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<b>13. SUPPLEMENTARY NOTES</b>						
<b>14. ABSTRACT</b> 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. This will be accomplished by advancing each of the following strategic areas: 1: Strengthen and support orthopaedic rehabilitation research capabilities through infrastructures and partnerships; 2: Conduct a variety of innovative, high impact, and clinically relevant research studies; 3: Establish a self-sustaining research enterprise by broadening the scope of impact and support for the BADER Consortium. <b>Key Accomplishments to date:</b> Established: Administrative Core, Clinical Research Core and Scientific Technical Cores; approval and establishment of eight clinical research projects; development and implementation of an Omnibus CRADA; established a consortium-wide omnibus PDMS; partnership with the DoD and VA's Extremity Trauma and Amputation Center of Excellence (EACE); developed research focus (gap) areas in partnership with EACE; established and implemented a complete process for the call, submission, review and selection of Consortium funded projects; published the annual BADER call for clinical research proposals, established the BADER Consortium SOPs; completed the hiring of eight research support staff to be placed onsite at MTFs; established partnerships with the VA and NIH; obtained over \$4M of external funding						
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## Introduction

### The BADER Consortium

The **overarching goal** of the BADER Consortium is to Bridge Advanced Developments for Exceptional Rehabilitation. The omnibus consortium model system, as opposed to a project centric model, focuses on the rapid forming and execution of many projects within broad research initiative areas. It avails to investigators unique human resources recruitment processes, incorporates innovative strategies including an omnibus CRADA and is uniquely suited to being a vehicle for technology companies to propose clinical trials for highly advanced technologies. 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

If developing research cooperation between a civilian organization and a government agency is considered by most to be a challenging endeavor, establishing an effective and dynamic research Consortium across multiple agencies, academic centers, and industrial leaders would be considered daunting. To tackle this task, the BADER Consortium has established a series of model omnibus administrative and research tools and standard operating procedures. Fundamentally, these tools and associated policies and procedures support partnership building, streamline the project initiation process, strengthens the project execution phase, enhances the scope and impact of research while ensuring protection of critical assets such as the US Governments rights to intellectual property and data, patient confidentiality, and protection of human subjects.

This report describes how the BADER Consortium has made progress based on the approved Statement of Work for the period September 29, 2014 – September 28, 2015.

Research accomplishments to date based on Statement of Work

## **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 – months 1-60
  - 1b. Ensuring all Military Treatment Facilities (MTFs) receive infrastructure support as required including procurement of materials, personnel, equipment – months 1-60
  - 1c. Manage costs supporting the Cores and Clinical Study Sites – months 1-60
  - 1d. Perform quarterly financial audits for compliance – months 1-60
  - 1e. Maintain files for internal or external audit purposes – months 1-60
- Provided financial oversight of the Consortium.
  - Quarterly financial audits of the BADER Consortium have had no significant findings.
  - Complete and accurate files have been kept for internal and external auditing purposes.
  - Charges from the BADER Consortium were randomly selected for audit under the annual University of Delaware A-133 audit. Back-up for selected expenses was submitted to the Research Office for audit review. This University-wide annual audit is routine for compliance with federal regulations.
  - Developed Consortium budget for no cost extension year.
  - Provided infrastructure support to NMCS D (lab equipment); CFI (software license renewal); WRNMMC (small lab expenses)

### **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 – months 1-60
  - 2b. Provide support as needed for labor relations actions – months 1-60
  - 2c. Manage payroll function for UD employees (at UD and MTF sites) – months 6-60
  - 2d. Work with Steering Committee to develop appropriate job descriptions – months 1-3
  - 2e. Manage recruitment activities of personnel – months 1-60
- Received notification from CAPT Rosenthal (NMCS D) that Shawn Farrokhi, PhD and Marilyn Wyatt will be co-MTF representatives.
  - NMCS D (Farrokhi) has requested a new Research Physical Therapist position. With other savings realized in the budget, we are able to meet this request.
  - Steve Jamison, limited term researcher working at Spaulding, was given notice of termination effective October 31, 2015 due to the end of his three-year, Limited Term Researcher contract.
  - John David Collins will complete his coursework at University of Delaware in December 2015 and will return to NMCS D in January 2016. Arrangements have been made to have him work in Ms. Wyatt's lab with doctoral research training oversight provided by Dr. Farrokhi.

- We have received approval from CDMRP to recruit CAPT (ret) Ziemke into a Limited Term Researcher position at NMCP. This recruitment action has also received NMCP legal approval. Mr. Ziemke retired from NMCP on May 28, 2015. Having CAPT Ziemke as a BADER employee will provide the opportunity to continue the development of the research program at NMCP.
- NMCS D protocol coordinator. This position was vacated by Amanda Branick in Spring 2015. Dr. Stanhope has discussed the concerns with refilling the position with CAPT Rosenthal.
- Recruited Elizabeth Husson into the Research Associate position at WRNMMC.
- Recruited Adam Yoder into the Gait Lab Engineer position at NMCS D.
- Recruited Simon Brown into the Protocol Coordinator position at BAMC.
- Renewed the Limited Term Researcher appointment of Dr. Hiebert, Research Associate at NMCP.
- Manager, Clinical Research Core (UD): The current CRC manager is working at 25% capacity and this effort has been successful to date.
- This fiscal year has seen substantial movement towards growth and sustainment. Several proposals involving BADER staff buy-out have been recommended for funding which frees up funds to provide MTFs with additional support. Having MTFs budget for staff salary on external grants promotes sustainability and research programs.
- All BADER CRC staff are currently funded 5% on supplemental funds (F&A) to allocate time to support grant writing activities that cannot be charged directly to BADER funds.
- BADER has placed an employee at the NIH to support the CTDB implementation.
- The Administrative Core provided oversight of annual performance appraisals of CRC staff and BADER administrative staff.
- Hired Communications Specialist II. This new position is responsible for coordination and execution of a communications strategy for the BADER Consortium. This position is supported by University of Delaware F&A dollars.
- Graduate education: The first MTF employee (Collins) to enroll in the UD BIOMS PhD program will return to NMCS D in January 2016. We have received interest from 12 other MTF staff to enroll, however, funds are not currently available to support stipends for these individuals. While the University of Delaware provides waived tuition, funds are not available to support multiple stipends.

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

<b>Position</b>	<b>Location</b>	<b>Current Status</b>
Director, Administrative Core	University of Delaware	Filled, full-time
Manager, Clinical Research Core	University of Delaware	Filled, part-time
Administrative Assistant	University of Delaware	Filled, full-time
Administrative Assistant	Spaulding Rehabilitation	Vacant, not filling
Research Associate	WRNMMC	Filled, full-time
Laboratory Engineer	NMCS D	Filled, full-time
Research Associate	NMCP	Filled, full-time
Physical Therapy Assistant	BAMC/CFI	Filled, full-time
Protocol and Data Coordinator	WRNMMC	Filled, full-time
Protocol and Data Coordinator	NMCS D	Filled, full-time
Protocol and Data Coordinator	NMCP	Filled, full-time
Protocol and Data Coordinator	BAMC/CFI	Filled, full-time
Research Associate	NMCP	Recruiting CAPT Ziemke

Research Physical Therapist	NMCS D	Recruiting
Limited Term Researcher	NMCS D	Transition Collins in Jan 2016

**Problem areas related to this task:**

- The quality of the personnel in BADER funded positions has led MTFs to actively recruit them into other MTF positions. While this is a positive for sustainability and providing MTF support, it leads to a disruption of activities and additional time commitment to recruiting.
- NMCS D lost its second on-site BADER funded Protocol Coordinator. Cultural factors at the MTF have been identified that may have contributed to the departure of the second Coordinator. We are working with NMCS D (M. Wyatt) to mitigate any inherent issues and re-fill the position.

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

- 3a. Request, coordinate and submit all required technical reports – months 1-60
  - 3b. Preparation of all required financial reports – months 1-60
  - 3c. Develop templates for reports to ensure consistency – months 1-4
- Coordinated the compilation, editing and submission of annual report.
  - Oversaw timely completion of quarterly technical and financial reports.
  - Submitted progress reports on all BADER funded studies as requested by the GSC.

**Task 4: General Administrative Support:**

- 4a. Coordinate meetings, calendars, travel, etc. – months 1-60
- 4b. Facilitate communications across Consortium
- 4c. Prepare administrative documents – months 1-60
- 4d. Coordinate all official BADER correspondence – months 1-60

**4a. Coordinate Meetings:**

**2015 Government Steering Committee Meeting:** A meeting of the BADER Consortium Government Steering Committee was held February 20 2015 in Ft. Detrick Maryland. The agenda is attached as Appendix C.

**BADER Consortium Committee (BCC) meetings:** Monthly BCC meetings are held via teleconference to update Consortium members on BADER activities, receive updates from MTF representatives and Core Directors, problem solve and plan activities. A topic of recent interest from the MTF representatives the development and implementation of the human subject recruitment initiative in response to the declining number of injured soldiers returning from war. See Appendix D for composition of BCC.

**MTF Representative Teleconferences:** Individual monthly teleconferences with the MTF representatives and Dr. Milbourne have been initiated.

AMSUS Annual Meeting: Dr. Kaufman has led the planning for BADER's participation in the AMSUS annual meeting with administrative support at the University of Delaware. Planning is nearing completion for two rehabilitation-focused symposia at the 2015 AMSUS Annual Meeting, to be held December 1–4, 2015 in San Antonio, TX. This year's theme is "Federal Health, the New Normal". The theme integrates well with rehabilitation of service members to achieve optimal function following a devastating injury. There is a need for rehabilitation of service members and civilians following amputations or severe extremity trauma regardless of whether those injuries are or are not a result of battlefield trauma. A series of activities during the week of the meeting is being planned.

Details of the meeting are as follows:

### WARRIOR Symposium

There is a need for rehabilitation of service members and civilians following amputations or severe extremity trauma regardless of whether those injuries are or are not a result of battlefield trauma. This program will be dedicated to advancing rehabilitation of individuals with limb trauma. On Monday 30 November, the **WAR**fighters **R**eceiving **I**nnovative **O**rthopedic **R**ehabilitation (**WARRIOR**) Symposium will be held.

The Learning Objectives of this symposium are:

1. Gain an understanding of national state-of-the art programs that provide care and conduct research in the federal and civilian communities for patients with limb trauma
2. Recognize how advanced amputee care, rehabilitation, and research work together effectively to ensure functional capabilities and enhance quality of life
3. Define the requirements to maintain momentum and sustain the highest quality delivery of health care and research

The Program is as follows:

#### **I. Roadmap for Change**

Defense Health Board Report: Sustainment and Advancement of Amputee Care  
Maj Gen (Dr) Douglas J. Robb

#### **II. Federal Programs**

Extremity Trauma and Amputation Center of Excellence (EACE)  
LTC Owen Hill PhD, Chief- Research & Surveillance Division  
Center for Rehabilitation Sciences Research  
Col (Ret) Paul Pasquina MD, Director

#### **III. Bridge Programs**

BADER Consortium  
Steven Stanhope PhD, Principal Investigator

#### **IV. Civilian Programs**

American Orthotic and Prosthetic Association  
James Campbell PhD, CO, President  
American Academy of Orthotists and Prosthetists  
Jason Highsmith PhD, PT, CPO, President  
Orthotic and Prosthetic Group of America



Dennis Clark CPO, President  
Economic Value of Orthotic and Prosthetic Services among Medicare Beneficiaries  
Al Dobson PhD

## **V. Panel Discussion**

### Reveille Session

The Defense Health Board has made recommendations for the sustainment and advancement of amputee care. An expert panel will deliberate on how to operationalize these recommendations. Approaches for sustainment of the remarkable advancements made in amputee care during the conflicts in Iraq and Afghanistan and recommended strategies for advancing the field to maintain readiness for future conflicts will be discussed. On Friday 4 December, there will be Spotlight Event entitled “The New Normal: Sustainment and Advancement of Care for Warfighters with Extremity Trauma”.

