied with the APA ethical principles regarding human participant research at the participating site.
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- The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of the Department of Defense, the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of Defense, the Department of Veterans Affairs, or the U.S. Government.

BACKGROUND

- For persons with transtibial limb loss, powered ankle-foot prostheses (POW) can improve metabolic efficiency by normalizing step-to-step transition work [1,2].
- However, these prior evaluations have primarily focused on high-functioning individuals. The effects of such POW devices for individuals at a lower functional classification (i.e., Medicare Functional Classification Level (MFCL) - 2 and MFCL - 3) are unclear.
- POW are not recommended for MFCL-2 ambulators due to inability to vary cadence (a requirement for POW setup). However POW may still provide gains in mobility and efficiency for those able to complete the programming aspect.

**Purpose:** To evaluate metabolic efficiency and associated biomechanical outcomes, with a POW and unpowered ankle prostheses (UNPOW) among individuals with transtibial limb loss at MFCL-2 and MFCL-3.

**Hypothesis:** Consistent with prior work, POW (vs. UNPOW) would produce greater prosthetic limb push-off work, less intact limb collision work, thereby improving metabolic efficiency.

METHODS

**Participants:** 8 males with transtibial limb loss (Table 1) participated following informed consent to procedures approved by the local IRB.

Table 1. Mean (SD) participant demographics.

| Participant Characteristics |             |
|-----------------------------|-------------|
| Age (year)                  | 68 (14)     |
| Stature (m)                 | 1.76 (0.04) |
| Mass (kg)                   | 94.5 (13.0) |
| Time (months)               | 200 (284)   |
| AMP Score                   | 37 (5)      |

Time indicates duration since amputation, AMP = Amputee Mobility Predictor. Note: K2: AMP = 27-36; K3: AMP = 37-42

Procedures:

- Wearing an UNPOW and then POW device (minimum 9 day acclimation period), participants completed:
  1. Metabolic Evaluation: Measured O2 consumption (Oxycon Mobile; CareFusion) during 5 min treadmill walking at self-selected pace (SSP). Gross metabolic cost was calculated by normalizing O2 with SSP during last 2 min of steady-state walking.
  2. Biomechanical Evaluation: Calculated transitional (Figure 1) external mechanical work [3] and joint work, from data collected along a 15-meter walkway using a motion capture system (Qualisys) and 6 force platforms (AMTI). Subjects walked at a 0.7, 1.0 or 1.3 m/s forced pace (whichever was closest to over ground SSP).
  3. Prosthetic Evaluation Questionnaire (PEQ) [4] to assess prosthetic-related changes in quality of life.
- Paired t-tests were used to compare all outcomes between UNPOW and POW conditions (P<0.05).



Figure 1. Step-to-step transition with intact limb leading and prosthetic limb trailing.

RESULTS

- Participants selected a similar (p=0.64) over ground speed (UNPOW = 1.06±0.27 m/s; POW = 1.04±0.22 m/s).
- Step-to-step transition work was not different between UNPOW for the intact limb when leading (p=0.19) or the prosthetic limb when trailing (p=0.37; Figure 2a).
- Trailing prosthetic ankle work increased when using POW vs. UNPOW, but prosthetic-side hip work decreased and prosthetic-side knee work became more negative (Figure 2b).