The Learning Objectives of this event are:

1. Understand core competencies required for achieving optimal function and quality of life and the process to identify and define them
2. Be able to identify key partnerships and support structures across a variety of disciplines and sectors that are critical for advancing amputee care
3. Identify resources needed to continually advance the new normal of a world-class model of care

This event will be moderated by Fred Cecere, MD.

The panel will be as follows:

- John Shero, Director, Department of Defense and Veterans Affairs (DoD-VA) Extremity Trauma and Amputation Center of Excellence (EACE)
- Steven Stanhope PhD, Principal Investigator, BADER Consortium
- Col (Ret) Paul Pasquina MD, Director, Center for Rehabilitation Sciences Research
- James Campbell PhD, President, American Orthotic and Prosthetic Association
- M. Jason Highsmith PhD, President, American Academy of Orthotics and Prosthetics
- Dennis Clark CPO, President, Orthotic and Prosthetic Group of America
- Erik Wolf PhD, Congressionally Directed Medical Research Program

### **4b: Facilitating Communications**

Teleconference support: The University of Delaware has established three teleconference phone accounts that are available for use by all Consortium members. MTFs and other BADER constituents have used the teleconference lines extensively to conduct business.

Communications specialist: Using supplemental UD F&A funds, BADER hired a Communications Specialist II to oversee and manage a comprehensive communications strategy including social media, blogging and articles to support our sustainability phase. An important part of this communications strategy will be recruiting human subjects through social media. This is not a direct expense to the award, rather it is supported by UD F&A funds generated by BADER.

Website (bader-c.org): Launched new BADER website. Costs related to the website are not direct expenses to the award, rather it is supported by UD F&A funds generated by BADER.

Coordinated BADER's participation in UD Day in DC. This bi-annual event showcases high profile research at the University of Delaware. We are proud to note that BADER has been invited in the last two UD Day in DC events. The Delaware Congressional delegation along with government officials from numerous executive branches (NIH, DoD, NSF, etc) are invited to this event.

#### **4c: Prepare administrative documents**

Provided extensive support for the Discovery phase of lawsuit brought against University of Delaware by Esprit, LLC for not purchasing the eSphere software. Esprit Health initiated legal action against the University of Delaware and Dr. Stanhope for not purchasing the Esphere software. Esprit alleged that since Esphere was included in the proposal, that a contract was guaranteed. As previously reported, the NIH CTDB software was chosen for implementation. Several members of the Consortium were deposed and appeared for the jury trial. The production of documents under this lawsuit put considerable pressure on the BADER staff, however, it should be noted that no BADER funds were used to meet this task.

- Coordinated submission of three BADER abstracts for MHSRS:
  - ***Research clinical trials infrastructure: BADER Consortium - capable of supporting data collection, sharing, monitoring and reporting.*** Suzanne Milbourne, PhD
  - ***The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium: Reaching for Optimal Orthopaedic Rehabilitation Outcomes.*** Steven Stanhope, PhD
  - ***The BADER Consortium Master CRADA: Facilitating the Establishment and Execution of Government Funded Clinical Research Consortia.*** Rachel Strickland, MBA
  
- Provided strategic support for Defense Health Board briefing materials.
- Established partnership with team leaders at Leidos for the Homeland Defense TATs IDIQ mechanism (solicitation FA8075-12-R-0002, Leidos award: FA8075-14-D-009). The University of Delaware and BADER are exclusive team members with Leidos on this initiative. The IDIQ provides a funding mechanism to government agencies to direct dollars to entities under a limited competitive opportunity.
- Met with representatives from CISCRP to begin discussions on the Human Subject Recruitment Initiative.
- Coordinated travel arrangements and proffer letters for MTF staff to attend scientific meetings per BADER travel policy.

#### **Task 5: Policies and Procedures:**

- 5a. Develop, implement and ensure compliance of all SOPs for The BADER Consortium (months 1-60)
- 5b. Ensure compliance with all existing policies and procedures (months 1-60)
- 5c. Create a policy and procedure manual to be distributed to all BADER stakeholders (months 1-12)

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

- 6a. Management of annual project solicitation process to BADER Affiliates – months 1-48
  - 6b. Management of approved projects (financial, HR, administrative support) – months 13-60
  - 6c. Oversight of all subawards for technical and financial compliance – months 1-60
- Subcontract for the METRC/BADER Collaboration “**The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees**” has been received and fully executed.
  - Maintained all subcontracts related to research projects and cores. Issued year 4 modifications. Reviewed and approved invoices on subcontracts - subcontractors are reminded to bill on a regular basis
  - NYU/NMCP project titled “**A pilot study to test the efficacy of psychologically-based physical therapy training for treating deployed US Sailors and Marines with Musculoskeletal injuries**” was fully executed.

**Problem areas related to this task:**

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

- Delays in GSC response to BADER funded project status reports has left uncertainty for the continuation of projects past their current end date.
- Delays in invoicing by subcontractors puts overall award spending behind resulting in excess cash on hand. Subcontractors are reminded to bill timely.
- BADER has supported the development of several successful research proposals through staff time, travel support for research collaboration meetings and proposal preparation support. Despite this effort, MTFs are still guarded on providing high-level details (title, agency, investigators) of the proposals so BADER can report the activity. Being able to report this activity will help demonstrate impact of Consortium efforts.

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

- 7a. Management of IP, MP, Invention and Patent agreements – months 1-60
  - 7b. Consult with legal experts as necessary for compliance – months 1-60
- Executed amendment for NMCS D CRADA to allow the addition of the Toolbox (Tulsky) study.
  - Executed amendment for NMCP to replace CAPT (ret) Ziemke with CMDR Iveson as MTF representative.
  - Worked with University of Delaware Counsel to write language to be added to certain emails going forward to include a disclaimer we can use to lower the risk of future Esprit-like disputes with potential vendors. For emails with any potential vendor, we will use the following language:

*“Notwithstanding the contents of this or any other communication from BADER personnel, no such communication is intended to form an enforceable agreement for which BADER or the University of Delaware is liable, unless and until there is a written agreement, signed by an authorized University of Delaware agent pursuant to the University’s procurement policy. Thus neither the University of Delaware nor BADER is liable for any actions purportedly taken in reliance on the contents of the information herein.”*

Omnibus BADER CRADA: Current status of the CRADA is detailed in Table 2.

Table 2: List of current and pending BADER CRADA partners

<b>Institution</b>	<b>Date of completed agreement</b>
University of Delaware	November 7, 2012
Brooke Army Medical Center	January 3, 2013
C-Motion, Inc	September 20, 2012
Christiana Care Health Systems	October 18, 2012
Mayo Clinic	November 1, 2012
Spaulding Rehabilitation Hospital	October 11, 2012
University of Michigan	Cancelled (Tulsky relocated)
Naval Medical Center San Diego – omnibus CRADA	Rejected
Naval Medical Center Portsmouth – omnibus CRADA	Rejected
Naval Medical Center Portsmouth – Project specific	March 2014
Naval Medical Center San Diego – umbrella Navy CRADA	April 2014
Walter Reed National Military Medical Center	April 2013
Denver Research Institute (DRI) (Grabowski project)	June 2014

**Task 8: Evaluation:**

- 8a. Management of internal evaluation process – months 1-60
- 8b. Primary liaison with external evaluation service (AAAS) – months 1-60

BADER Administration has 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:**

MTF representatives appear less sensitive to disclosing research and proposal development activities. We are receiving a general sense of the contributions of the Consortium (i.e. staff, Cores) to these efforts, but the MTFs are still hesitant to provide high level details (title, agency) so we can report these activities.

**Administrative Core Problem Areas (Overall):**

Delays in EACE hiring of senior scientists. Many of our current MTF representatives are new and early career scientists focused on their individual research agendas versus driving large scale initiatives. As EACE continues to fill senior leadership positions, we hope to formalize relationships with those individuals who will have the capacity to put major initiatives in place.

## 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 (months 1-2).
  - 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 (months 2-48).
- CRC staffs continue to fully participate in and support the approval of human subject protocols. Per individual protocols as needed, authorization agreements are executed. The CRC Manager is provided “view” privileges into the protocols submitted to the UD IRB and is copied on emails addressing USAMRMC ORP review/requests of BADER-funded protocols. The process of enacting a standard work flow for reciprocal authorization continues. A template letter is available to assist PIs and their research teams in preparing for and submitting protocols according to UD policies and procedures.
  - Currently, a total of 14 protocols (12 active; across 8 investigators) have been shared with the CRC manager in IRBnet. The CRC manager continues to monitor the status of these protocols.
  - DoD announced that it will not renew its contract with IRBnet. CRC staff responded accordingly and met the dead line to download and store all IRB documents from the IRBnet system onto a secure server at their study location.
  - In addition to their assignments on BADER-funded research projects, this quarter seven CRC field staff additionally provided support for 64 “other-funded” studies. These contributions range including the completion of literature reviews in preparation of project presentations/ publications, conduct of volunteers for study participation, assisting with the preparation of research proposals, monitoring regulatory documents and processes, and assisting to evaluate and acquire lab equipment.
  - With regard to the conflicting Navy IRB, the CRC has connected with the Human Subjects Protection Scientist, Office of Research Protections (ORP), U.S. Army Medical Research and Materiel Command Fort Detrick. Together, they have initiated conversation about the design of a work-flow to efficiently move Navy Investigator protocols through the ORP review process. Based on those continued efforts, CRC staff have facilitated one Navy protocol through the Army HRPO approval process. Additionally, the CRC has facilitated the approval of a civilian/VA collaborative protocol through the Army HRPO.
  - On-site Protocol and Data Management Coordinators provided by BADER funds have gained access to and utilize the military IRB electronic systems for their assigned location. They are trained in local IRB guidelines and procedures. Each has been successful at assisting with the preparation of IRB materials and in submitting protocols through their respective IRBs.
  - The CRC Manager and Consortium Director have designed several example work flow models representing the complex and coordinated effort necessary to fully secure approval to conduct BADER-related human subjects research. These work flow models have become a mechanism for discussion with several key individuals. For example, the CRC, along with support from the Administrative Core, is coordinating with the University IRB Compliance Officer to streamline the documentation work flow process necessary to secure agreements between the University and each of the participating BADER investigator sites. The process of enacting a standard work flow for reciprocal authorization was adopted and has been applied.

- The CRC Manager and Consortium Director met with the UD IRB representative and identified three standard situations for which BADER investigators may submit to the UD IRB. These three situations are modeled and materials to support investigators have been distributed.

**Problem areas related to this task:**

- It continues to be the case that the amount of time that passes between the initial submission of a protocol through final IRB approval is, in some cases, extensive.
- The process of approving non-Army protocols through IRB review to facilitate the approval of BADER investigator protocols in a timely manner is under discussion. Formal discussions with HRPO began in May 2014.
- The disconnect between supporting the initial IRB submission process to OHRP (responsibility of the CRC Manager) and the monitoring of study human subjects approval status across the life of the protocol (responsibility of the BADER Director of Research) continues. The CRC manager, not the Director of Research, receives copies of protocol renewal email reminders that are sent from OHRP to the BADER funded PIs.

**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 (months 1-3).
- 2b. Identify and hire Consortium Protocol and Data Coordinators Managers (months 1-3).
- 2c. Identify and hire On-site Protocol Managers and Technicians for MTFs and clinical study sites (months 1-6).
- 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 (months 6-12).
- 2e. Train Consortium Protocol and Data Coordinators in modeling protocols in Data Monitoring System (months 6-12).
- 2f. Implement the Protocol and Data Management System (PDMS).
  - The CTDB Operations Core continues to engage with BADER investigators regarding the collection of data using the CTDB.
  - The Operations Core continues work to establish a CDTB question bank to support the creation of electronic data forms specific to the collection of orthopaedic rehabilitation variables. It has also generated a method for DOD study investigators to accurately collect and enter military service personnel MOS (Military Occupational Specialty) codes into the CTDB. This development work stemmed from a request of one BADER-funded investigator but is now available to any and all BADER-CTDB user groups. Additionally, the Operations Core started to create standard data report templates and a model system for working with CTDB investigators to request and receive regular study reports.
  - It also continues to create standard data report templates and a model system for working with CTDB investigators to request and receive regular study reports.
  - The Operations Core continues to develop the “rules of engagement” in order to support non-BADER affiliated/funded investigators and to address an excess of change-requests received when modeling a protocol into the CTDB.
  - The Operations Core has initiated conversation with the NIH-Central IT (CIT) department to learn more about their research support tools: 1) protocol and data management system called BRICS and 2) a protocol tracking and monitoring system (PTMS).

- Modeled BADER-related studies into the CTDB.
- Finalized a model for requests from non-BADER investigators to model and support protocols into the CTDB; also design a model for addressing change-requests.
- Provided first level TA to those with active protocols; activate BADER administrative protocols.
- Continued the build-out of the CTDB user web portal and secure log-in BADER CTDB user web site.
- The CRC CTDB Operations Core has activated a total of six protocols in the CTDB system. Currently, two members of the CTDB Operations Core have access to the CTDB behind the NIH firewall. Access behind the NIH firewall for these two individuals has maximized the Core's ability to respond to PI request for technical assistance and data reporting.
- The leader of the NIH-NICHD CTDB team resigned from his position. To date this has not posed particular problems however, there is concern regarding the future location of the CTDB. We will soon learn if the CTDB will be moved from its current location on an NICHD server to another server within the NIH at the Clinical Center. This potential move may bring about the need to reestablish the need for the NIH to host the BADER instance of the CTDB.
- A two-year extension Collaborative Agreement between the University and the NIH-NICHD was secured.
- The CRC Manager instituted a contract with an independent contractor that currently supports NICHD CTDB to fully establish a mirror image of the NICHD CTDB environment to ensure that BADER investigators will have access to the full capabilities of the system. These capabilities include patient self-reporting abilities and full data reporting capacity. Contract activities are currently operational.
- Introductory training sessions were conducted for four new BADER-CTDB users. The BADER CTDB user portal was updated with publically accessible informational materials.
- Under the leadership of the CRC Manager, the BADER-CTDB Operations Core collaborated with the NICHD on testing a newest version of the CTDB. The Core was also successfully in collaborating with the NICHD to alter the times-of-day when data was transferred from the CTDB "front" to a data-warehouse. This change was necessary to address the various time zones in which BADER investigators function (ET, CT, PT) and allowed uninterrupted access to the "real-time" data entered into the CTDB.
- UD has embedded a BADER staff member at NIH to support CTDB implementation.
- The Operations Core continually updated the CTDB user portal (publicly available materials) and the secure BADER-web site "Boost-up" material repository. This repository contains instructional materials specific to BADER CTDB users. Most recently the Core created a process for BADER affiliates to request assistance with converting video files for display/presentation when using Adobe Connect the primary on-line virtual meeting software program regularly used by BADER Clinical Research Core team members and their affiliate site research teams.
- The CTDB Operations Core has begun to collect considerations for the design of a business plan in order to support non-BADER affiliated/funded investigators and to address an excess of change-requests received when modeling a protocol into the CTDB.
- The Operations Core in collaboration with the NICHD recorded and produced eight videos. The videos will be used to provide introductory and basic level instructions for CTDB users. The intent is for the videos to be made accessible directly from within the CTDB system through an easily accessible link in the CTDB toolbar.
- The new quality assurance process developed has been instituted with the first two protocols and has resulted in an efficient and effective mechanism for both CTDB administrators and the investigators. This process will be instituted with all new protocols modeled into the CTDB.
- Work continues on the development of the user materials. A CTDB web portal has been built (<https://sites.google.com/a/udel.edu/bader-ctdb/>) and is continuously being updated with user materials.

- We created an identity for the key CRC personnel who support the implementation of the CTDB, now called the CTDB Operations Core. This Core consists of the CRC Manager, the IT Consultant and the Master Protocol Administrator. Modeling a protocol starts with a meeting of the Principal Investigator and the Master Protocol Administrator to discuss the research project and how it will can best use the BADER CTDB. It is the first step in an iterative process of designing and setting up the research protocol and associated data collection forms in the CTDB. The interview is an information-gathering meeting where the Master Protocol Administrator asks about specific characteristics of the protocol design. It also provides the PI the opportunity to learn more about CTDB functions and to see if particular ones will complement and benefit the protocol data management.
- We opened the CTDB user portal to the BADER community. The portal is designed to assist end-users with various related tasks including adding patients to the data base; generating a unique identifier for each patient; and entering patient data.
- The CRC requested and collaborated with the Administrative Core to establish a “Virtual Collaborative Environment” (VCE) webpage on the BADER website <http://bader-c.org/virtual-collaborative-environments/> . This VCE page describes the opportunities for BADER investigators and affiliates to access the variety of options for collaborating across sites and geographic regions. This page also includes the request for video conversion services recently established and reported in the previous quarter.
- In this quarter BADER CTDB “Huddle Up” sessions continued to be scheduled on the first Wednesday of each month. Session topics included: CTDB patient screening record and how it is being used across the various studies; practice using the CTDB Quality Assurance tools; “double key data entry”; sample management and labels; steps involved in adding patients to protocols, administering data forms, and optimizing workflow.

#### **CRC Staffing:**

- One CRC field-staff position is still vacant at NMCSD. The CRC Manager is working in concert with BADER leadership to determine best pathways for filling the now-vacant NMCP Protocol and Data Management Coordinator position. One CRC staff person (Jamison) assigned to a civilian study site with a BADER-funded study end date of September 30 was given 3 months notification that that his hiring contract expires on October 30. The CRC Manager provided support to make this transition as smooth as possible.
- The first of several CRC staff facilitated “learning opportunities” was conducted. One CRC member facilitated a session on conducting highly impactful literature reviews. CRC staffs are often called upon by MTF investigators to conduct reviews for scientific posters/publications and grant proposals. The topic of the second CRC staff facilitated “learning opportunity” was a session on maximizing use of the University and other publically available data bases to identify resources/materials/peer-reviewed publications.

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

- While this is improving over time, there appears to be differing expectations from the MTF about CRC staff roles and responsibilities. As a result, one CRC Protocol and Data Management Coordinator resigned when offered a position with an Investigator independent of the BADER Consortium. This particular Coordinator was only provided opportunity to partake in about half of the responsibilities listed in her job description.
- During BCC meetings MTF representatives and PIs are reporting increased challenges to recruiting human subjects. They have approved the launch and funding of a broad-based Human Subject Recruitment Initiative.



**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. (months 9-60).
  - 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. (months 9-60).
  - 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 (months 12-60).
- All CRC field staffs maintain CITI certification and site-specific training requirements relevant to study procedures for conducting research with human subjects. Individual CRC staff has completed as available on-site training at their research location. CRC staffs continue to actively participate in the monthly CTDB Huddle-Up training sessions. In this quarter five CRC staffs enrolled in and started the on-line UD Office of Professional and Continuing Studies' certificate course, Clinical Trials Management.
  - Until the third quarter, CRC staffs from each assigned study site continue to participate in a weekly conference call with the Clinical Research Core Manager to discuss issues related to human subjects research generally and specific to their study site research projects. This quarter the CRC decided to decrease weekly site-specific conference calls to 2x/month. All CRC staffs participate in a virtual meeting one-time per month to discuss a variety of topics related to the coordination and conduct of research.
  - The four CRC staff members responsible for protocol coordination, data management, and study compliance gathered for a full day meeting. The outcome of this meeting is sharing of strategies, techniques, resources, and documents that will maximize their ability to fulfill their roles and responsibilities.
  - The CRC continues to coordinate with the Outcomes Core to build into the CTDB all outcome measures identified by the Outcomes Core as commonly used and/or published measures of orthopaedic rehabilitation outcomes (legacy measures). Additionally, and inclusive of the Administrative Core, this group has tested the set-up of a web-based resource of a summary of these measures and continues to secure permission from authors to post the selected measures in a new BADER on-line resource library.
  - Individual CRC staff has completed as available on-site training at their research location.
  - Supported CRC Staff member Dr. Steve Jamison (Spaulding) to attend the US Bone and Joint Young Investigators Initiative Grant Mentoring Program in November 2014. This intensive three day workshop provided Dr. Jamison with essential grant proposal skills that led to a submission to the CDMRP Fall 2014 call for proposals. Dr. Jamison was invited to submit a full proposal, however, he was not able to obtain enough pilot data to prepare the full proposal. We congratulate Dr. Jamison on being invited to submit a full proposal on his first white paper submission to a CDMRP call for proposals.
  - A CRC staff member studied for and passed the Association of Clinical Research Professionals certification exam and is now officially a "Certified Clinical Research Coordinator". She joins two other members of the CRC who also hold this certification.
  - Coordinated and facilitated by the CRC Manger, this quarter the CRC field-staff joined together for a variety of team building activities during a face-to-face meeting.

- Work related to the collective effort regarding literature search/review assignments continues under the leadership of one CRC staff member. This team member conducted a training session during the February 2015 CRC annual face-to-face meeting. At this same meeting the CRC Manager conducted a session related to the recruitment of human subjects. As a result, a four-page document was generated and shared with all CRC field-staff and includes potential recruitment sources, recruitment strategy options, methods to maintain study subject enrollment, and methods of advertising study recruitment.
- All of the leg-work has been completed to prepare to build into the CTDB the selected outcome measures identified by the Outcomes Core.
- At their respective site, CRC staffs have engaged in discussion about modifications to human subject recruitment and retention strategies. As a result, CRC staff at some locations have prepared and submitted documents to their site IRB for approval to test or use these new strategies.
- Each CRC staff completed an individual UD performance appraisal in which they identified training goals that will enhance their professional performance and site-specific research contribution capabilities. For the first time MTF-POCs actively contributed to the UD annual performance appraisal of BADER CRC staff at their respective site.

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

- There is a perception among the CRC on-site staff that the more information/training/knowledge they gain through support from the BADER Consortium the more of a “threat” the staff become to the MTF setting. Select staff have expressed that they sense hesitancy on the part of the MTF to “trust” the research enterprise processes attempted to be implemented by BADER. For example, it is acceptable for a CRC staff member to design an Excel data base for tracking publications at the request of an MTF representative; however, it has been unacceptable if a CRC staff alternatively suggests the use of the CTDB publication built-in tracking function.

#### **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 (months 6-24).
  - 4b. Track study progress monthly and notify Administrative Core of underperforming sites and suggest solutions to improve performance (months 12-60).
  - 4c. Provide input to Administrative Core for quarterly progress reports of clinical research studies (months 4-60).
- Worked with the PIs for each active protocol to enter data into the CTDB that will offer opportunity to collect and record human subject recruitment efforts and subject enrollment and completion counts.
  - Three of the eight CRC staff provided oversight and/or mentorship to intern students from various institutions.
  - CRC staff presented a total of four abstracts at the MHSRS conference. (See below).
    - **Title:** Does a coordinated, multidisciplinary Spine Team limit medical attrition related to work disabling spine conditions in the US Navy?
      - CAPT Gregg Ziemke, Marco Campello, **Rudi Hiebert**, Shira Schechter Weiner, Christopher Rennix, Margareta Nordin
    - **Title:** A Case Report on the Effect of Real Time Biofeedback Training During Running in a Service member with a Unilateral Transtibial Amputation

- **Elizabeth Husson**, Erik Wolf, **Amanda Wingate**, Irene Davis, Alison Pruziner
- **Title:** Comparison of Patient-Reported to Performance-Based Functional Outcomes in Individuals with Unilateral Transtibial Amputation
  - **Amanda Wingate**, Pamela Kisala, Alison Pruziner, Christopher Dearth, David Tulsy
- **Title:** Gait-retraining to improve stance time asymmetry reduces knee external adduction moments: a case study of an individual with a unilateral transtibial amputation
  - Hannah M. Rice, **Steve T. Jamison**, Alison L. Pruziner, Irene S. Davis

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

- 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.