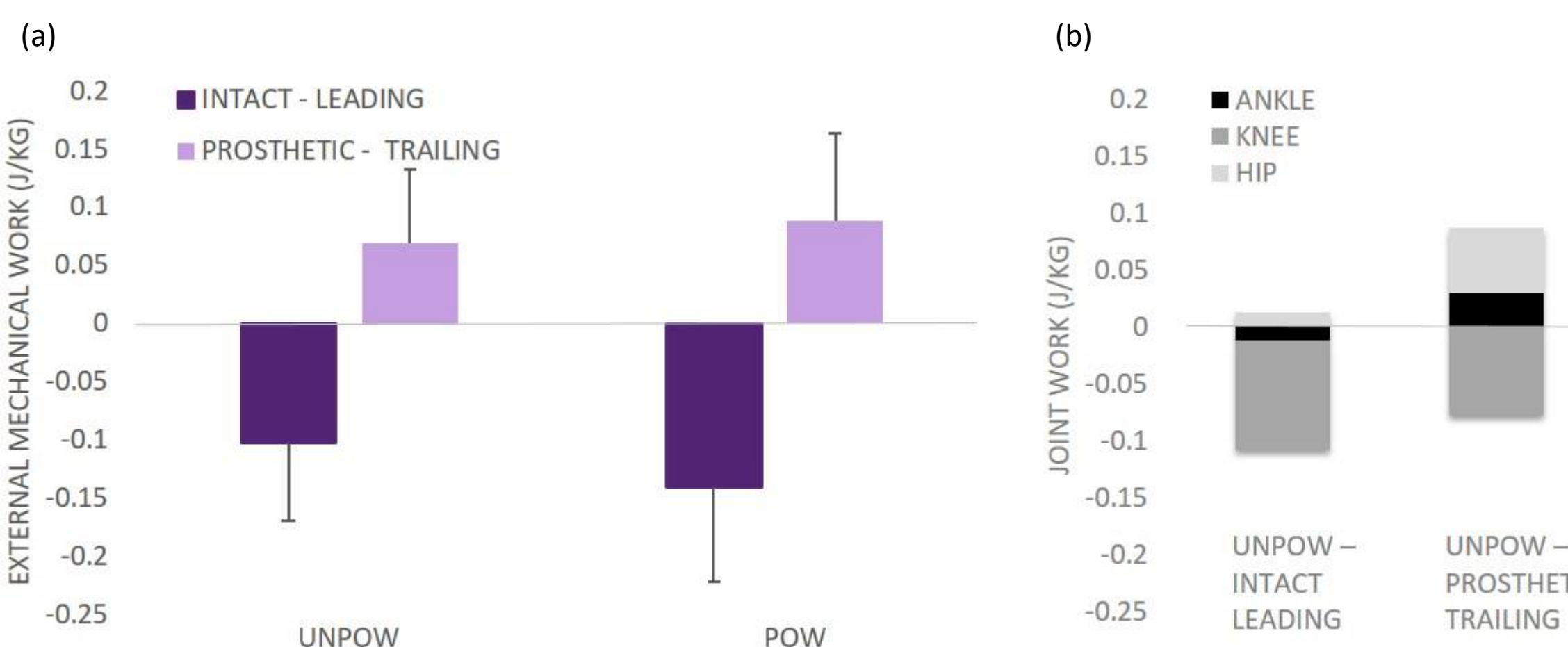


Figure 2. Transitional individual limb external mechanical work (a) and joint work (b) calculated during the UNPOW and POW conditions.

- Metabolic efficiency was not different (p=0.48) between UNPOW (0.255±0.087 ml/kg/m; POW = 0.259±0.087 ml/kg/m).
- Overall user satisfaction did not change (p=0.20) between UNPOW (80.7±9.8; POW = 86.4±11.8).

CONCLUSIONS

- In contrast to our hypotheses and previous work in higher-functioning individuals, there was no difference in individual limb external work, nor metabolic efficiency between the POW v. UNPOW conditions.
- An increase in trailing prosthetic ankle work is dissipated by more negative trailing prosthetic-side knee and hip work, leading to no change in trailing prosthetic limb work during POW (v. UNPOW).
- An increase (from UNPOW to POW) in negative leading prosthetic external work (Figure 2a) may be due to soft-tissue contributions, since summed intact limb joint work did not become more negative.
- Overall, these preliminary results suggest individuals with limb loss at lower (vs. higher) MFCL likely utilize different strategies when walking with a POW vs. UNPOW device.
  - However, alterations in lower-extremity motor patterns (e.g., redistribution of joint powers) with a POW device (and deficits/pathologies [5,6] may necessitate additional considerations in device programming for this population).
- Additional participants and (comprehensive) longitudinal studies will help clarify guidelines for initial prescription and long-term as clinical expectations over the longer term.

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