- The identification of gap research areas has been determined at our annual strategic planning meeting leading up to our calls for proposals. There will be no further BADER calls for proposals during this grant cycle. However, BADER needs to continue to be involved in the identification of Gap Areas to be addressed in future NIH and DoD calls for proposals.
- The visit to NMCP planned for this quarter to discuss potential avenues for MSK research at NMCP had to be delayed. We are continuing to await Gregg Ziemke's established employment as a retiree so he can officially do business on the facility.
- The visit to NMCS D has also been delayed. The outside running lab at NMCS D is currently being moved as they are redoing the track where it resides. Therefore, we are planning my visit for the beginning of the year. We will also be discussing potential collaborations for prosthetic running research.
- We received a proposal from a clinical trials recruitment company, BBK Worldwide. The proposed cost of this was \$65,000 and there would be no guarantee of recruitment metrics. We have therefore decided to explore other routes of recruitment including
- Providing payment to entities that see individuals with amputations, such as prosthetic offices, to identify potential participants that could then be contacted. This is currently being reviewed by both WRNMMC and Spaulding's IRB. Recruitment seems to be most problematic with the two BADER training studies due to time commitments.
- Connected Dr. Jamison (BADER Limited Term Researcher, Spaulding) with collaborators within the Boston community to work to develop a mobile app system using IMU devices to monitor the gait of individuals with amputations while ambulating in the community. We currently have a prototype system for reducing impacts during running and are working on a prototype for symmetry of loading during walking.
- Received a proposal from WRNMMC for a variety of recruitment strategies for their site. This was approved by BADER leadership and the various recruitment activities are beginning to be implemented provided IRB approval obtained.
- Human Subject Recruitment is an ongoing concern. During this period of performance, we engaged RESolutions LLC for specific support on the RETRAIN study, however, after discussions, they could not provide the services that were needed. We have engaged the Center for Information and Study on Clinical Research Participation (CISCRP) to begin discussions on a developing a nation-wide initiative. A nationwide education campaign with CISCRP may help to ensure recruitment is not a problem in the future. We have received a proposal from

CISCRP and await approval from CDMRP to execute the statement of work for this fee-for-service agreement. Drs. Wilken and Stanhope have begun discussing the formation of a committee to explore this important initiative. We have been notified by WRNMMC and BAMC that civilians will be allowed to participate in clinical trials that are deemed 'less than minimal risk.' We have asked for an official policy and have been told it is not in writing, but rather a verbal approval from the WRNMMC IRB.

- Apart from the need to recruit subjects for the current BADER studies described above, the BADER Consortium is developing a large scale Human Subject Recruitment Initiative to find solutions to the larger systemic issue of subject recruitment. We have been discussing strategies with The Center for Information & Study on Clinical Research Participation (CISCRP) a non-profit in Boston whose mission is to educate and inform the public and patients about clinical research. The B2C has been engaged in finding solutions. BADER leadership would like to engage the GSC in providing guidance moving forward with this critical initiative.
- Using supplemental funds, BADER funded and developed a research page on the Amputee Coalition's website that will extend our reach and provide a source of recruitment for BADER related studies across the US. We are currently working to develop a similar relationship with the Wounded Warrior Project to be able to recruit from within this group as well. Finally, we are beginning to connect with Team Red White and Blue as another source of wounded warriors who might benefit from the work of BADER.

**Problem areas related to this task:**

- BADER continues to assist MTFs with research team building and proposal development per requests. This quarter, the BADER Cores supported 6 research proposals. This assistance, responding to RFAs, is via a reactive mode versus a proactive mode. To encourage a proactive mode, the leadership of the Consortium is exploring ways to develop research teams across the BADER Consortium Affiliates (BCAs) to go after large scale initiatives.

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

- BADER completed Task 6 in Year 3. BADER has eight approved protocols up and running meeting the original goal of funding 6-8 projects.

## Scientific Technical Cores:

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

#### **Task 1: Assessments**

- 1a. Assessments of all MTF equipment, facilities, motion capture technologies, clinical testing processes, and quality assurance policies and procedures (months 1-6).
  - 1b. Assessment of MTF commonalities and collaborative standards and processes (months 1-6).
  - 1c. Evaluation of the MTF CAREN Virtual Reality systems for Visual3D integration and data collection support (months 1-6).
  - 1d. Evaluation of motion capture protocols, marker sets, processes, and data management (months 1-6).
  - 1e. Dissemination of collaboratively developed protocol standards to MTFs (months 6-12).
- 1d. This task has been re-opened. Dr. Selbie (C-Motion) and Ms. Wyatt (NMCS D) met in September 2015 to discuss the possibilities of developing a quality assurance application and a data analytics program based on the Visual3D cmo library.
  - All other subtasks are completed.

#### **Task 2: Standards:**

- 2a. Develop common data management pipelines, scripts, and motion analysis techniques across all MTF and clinical research labs utilizing Visual3D (months 7-12).
  - 2b. Support for “aggressive rehabilitation” protocol adaptations (months 7-60).
  - 2c. Evaluate the protocols for pooling and sharing data across institutions (months 7-60).
- Using the cmo library it will be straightforward technically to combine the cmo files from all of the MTF sites. The new Quality Assurance application and Analytics being developed will address the issue of pooling data. The data encryption algorithms will ensure the privacy of the patient information in the cmo library while not restricting access to the *sanitized* data.
  - Elaborated the report header to fully satisfy the request from NMCS D.
  - Provided the user with the ability to encrypt the text information in the cmo file.
  - Implemented a strategy for the user to expose this information in a report using a password protected login within the file.

#### **Task 3: Certifications:**

- 3a. Identify DoD processes for the implementation of initial motion analysis Certification procedures (months 7-12).
- 3b. Identify DoD processes for the implementation of additional Certification procedures (months 12-18).
- 3c. Develop Certification procedures and criteria (months 12-24).
- 3d. Initiate the establishment of Certification courses (months 12-24).
- 3e. Develop Certification courses for dissemination and implementation of the criteria (months 24-30).

- The Biomechanics Core recommends that this task be modified to focus on customized training for the MTFs, rather than certification programs. As the number of BADER staff increases and there is movement of staff between MTFs, it is critically important to train these researchers. In the future, as the number of BADER Affiliated projects increases, we will revisit the need for certification programs.

**Task 4: Support and Collaboration:**

- 4a. Collaborate with the MTF sites to implement data collection protocols for proposed experiments (months 12-60).
- 4b. Collaborate with BADER projects to implement data collection protocols consistent with MTF guidelines (months 12-60).
- 4c. Implement biomechanical model templates for the MTF and BADER projects (months 12-60).
- 4d. Implement Visual3D processing pipelines for each project (months 12-60).
- 4e. Implement Visual3D reporting templates for each project (months 12-60).
  
- 4f. Implement process and protocol management standards across MTF sites for new data analysis routines (months 25-60).
- 4g. Implement written standards (checklists) for data collection protocols (months 25-60).

**New Real-time biofeedback client for WRNMMC.**

- The Core soon expects to receive a specifications document that will initiate our development.

**Inverse Dynamics on the Caren system at WRNMMC**

- In December the Core received an inquiry from WRNMMC about the possibility to use Visual3D to perform inverse dynamics on a moving platform. This is possible and the Core offered to help.
- If WRNMMC elects to move forward with the idea of trying to compute inverse dynamics with a moving (Caren) platform the Core will help them set up the models and scripts needed to process the data in Visual3D.

**OpenSim Modeling with a prosthetic foot with some energy return**

- Consortium members have expressed interest in the development of a new Induced Acceleration Analysis (IAA) Visual3D plugin for use with prosthetic foot analysis. This quarter we generated and tested our first new Induced Acceleration plugin in over 5 years. We are now ready to handle request from University of Delaware and/or other BADER members regarding the use of IAA in prosthetic research.
- This quarter Core staff developed an additional method for exporting data from Visual3D to custom OpenSim models. This supplies support of OpenSim for use on prosthetic foot simulation and provides a general workflow for exporting data to OpenSim.
- Work has been completed updating Visual3D's Induced Acceleration plugin so that it is compatible with the latest release of Visual3d (version 5.01.25). This will allow the Core to move forward developing custom Induced Acceleration plugins for the University of Delaware for prosthetic foot analysis. Core staff also started getting C-Motion's latest software to work with non-standard SD/Fast models (SD/Fast is used to compute the dynamics in Induced Acceleration); this will allow the University of Delaware

to give us specs for custom models on which they want to conduct Induced Acceleration Analysis.

### **Mechanical Work calculations across the gait cycle.**

- No work was done on the implementation of mechanical work calculations across the gait cycle. C-Motion has yet to establish the requirements for this development because there are several options available based on the work of Max Donelan.

### **Inertial Measurement Unit (IMU) Development**

- At a request from NMCS D, Core staff initiated the development of a biofeedback application to measure trunk velocity and trunk acceleration using Delsys IMUs during a perturbation on the treadmill. Core staff with Delsys in Boston on October 23rd to initiate cooperation on the implementation of a plugin to Visual3D server for the upcoming release of their new IMUs. In addition, after the Delsys meeting core staff restructured Visual3D's IMU code to make it generalizable so that Visual3D can be easily adapted to read and use data from variety of IMUs including Delsys.
- In this quarter Core staff met with a representative from XSens, and had a follow up conversation about implementing the XSens IMUs in Visual3D. XSens has solved the challenges of synchronizing the IMU signals, and offers the best short-term chance of delivering on a biofeedback application. Regardless of whether any of the MTF's elect to purchase an XSens system, this will at least give us the opportunity to develop the application without waiting for a specific IMU system to be made available.
- Introduce the symmetry score to the labs. The Core will work with the group in NMCS D to adapt this index to be suitable for their experiments, and one that addresses the common issues noted above.
- In December C-Motion received a set of IMUs from Myon (Switzerland). The SDK received from Myon is similar to the preliminary SDK received from Delsys, which allowed C-Motion to implement the data collection module in Visual3D server and begin to develop the analytical algorithms for working with IMU data.

### **Implement Compute\_UD\_Power command into a LinkModelBased item within Visual3D**

- A new LinkModelBased command was added to Visual3D to perform a UD Power analysis. This analysis previously existed only as a (non-LinkModelBased ) pipeline command. By making the command a LinkModelBased based item, the user can now run this analysis from the Reporting Tab. More importantly the UD Power Analysis command will now automatically go into the RECALC pipeline so its output will be updated as changes are made to either the model or the processing of the original motion capture data occur.

### **Ongoing support of "Returning to High-Level Performance: Walk to Run Training with Real-time Kinetic Feedback" Protocol:**

- C-Motion has worked closely with Steve Jamison at Spaulding to adapt the biofeedback client to satisfy requested enhancements to the protocol. C-Motion addressed issues related to the sampling rate of the data collection and its effect on the update performance of the biofeedback. The Core released a new version of

Visual3D server and biofeedback client that has been tested successfully at Spaulding with sampling rates satisfactory to Spaulding, and with biofeedback performance satisfactory to Spaulding.

**Modifications to the C-Motion output graphs and tables.** These tasks were initiated per request by the lab at NMCSO.

- Time-Distance parameter page. Per NMCSO: *“We would like the data to be presented in a different graphic format where the data are plotted in boxes that define 5-95% of the normative data with the mean demarcated. We would like a “table” for the right side and a separate “table” for the left side. We would like the normative data to also be printed on the table with the patient data displayed as well. On the second page we would like a set of “boxes” that show the symmetry between right and left, in particular comparison of single stance percentage (%) and step length (cm). I also like to see the plots of the bilateral variables (stride length, step width, cadence, and velocity) side-by-side (table 4 if you will).”*
  - The Biomechanics Core has implemented the infrastructure for the new temporal-distance page in Visual3D. Tasks completed include:
    - New report item plus report dialog have been added to Visual3D.
    - Serialization (e.g. saving the information to the cmo library is complete)
    - Adding the functionality to retrieve the control data and add it to the report item is complete
    - The report item is not yet completed and is hidden from the users.
- Professional Header information. Per NMCSO: *“We need a way to put in patient information that will appear on all pages of the output as well as professional identifiers for the laboratory so this document can become part of the medical record. What we like to put in are name, age, date of study, patient number or identifier, diagnosis (es), and conditions. We need the ability to compare at least 3 condition to normative data set, 4 would be better. Maybe a designation of which normative file is being used for comparison purposes. This would be important in a pediatric setting (normal 5 year olds), but in adult labs as well where you might want to use female or male normative data for example.”*
  - Core staff have been working on the encryption of the patient information in the data file. This is a complicated process requiring multiple layers of encryption certification so that the patient information stored in the data files is protected. In this quarter we implemented SHA1 encryption on the signals. We will enhance the encryption to use SHA2 instead of SHA1. Considerable testing needs to occur before the MTFs should enter subject information in the data files.
  - This is a challenge for the cmo library because we have separated the patient information from the data in the cmo files and cmo library. After discussing options, we have elected to introduce an encrypted protected data section in each cmo file, and have determined a strategy for the user to expose this information in a report using a password protected login within the file.
  - During this period of performance, the Core modified the Signal Class in Visual3D to allow text strings to be specified instead of numbers. The Core implemented the functionality to allow the report page header to refer to the text signal name instead of a hard coded value.
- EMG output. Per NMCSO: *“We would like the ability to change the order the muscles appear in the report. Presently the order is controlled by the order they are entered into the system during the data collection phase of the study. Also it would be nice to link the c3d name for the EMG signal and the whole muscle name for the plot (output) title. This is time consuming and repetitive.”*



- A Visual3D pipeline has been provided for this request
- Introduce the symmetry score to the labs. We will work with the group in NMCSO to adapt this index to be suitable for their experiments, and one that addresses the common issues noted above.
- The gait symmetry index will be implemented into a biofeedback client in the next period of performance.

### **Development of a Symmetry Index**

- A symmetry index for gait has been developed and is in press with the Journal of Applied Biomechanics.
- As part of a PhD dissertation supervised by Scott Selbie, a symmetry index for gait that has been developed and tested. The symmetry score seems robust enough for classification and in this quarter we will implement the symmetry score into Visual3D for use by the MTFs
- It is generally accepted that high levels of gait asymmetry are associated with pathology. Popular measures of symmetry are limited by their potential for artificial inflation, the choice of a reference value and/or the use of discrete metrics. Furthermore, these tend to report symmetry at a local level, making the assessment of a patient's overall symmetry challenging.

### **Instrumented Treadmill Development**

At the request of the lab at WRNMMC, the Biomechanics Core has created a pipeline for identifying gait events on their instrumented treadmill without using the force data, and a pipeline to identify belt speed using the velocity of the foot during stance was created.

- Pipelines using different algorithms to define kinematic gait events were created so a comparison can be completed to determine the best method for their patient population. We began creating commands to replace the pipelines and will work on this further during this quarter.
- A pipeline using the velocity of the foot during single limb stance was created to determine belt speed using a self-paced treadmill. The temporal distance calculations were modified to correctly use this signal in metric calculations.
- The challenges of verifying the functionality of instrumented treadmills is ongoing. Core staff worked with the BADER group at the University of Delaware to identify the source of errors in their ground reaction force data to develop strategies to provide to MTFs.
- Core staff will continue to collaborate with the University of Delaware to get reliable Center of Pressure data from their instrumented treadmill. The Caltest results were inconsistent between the different methods and the reasons for the inconsistencies were not intuitive. C-Motion will continue to work with University of Delaware to help resolve these issues and hopefully obtain consistent treadmill data with the plan to be able to address similar issues being encountered at the MTFs.
- We are continuing to work with data from instrumented treadmills. We are currently trouble-shooting the instrumented treadmills at the University of Delaware. We seem to have resolved the issues at Spaulding.

**Task 5: Custom Database Development:**

- 5a. Custom database development for specific MTF interactions with Visual3D to facilitate concurrent protocols in use by multiple MTFs (months 13-60).
  - 5b. Implement a clinical interface to the database software for clinicians within a specified clinical framework (months 13-60).
- At this time, the MTF's have not expressed interest in this development with each other. It does, however, appear that the Mayo Clinic and NMCS D are consolidating their pipelines and reporting tools within Visual3D.

**Task 6: Visual3D Enhancements for MTFs:**

- 6a. Integration of existing MTF data collection equipment into Visual3D (months 13-60).
  - 6b. Perform experimental tests to estimate the effective latencies of the real-time motion capture systems, including the CAREN system (months 13-60).
  - 6c. Test, or collaborate with the appropriate manufacturer, to test all force sensing equipment used in the MTFs (months 13-60).
- Staff from C-Motion went on site to WRNMMC to test the Force Plate data from the WRNMMC instrumented treadmill and two running force platforms. Over 100 CalTester trials were collected to test and relocate the instrumented force platforms on the treadmill and the two running force platforms. Minor changes were recommended for the position and orientation of the treadmill plates. At the end of recalibration, additional testing on the treadmill was performed and the treadmill was found to be operating at the level that would be expected from this instrument.
  - For the two running force platforms the CalTester force platform relocation software was also run. For one the two platforms no change in the position and orientation of the platform was recommended and the platform was found to be performing accurately. The data from the second platform was found to be highly inaccurate. After running the CalTester relocation software we found that optimizing the position and orientation of the platform did little to improve the accuracy of the plate. All settings for the platform were double checked against the Owners Manual and found to be correct. The plate was switched to another amplify to confirm that problem was not at the amplifier. After multiple addition CalTester collections we determined that this second running force platform was not operating properly and that the manufacturer (AMTI) needs to be contacted to examine the platform.
  - C-Motion has explored the integration of three different IMU sensors into the Visual3D server (X-IMU, APDM, and Invensense). They have made progress calibrating the X-IMU sensors, but are waiting for the next release of X-IMU sensors that will allow us to synchronize the IMU data with MoCap data.

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

**Note: Dr. Tulskey relocated to the University of Delaware effective September 23, 2014 and the Core has been established at UD.**

### **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).

1a. All sites have valid IRB-approved protocols. Staff are in the process of contacting sites to ensure our records are kept current.

1b. Staff have conducted and finished our systematic review of 32 measures of physical functioning that have established use in orthopedic/amputation research in amputee populations and have documented the relevant research on the psychometric properties and construct validity. Extensions of this work are occurring as part of BADER Toolbox. The reviews have been shared with Linda Resnik and Jason Wilken and have asked for a peer review. Core staff are preparing a manuscript for publication based on these findings. We have met with BADER leadership to discuss how to disseminate the systematic review.

1c. These literature searches and reviews have facilitated establishment of a measurement library for BADER-relevant outcomes measures. The library has been updated with recent 2014 publications. We have provided information to the BADER Clinical Trials Data Base team to see how this work could be integrated with the Clinical Trials Database. We have obtained permissions for 24 of the 32 of the measures to be included thus far. For 15 of the measures, response items have been converted into the CTDB. In addition to the previously described 28 measures of physical functioning, seven measures of prosthetic function and satisfaction, and eight measures of physical symptoms that have established use in orthopedic/amputation research in amputee populations have been identified. The library has recently being updated with recent 2014 publications.

1d-e. We developed and delivered training materials so that investigators could utilize PROMIS from Assessment Center.

1f. Core staff have, on a customized basis, built Assessment Center data collection platforms for the MORE study and the K2 Power BIOM study.

Work on Task 1 is largely completed and Task 1 deliverables have been met. We will continue to obtain permissions for remaining measures of the 32 if authors are receptive.

**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).

As outlined in our project, focus group data collection has been completed with focus groups being conducted at NMCS, WRNMMC and CFI/BAMC.

The already-conducted focus groups have been transcribed, NVivo coding guides created, and coding and reconciliation is in process. New item content has been preliminarily documented for item writing.

Focus groups are being transcribed. Core staff will begin the qualitative analyses in the quarter with the goal of completing the analyses by the end of the calendar year. Core staff are also preparing for groups at the Tampa VA.

**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.

3a & b. We continue to discuss new research with other members of the BADER consortium. We met with Dr. Jason Wilken and team to discuss research agendas and to build the data collection platform for the MORE proposal. We met with Drs. Chris Dearth and Alison Pruziner to consult on the BIOM proposal and to review and discuss research agendas.

Core staff will schedule a meeting at WRNMMC to meet with Orthopedic and TBI research units to plan studies related to polytrauma/dual diagnosis.

The Core staff are on advisory board for a grant at NMCP.

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

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

- Statistical assistance has been requested for a study entitled “Limb Trauma and Amputation Enhance the Risk of Cardiovascular Disease” from USUHS & Walter Reed BE Physical Med-Rehab (PIs: Paul F. Pasquina, MD, Renata Engler, MD). This is a 3-year study that will investigate whether limb trauma and amputation increase the risk of cardiovascular disease. The study will assess, in addition to standard CV risk factors, the role specific changes in gene structure may have in increasing CV risk.

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

- Statistical analysis plans and sample size calculations are in development for **five** proposals to be submitted for the Clinical and Rehabilitative Medicine Research Program funding cycle. These proposals are due January 16, 2016.

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

- At this time, there have not been any requests from Consortium members for this service.

### **Task 4: Conduct statistical analyses.**

- Data analysis for “Gait Characteristics and Functional Outcomes in Service Members with Traumatic Unilateral Transfemoral Amputation” (Pruziner, et. al.) initiated in March, 2015.

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

- At this time, there have not been any requests from Consortium members for this service.

## **PROGRESS REPORTS ON CLINICAL STUDIES**

Summary of BADER funded projects:

	<b>2012.1 – Step2Step</b>	<b>2012.2 - RETRAIN</b>	<b>2013.1 – ProLeg Rx</b>	<b>2013.2 – K2Power</b>	<b>2013.3 – Outcomes Toolbox</b>	<b>2014.1 MORE</b>	<b>2014.2 Backpack</b>
<b>Proposal submitted</b>	Oct 2010	Oct 2010	Dec 2012	Dec 2012	Dec 2012	Nov 2013	Nov 2013
<b>Scientific Review</b>	May 2011	May 2011	December 2012	December 2012	December 2012	December 2013	December 2013
<b>GSC approval</b>	June 2012	April 2012	March 18, 2013	March 18, 2013	March 18, 2013	February 28, 2014	February 28, 2014
<b>Contract negotiation docs sent to CDMRP</b>	June 2012	July 2011	August 2013	August 2013	December 2014	December 2014	December 2014
<b>CDMRP approval</b>	August 2012	August 2012	February 2014	February 2014	February 2015	February 2015	February 2015
<b>Omnibus CRADA executed</b>	December 2012	October 2012	March 2014	March 2015	February 2015	Amendment pending	Amendment pending
<b>BADER PI agreement signed</b>	August 2012	October 2012	April 2013	Pending	Pending	April 2014	March 2014
<b>IRB approvals</b>	August 2012	June 2013	Oct 2013	May 2014	May 2015	June 2015	June 2015
<b>HRPO approval</b>	September 2012 (aim 1) April 12, 2013 (aim 2)	June/July 2013	COMIRB approval Oct 2013	June 2014		June 2015	June 2015
<b>Subject pool</b>	*	*	40	4	0	0	3
<b>Subjects screened</b>	23	14	30	4	0	0	3
<b>Subjects enrolled</b>	21 (Aim 1: 21, Aim 2:1)	3	28	4	0	0	3
<b>Subjects Completed</b>	21	0	0	0	0	0	0
<b>Presentations</b>	15	5	8	0	0	0	1
<b>Publications</b>	2	4 (in progress)	0	0	0	0	0

**2012.1: “Improving Step-To-Step Control of Walking in  
Traumatic Amputees”**  
**“STEP2STEP”**

**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) Aim #2: 1 subject	
IRB Approvals:	Our IRB application for Specific Aim #1 was determined to qualify for “ <i>exempt</i> ” status so therefore no annual renewals are required. Our IRB application for Specific Aim #2 has been approved by BAMC IRB and has received HRPO approval. Approval expires: January 9, 2016	
Amendments to IRB	None reported.	



Adverse events:	None reported.
Serious adverse events:	None reported.
Problems or barriers to research:	None reported.
Finances:	Awarded a no cost extension through September 2016 Award amount: \$679,300 Spent to date: \$487,897 % spent to date: 72% % award period complete: 66.7%

**Research Progress Update:**

**Personnel Changes:**

- Dr. Riley Sheehan accepted a full-time position to work in Dr. Jason Wilken’s lab at CFI / BAMC under government civil service status. Dr. Sheehan continues to work on this project, but is no longer being financially supported by this grant.
- Ms. Preeti Chopra, a Master’s/Doctoral student in Dr. Dingwell’s lab was hired to assist with data processing and analyses.
- Dr. Nicole McLagan moved on to a position as a Lecturer in Dr. Dingwell’s department. Dr. McLagan is still assisting with some project efforts, but has been rotating her responsibilities over to Ms. Salinas and Ms. Chopra.

**Collaborative Efforts Ongoing:**

- Dr. Dingwell continued to travel to CFI / BAMC regularly for full-day meetings with Drs. Wilken and Sheehan, and with other project personnel to discuss progress.
- Drs. Dingwell and Wilken continued to maintain regular contact with Dr. Rylander (former post-doc on the project) as he continues to work on manuscript preparation.
- Dr. Nicole McLagan and Ms. Mandy Salinas continued to assist efforts from Austin, TX.

**Specific Progress on Aim 1:** *To quantify the extent to which patients with transtibial amputation exhibit step-to-step control strategies that are different from appropriately matched non-impaired control subjects.*

(a) This project involves secondary analyses of previously collected data. We have completed all analyses of both experimental and simulated (modeling) data. Our first journal publication related to this work is now published. Our 2<sup>nd</sup> journal publication related to this work has since been re-revised and re-submitted for publication. Dr. Dingwell continues to work on a 3<sup>rd</sup> manuscript and Dr. Rylander on a 4<sup>th</sup>. Since our requested no-cost-extension was granted, we are now starting the process of working towards the 5<sup>th</sup> manuscript previously described as well. Dr. Dingwell will presented portions of this work at the

Dynamic Walking Conference in Columbus, OH in July 2015, and Dr., Rylander will present portions of this work at the American Society of Biomechanics Annual Conference in Columbus, OH in Aug., 2015. Dr. Cusumano is assisting Dr. Dingwell and Dr. Rylander with the mathematical interpretation and proper construction of the modeling aspects of these papers. Dr. Cusumano and Dr. Dingwell maintain in regular and consistent communication.

- (b) The primary next steps are to finalize and submit the 3<sup>rd</sup> (Dingwell et al.) and 4<sup>th</sup> (Rylander et al.) manuscripts and to move the 5<sup>th</sup> manuscript forward as well.

**Specific Progress on Aim 2:** To determine if a VR based gait re-training intervention that explicitly exploits each patient's own step-to-step control is more successful than VR based gait stability training and/or conventional therapy for improving walking in patients with transtibial amputation.

- (a) Since our previous report, Dr. Sheehan has submitted the final draft of a manuscript of the "Case Study" paper we were working on. This was submitted to *Physical Therapy*.
- (b) Dr. Sheehan is continuing to collect data on the "Rehab Frogger" project. Dr. Sheehan will also present our Case Study results at the 2015 *American Orthotic & Prosthetic Association National Assembly* meeting in San Antonio in October.
- (c) Our only "administrative" challenge continues to be finding qualified and willing participants. This is a long intervention study. There are other studies going on in the MPL and there continue to be fewer new patients coming into BAMC
- (iii): One "technical" challenge we faced was that the CAREN system at CFI/BAMC was out of commission for quite a few weeks for much needed and significant repairs and upgrades. While good in the long term, this prevented us from collecting new data in the short term. However, those repairs have now been completed and the CAREN system is now once again fully functioning.

### **Preliminary Results:**

For Specific Aim #1, Dr. Rylander has completed all primary experimental data analyses. This work compared the frontal (coronal) plane stepping control strategies of patients with unilateral transtibial amputation to those of healthy controls. All subjects walked with either no perturbations or with mediolateral *visual* field or treadmill *platform* perturbations. Both subject groups most strongly corrected deviations in *step width* from stride-to-stride. These findings have been verified and validated by computational control models developed by Drs. Dingwell, Cusumano, and Rylander. Patients with amputation exhibited significantly greater variance in their stride-to-stride corrections across all conditions, but particularly during platform perturbations. Thus, although patients with amputation appeared to adopt the same overall control strategy as healthy controls, they were less successful at implementing that strategy.

Additional results of this work will be presented at the *Dynamic Walking* annual meeting (July, 2015) and the *American Society of Biomechanics* annual meeting (Aug., 2015) as specified above. Drs. Dingwell & Cusumano have one journal article published and a second "In Revision" that establish the theoretical foundations for this

work. Drs. Dingwell and Rylander are each drafting a 3<sup>rd</sup> and 4<sup>th</sup> manuscript to be submitted for publication. A 5<sup>th</sup> publication is planned.

Drs. Dingwell & Cusumano have one journal article published and a second “In Revision” that establish the theoretical foundations for this work. Drs. Dingwell and Rylander are each drafting a 3<sup>rd</sup> and 4<sup>th</sup> manuscript to be submitted for publication. A 5<sup>th</sup> publication is planned and initial efforts on this work are under way.

For Specific Aim #2, data were collected for one patient. Analyses of those data are complete. Over the course of the intervention, this patient exhibited large decreases in mean step width and step width variability, and improvements in several other basic measures of gait performance. Moreover, these improvements were maintained at follow-up testing several weeks after the intervention ended. A “Case Study” manuscript has been submitted to *Physical Therapy* for publication based on this work. Dr. Sheehan will present these results at the *American Orthotic & Prosthetic Association National Assembly* in Oct., 2015.

The work we are doing on this BADER-funded project and the ideas and discussions generated have also helped inform the development of two other projects. In the first, we are studying the specific role that visual optic flow plays in helping to regulate sagittal plane stepping movements in healthy subjects. Ms. Salinas assisted with that study, which was conducted at UT Austin. Ms. Salinas presented some initial findings at previous conferences and will present additional results at the *American Society of Biomechanics* meeting (Aug., 2015). Additionally, Ms. Salinas has completed a draft manuscript to submit for publication.

Dr. Wilken and Dr. Dingwell also developed a new VR-based walking paradigm that directly targets lateral stepping control, as a novel extension of Dr. Rylander’s work. The paradigm creates a “virtual obstacle course” where patients must make rapid lateral shifts while walking to navigate successfully. Dr. Sheehan is currently assisting Dr. Wilken’s research group in collecting data from both patients with lower extremity injuries (amputation and/or limb salvage) and healthy control subjects. Data collection on this project was stalled for a while due to technical issues with the CAREN system at BAMC. However, the CAREN system has been fixed and data collection has resumed. We anticipate completion of all data collection for this project by end of October / early November, 2015. Dr. Dingwell and Dr. Sheehan gave two conference presentations on this work in 2014 and Dr. Sheehan will present additional results at the *American Society of Biomechanics* meeting (Aug., 2015).

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

Dingwell, J.B., and Cusumano, J.P. (2015) “Identifying Stride-To-Stride Control Strategies in Human Treadmill Walking” *PLoS ONE*, 10(4): e0124879. (Published on line 04/24/15: <http://dx.doi.org/10.1371/journal.pone.0124879>).

Additionally, we have a second BADER-related publication currently “in revision” (2<sup>nd</sup> set of revisions submitted back to the journal October, 2015), a third and fourth in draft form.

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

JB Dingwell\*, JH Rylander, JP Cusumano, & JM Wilken (2015) "Control Models of Lateral Stepping in Human Walking," *Proceedings of the 2015 Dynamic Walking Meeting*, Columbus, OH, July 20-24, 2015. (Podium Presentation).

JH Rylander\*, JP Cusumano, JM Wilken, & JB Dingwell (2015) "Frontal Plane Stepping Control in Persons with Transtibial Amputation," *Proceedings of the 39<sup>th</sup> Annual Meeting of the American Society of Biomechanics*, Columbus, OH, Aug. 5-8, 2015. (Accepted).

RC Sheehan\*, JH Rylander, JM Wilken, & JB Dingwell (2015) "Lower Limb Trauma Impairs Lateral Walking Transitions in a Virtual Obstacle Course," *Proceedings of the 39<sup>th</sup> Annual Meeting of the American Society of Biomechanics*, Columbus, OH, Aug. 5-8, 2015. (Accepted).

MM Salinas\*, JM Wilken, & JB Dingwell (2015) "How Humans Use Visual Optic Flow to Regulate Stepping Movements," *Proceedings of the 39<sup>th</sup> Annual Meeting of the American Society of Biomechanics*, Columbus, OH, Aug. 5-8, 2015. (Accepted).

Cusumano, J.P. and Dingwell, J.B. (Submitted) "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.

Rylander, J.H., Wilken, J.M., Cusumano, J.P. and Dingwell, J.B. (2013) "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.

Dingwell, J.B. and Cusumano, J.P. (2013) "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.

Rylander, J.H., Beltran, E.J., Wilken, J.M., and Dingwell, J.B. (2014) "Healthy Persons with Unilateral Amputation and Able Bodied Controls Respond Similarly To Visual Field Perturbations While Walking," *Proceedings of the 60<sup>th</sup> Annual Meeting of the Orthopaedic Research Society*, New Orleans, LA, March 15-18, 2014.

Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (Submitted) "Able Bodied Persons and Individuals with Transtibial Amputation Employ Similar Control Strategies in the Frontal Plane during Treadmill Walking," *Proceedings of the 7<sup>th</sup> World Congress of Biomechanics*, Boston, MA, July 6-11, 2014.

Dingwell, J.B. and Wilken, J.M. (Submitted) "Integrating Virtual Reality and Motion Capture for Clinical Assessment and Rehabilitation," *Invited Symposium Presentation, Proceedings of the 7<sup>th</sup> World Congress of Biomechanics*, Boston, MA, July 6-11, 2014.

Salinas, M.M. and Dingwell, J.B. (2014) "How Humans Use Visual Optic Flow To Regulate Stepping Movements During Walking," *Proceedings of the 7<sup>th</sup> World Congress of Biomechanics*, Boston, MA, July 6-11, 2014.

Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (2014) "Strategies for controlling lateral stepping movements in human walking," *Proceedings of the 2014 Society for Neuroscience Annual Meeting*, Washington, DC, Nov. 15-19, 2014.

Sheehan, R.C., Rylander, J.H., Wilken, J.M., and Dingwell, J.B. (2014) "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.

Rylander JH, Wilken JM, Cusumano JP, and Dingwell JB. "Strategies for Controlling Lateral Stepping Movements in Human Walking," [Abstract # 2014-S-10710-SfN].

Sheehan RC, Rylander JH, Wilken JM, and Dingwell JB. "A Virtual Reality Obstacle Course to Improve Lateral Balance Control in Lower Limb Trauma Patients," [Abstract # 2014-S-4958-SfN].

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

**“RETRAIN”**

**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, DPT, ATC	Walter Reed National Military Medical Center
Collaborators:	Steve Jamison, PhD Matthew Ruder, MS Devjani Saha, PhD Elizabeth Nottingham Elizabeth Husson Amanda Wingate, BA	
Accruals:	<b>SNRC:</b> Potential subjects contacted: 23 Potential subjects screened (phone): 15 Lab screened: 6 (5 did not qualify) Subjects enrolled: 1  <b>WRNMMC:</b> Potential subjects contacted: 10 Potential subjects screened: 6 Subjects enrolled: 1 active Subject withdrawals: 1	
IRB Approvals/ Amendments:	<b>SNRC:</b> IRB approval expires: April 22, 2016  <b>WRNMMC:</b> IRB approval expires: June 8, 2016  <b>SNRC</b> <b>Amendment 1</b> (submitted 06/02/13; approved 06/13/13) a. Inclusion of subjects with non-traumatic amputation (except dysvascular amputation) b. Addition of heel raise protocol to prepare subject for running portion	

- c. Addition of Illinois agility test as a functional measure for running
- d. Non-identifiable data will be shared with BCTDB

**Amendment 2** (submitted 07/19/13; approved 08/08/13)

- a. Removed Nike as study sponsor
- b. Addition of question to telephone script (year of amputation)
- c. Addition of anthropometrical measurements

**Amendment 3** (submitted 09/03/13; approved 10/02/13)

- a. Separate protocols for walking and running

**Amendment 4** (submitted 10/25/2013; approved 11/13/2013)

- a. Increase age limit from 50 to 60
- b. Include females
- c. Pregnancy added as exclusion criteria
- d. additional advertising text added

**Amendment 5** (submitted 12/16/2013; approved 12/17/2013)

- a. Add Steve Jamison to protocol

**Amendment 6** (submitted 12/19/2013; approved 01/21/2014)

- a. Add Steve Jamison to recruitment materials
- b. Modify inclusion/exclusion to not restrict all individuals with additional c. musculoskeletal injuries that might influence gait

**Amendment 7** (submitted 01/24/2014; approved 01/28/2014)

- a. Add Thaddeus Babiec, Phattarapon (Pat) Atimetin, Erin Futrell, and Zach Robbiano to protocol
- b. Eveline Graf and Cindy Samaan

**Amendment 8** (submitted 02/10/2014; approved 02/27/2014)

- a. Change contact information on flyers to reflect new lab gmail address

**Amendment 9** (submitted 02/10/2014; approved 02/18/2014)

- a. Add Matt Ruder to protocol

**Amendment 10** (submitted 03/19/2014; approved – pending)

- a. New flyers with more color
- b. Recruit via social media

**Continuing Review** (approved 04/04/2014)

**Amendment 11** (submitted 04/04/2014; approved 04/07/2014)

- a. Update colors on flyer to match those of Harvard/Spaulding

**Protocol Exception 1** (submitted 04/04/2014; approved 04/15/2014)

a. Include one individual with a unilateral transfemoral amputation

**Protocol Exception 2** (submitted 06/04/2014; approved 06/13/2014)

a. Include one individual with a unilateral transfemoral amputation (first individual did not qualify to continue with the study after signing consent)

**Protocol Exception 3** (submitted 07/31/2014; approved 08/01/2014)

a. Include one individual older than our maximum age allowed of 60 years old. We used the max age of 60 years old to exclude comorbidities and inactivity that are common in older individuals. This individual is very active, even participating in several sports (i.e golf, tennis, snow skiing). Given his activity level, and desire to improve his gait, we feel that he would be able to benefit and respond from the gait retraining that this protocol is studying.

**Amendment 12** (submitted 10/04/2014; withdrawn 12/10/2014)

a. expand study population to include transfemoral amputees and increase age range from 60 to 70 years

b. allow participants to remove harness if they desire and PT confirms it is safe to do so

c. withdrawn as this required a full review and DoD communication which there was not time for within study timeline

**Amendment 13** (submitted 12/03/2014; noted 12/03/2014)

a. add Hannah Rice, Taylor Schmidt, Ashvin Singh and Michelle Toyloy to study staff

b. remove Thaddeus Babiec and Zachary Robbiano from study staff

**Amendment 14** (submitted 12/09/2014; withdrawn 01/21/2015)

a.add gas reimbursement for subjects traveling from over 30 miles away

b. specify exclusion of dysvascular amputees is exclusive to those whose amputation was the result of a systemic dysvascular condition

**Protocol Exception 4** (submitted 11/18/2014; deferred 12/16/2014)

include one individual aged 73 years old with a transfemoral amputation. The individual is highly activated and extremely interested in being included in the study (exception 3 stopped responding to calls/voice mails)

**Amendment 15** (submitted 02/26/2015; accepted 03/25/2015)

- add gas reimbursement for subjects traveling from over 30 miles away



- double the stipend

**Amendment 16** (submitted 01/04/2015; withdrawn)

change the number of sessions required from 12 to 8, with the possibility of extension to 12 sessions if sessions are missed (must complete at least 2 sessions per week)

**Continuing Review** (submitted 03/26/2015; confirmed 04/28/2015)

**Amendment 17** (submitted 04/28/2015; accepted 05/04/2015)

Same change as Amendment 16. Had to be resubmitted with updated version numbers following Continuing Review

**Amendment 18** (submitted 05/04/2015; approved 06/04/2015)

Advertisement to be circulated in a monthly email by the Spaulding Rehabilitation Network

Prosthetists and rehabilitation clinicians to be offered 5-10% of administrative salary to identify potentially eligible participants and inform them about the study. This can be done in person, or by mail/email with a covering letter.

**WRNMMC**

**Amendment 1** (Submitted 7/8/13. Approved 7/24/13)

- a. Addition of heel raise exercises during walking portion of the study (assessment and training) (Section 5.5.5).
- b. Delinate procedure for qualifying a training session as a full session or as a session that should be repeated (Section 5.5.5).]
- c. Clarification on inclusion criterion for walking portion of the study (Section 5.4).
- d. The CAREN system will not be used for the training, instead the treadmill in the Center for Performance and Clinical Research at WRNMMC will be used for the study. Vanessa Gatmaitan has been removed from the protocol as an Associate Investigator because she is the CAREN operator and will no longer be involved with the protocol. This change has been reflected in the protocol, consent form, and flyer.

**Amendment 2** (Submitted 11/15/13. Approved 1/17/14)

- a. Subjects can participate if they qualify for either the walking OR the running portion of the study. Prior to this amendment, subjects needed to have qualified for the running portion of the study to participate.
- b. The demographics form was changed to include two additional questions: a) the side of amputation and b) the cause of amputation.

**Amendment 3** (Submitted 2/5/14. Approved 3/10/14)

- a. Name change: Alison Linberg to Alison Pruziner (Linberg)
- b. Addition of new associate investigators: Steven Jamison, PhD and Matthew Ruder.
- c. Removal of Eveline Graf and Cynthia Samaan as AI's.
- d. Update the protocol to reflect the same procedures for storing data as stated in the consent form. The master code and any will also be destroyed at the close of the study.
- e. Flyers will be distributed through Achilles Internatioanl to recruite potential participants.
- f. Subjects can participate for the running portion of the study if they use a powered ankle prosthesis. Prior to this amendment, if subjects use a powered ankle prosthesis they would be excluded from the study.

**Continuing Review** (Submitted 5/6/2014, Approved 6/18/2014)

**Amendment 4** (Submitted 5/30/2014, Approved 6/18/2014)

- a. Subjects can participate in just the walking portion of the study, but they must complete walking rehabilitation to qualify for the walking portion only. These subjects would complete 10 minutes walking on the treadmill and then complete the cognitive test. They will not be running. The 20 minute run, running biomechanics, and PEQ run will only be completed if the participant has been prescribed a running specific prosthesis and is completing the screening for potential participation in the running portion of the study.
- b. We will be recruiting non-DEERS eligible subjects through local prosthetists by distributing advertisements. If subjects are recruited for the study, we will meet them at the gates to escort them and/or add their names to the visitor log. Non-DEERS eligible subjects will also receive compensation.
- c. Between the initial screening and the baseline assessment, subjects will have a minimum of 2 weeks two to become acclimated to the study shoes and a maximum of two months. At the end of two months, we will re-assess why there was a two month delay and if the subject should be re-screened for the study.
- d. The master list will be a password-protected document stored on a secured network, only accessible to study personnel at WRNMMC. The consent forms will be secured in a locked file drawer in room B314 in the Amputee Care Center. All hard-copies of data collection forms will be secured in a locked file drawer in the Amputee Care Center (B322).
- e. Added version numbers to all data collection sheets.
- f. We will be collecting date of birth and city of birth to create a unique study code (GUID) for the Clinical Trials Database. This study ID is in addition to the one created by the study personnel. This information will be stored on the master list and will be destroyed at the close of the study. Study personnel will not be able to link the GUID to the name, date of birth, and city of birth after the GUID is generated.

	<p>g. Removal of Devjani Saha, PhD, as AI. Addition of new investigator: Elizabeth Nottingham.</p> <p>h. Email address change for Alison Pruziner, DPT (PI) to <a href="mailto:alison.l.pruziner.civ@mail.mil">alison.l.pruziner.civ@mail.mil</a>.</p> <p><b>Amendment 5</b> (Submitted 9/23/2014, Approved 9/26/2014)  Removal of Elizabeth Nottingham, as AI. Addition of new investigator: Elizabeth Husson.  Study personnel will visit local amputee support groups to recruit non-DEERS eligible participants.  Changed the page layout of the advertisement to landscape.</p>
Adverse events:	None reported.
Serious adverse events:	None reported.
Problems or barriers to research:	While encouraged by the HRPO to pursue becoming the IRB of record for project 2012.2, the researchers met a significant roadblock with the approval of an Interagency Authorization Agreement. They were advised by HRPO for both Spaulding and WRNNMC to each submit separate IRB documentation to their respective institutions. This set the beginning of the project back as the IRB documentation needed to be revised and resubmitted the local IRB.
Finances:	Award amount: \$708,524 Spent to date: \$618,162 % spent to date: 87% Project dates: 10/01/2012 – 09/30/2014 Dr. Davis has been granted a no cost extension to 09/30/2015. % complete: 100%

## 5. Research Progress Update:

Aim 1. To determine if a program of gait retraining using realtime kinetic feedback in soldiers with unilateral, transtibial amputations alters the asymmetry of gait during walking and running

Aim 2. To determine whether functional outcomes are altered with gait retraining during walking and running

a. Following a prolonged IRB process that began in June 2012, we received approval for aims 1 and 2 in July 2013. This delay has put us nearly 1 year behind which we expect will necessitate a 1 yr, no cost extension to complete aims 1 and 2. We have worked to refine our feedback program as well as to develop a marker placement device needed to improve the reliability of our repeated kinematic measures.

b. Recruitment has been slow. To date, we have been in touch with four different recruitment companies. Two did not feel they would be able to help us given the small numbers needed, the time demand of the protocol (involved multiple training sessions) and the population. Two companies provided proposals in the \$60K range, but neither would tie the payment schedule to recruitment.

WRNNMC has been able to include three individuals in the running portion of the study. One has completed the retraining and the other two have not yet begun. They are now allowed to recruit civilians and have gained

approval to recruit through local amputee support group meetings, and will begin that recruitment soon. They have also been granted additional recruitment funds through BADER to assist with their recruitment.

SNRC has recruited and screened five people in the lab, one of whom qualified for the walking portion of the study. This individual has completed the initial assessment, 12 out of 12 retraining sessions, the second assessment and the at-home training program. The final assessment was scheduled for 11/21/2014. This was rearranged by the participant to 12/8/2014 due to residual limb discomfort. This later date was postponed by the participant with a date to be confirmed. Three further individuals have completed telephone screening. One passed telephone screening to be included in the running portion of the study. Participation by this individual was subject to the successful protocol amendment allowing provision of gas cost reimbursement. A protocol amendment to provide gas costs has been approved. This participant is now unable to commit to the study for personal reasons. The latter two did not pass telephone screening. SNRC has recently received approval to recruit at local prosthetists offices. We have begun to contact some of these prosthetists to offer some compensation for providing patients information about the study. We also have a new summer intern who is an amputee and is going to focus some of his time helping to recruit through some of his resources and connections. We recently invited an individual that coaches some individuals with amputations (as well as other runners) to visit our center and learn about the retraining study. We have also contacted a fitness consultant who has some prosthetic clients and have invited her to visit our center in the next two weeks.

Over the past three months, we have continued our recruitment efforts. Our summer intern, who is an individual with an amputation, attended a number of events for individuals with amputations, but was unable to identify individuals within our local area that would qualify. He planned on attending the Challenged Athlete Foundation clinic that was to be held in Boston, but it was cancelled due to low registration numbers. He also reached out to all of his contacts, including prosthetists.

We did identify one potential subject who was interested in participating. However, they did not qualify due to being too symmetric in their walking gait.

WRNMMC has been visiting one prosthetist group/month to discuss the study, but have not had any additional potential subjects. There is now a new director of IRB who is revisiting the process of recruitment of civilian subjects and has put this on hold

**Aim 3.** To determine whether symmetry of loading and functional outcomes are influenced by the provision of feedback during community walking and running using a mobile monitoring device.

a. Due to the yearlong delay in approval from Nike to utilize their instrumented insole, we have scaled back the scope of Aim 3. We will establish the validity and reliability of the instrumented insole in the lab and in the community in 5 individuals with unilateral transtibial amputations.

b. We have been working with Sapient, a software development company, who will develop the mobile application needed to conduct our pilot study to validate the insole with the instrumented treadmill data. Steve Jamison will be heading this initiative. They have submitted a proposal to us to deliver a product in 5 weeks. Originally, they were asking \$80,000 to do the project. However, we only have \$20,000 in the grant for this project. Therefore, Sapient has agreed to do this project for \$20,000 with the possibility that this might become a commercial product.

c. We have spent the last six months working on agreements between Sapient, Nike and SNRC that satisfies each group's requirements, in particular for IP. We are currently working to bring Nike and Sapient in under the BADER CRADA as 3<sup>rd</sup> party entities. Once this is complete, Sapient has a team ready to begin work.

d. Unfortunately, the Partner's and Sapiient organizations came to an impasse in the verbiage of the licensing and intellectual agreements. However, over the past 6 months, we have developed a relationship with IMeasureU (New Zealand) and Runkeeper (Boston, MA). Together, we have been developing a hardware/software application that is superior to the NIKE insole to monitor impacts during running in the outside environment and provide realtime feedback to reduce these impacts. We are also working to develop a system to monitor symmetry of stance time using simple accelerometers. In this way, we will be able to monitor symmetry of loading during running and symmetry of stance time during walking out in the community. The pilot data from this project will serve as pilot data for grants we are currently planning. Steve Jamison is leading this initiative.

Dr. Jamison has now been working with IMU for the past 10 months. He has worked closely with them to improve the accuracy of the hardware, as well as has helped to develop the algorithms to analyze the data. He has worked on utilizing this technology for both walking and running. For walking, he has been collecting data on subjects coming through the clinic.

The following activities were to take place in the first year of the grant period. However, due to the delay in the approval of the project, the IRB process, which was to begin in the first year of the consortium, did not begin until 9 months into this year. The IRB process was significantly delayed and both sites were unable to begin recruitment until near the end of the second year. Therefore, we are approximately 1 year behind. The following activities of our timeline will take place in year 2 of the grant:

- Baseline gait analysis and outcome measures
- 12 Sessions of walking gait retraining
- Post-training gait analysis and outcome measures
- 1 mo. follow-up gait analysis and outcome measures
- 12 Sessions of running gait retraining
- Post-training gait analysis and outcome measures
- 1 mo. follow-up gait analysis and outcome measures
- Pilot study with instrumented shoe

The following activities of our timeline will take place in year 3 (no cost extension will be requested) of our timeline:

- Completion of Retraining
- Comparison of walking variables across time
- Comparison of running variables across time
- Data Dissemination
- Prepare RCT for submission to DoD/NIH
- Completion of pilot instrumented insole project

**Plans for seeking other or continued support when current funding for this research expires:**

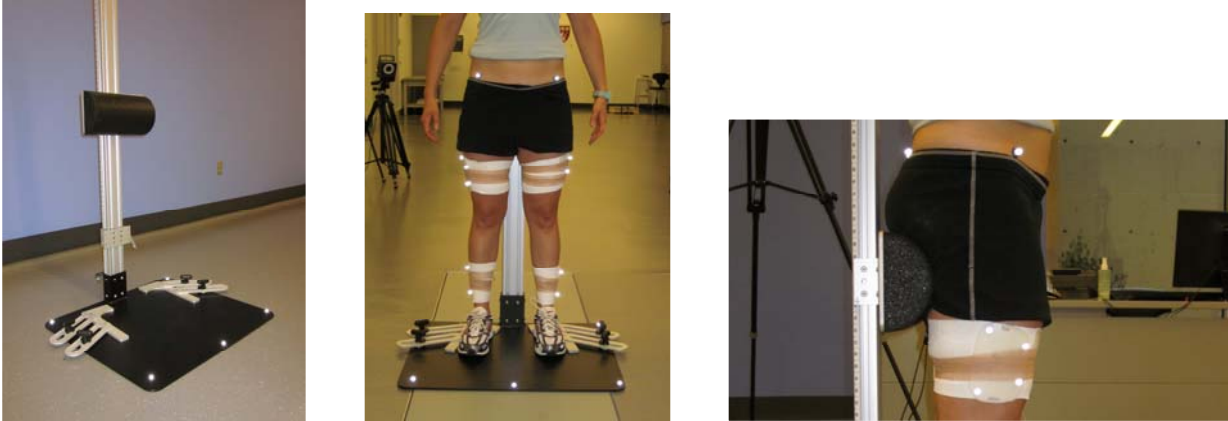
We plan to submit a grant on the use of mobile monitoring to reinforce proper gait mechanics in individuals with amputees. Steve Jamison was accepted into the US Bone and Joint Initiative Program and attended his first meeting. He submitted a pre-proposal to the DoD, which was invited for a full proposal. Unfortunately, due to some technology limitations, he was unable to complete the pilot work needed in time to submit the full proposal. We are also planning on submitting a K99/R00 Training Grant this October.

Steve was planning to resubmit his pre-proposal to the DoD for the 2015 call as he now had the pilot data he needed. However, he was unexpectedly notified in early August that his employment contract would not be renewed. As he was unsure of his employment status and where he would be, he chose to hold off on this submission. This also caused us to hold off on the K99/R00 Training Grant submission.

## KEY RESEARCH ACCOMPLISHMENTS:

### 1. Marker Alignment Device

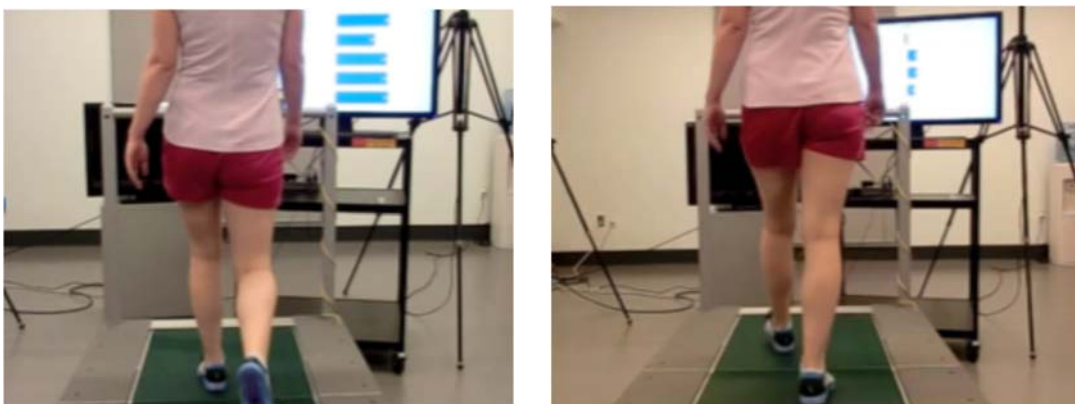
We were successful in developing a Marker Alignment Device (**Figure 1**) and establishing a method of repeatability of kinematic data for studies involving multiple data collections over time. This is especially important for data in the frontal and transverse planes. This device has a global reference frame within it. Using this device requires that anatomical markers are only placed the first time the subject is seen. The mathematical transformations between the anatomical and tracking markers are saved and subsequent visits only require tracking markers to be placed. We have shown that positioning of the subject is very repeatable and the day-to-day reliability is significantly improved with the device.



**Figure 1.** Left: The Marker Alignment device; Middle: Participant standing in the device in recorded position; Right: Posterior support to improved standing position repeatability.

### 2. Walk Retraining

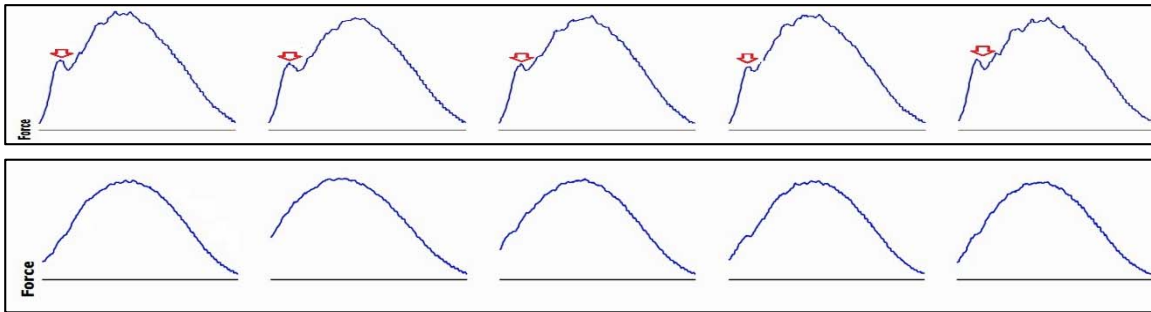
We were successful in developing, along with the Biomechanics Core - Visual3D, a walk retraining system that provided realtime feedback to the subject to improve their stance time symmetry (**Figure 2**). We retrained one individual with a unilateral transtibial amputation to improve their symmetry of gait.



**Figure 2.** Left: Participant walking and exhibiting asymmetry of stance time as seen by length of bars. Right: Improvement of symmetry (smaller bars) achieved with the realtime feedback.

### 3. Run Retraining

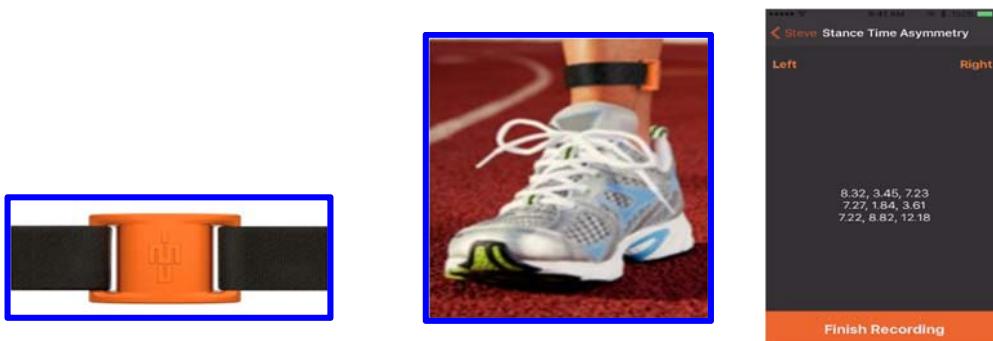
We were successful in developing, along with the Biomechanics Core -Visual3D, a run retraining system that provided realtime feedback to the subject to reduce their vertical impacts during running. (Figure 3). We retrained one individual with a unilateral transtibial amputation to eliminate his vertical impacts.



**Figure 3.** Top: Vertical ground reaction force (VGRF) of the intact leg of a participant with a unilateral transtibial amputation. Note the impact transients with each footstrike. Bottom: VGRF of the intact leg of a participant with a unilateral transtibial amputation utilizing the realtime feedback provided.

#### 4. Mobile Monitoring for Walking

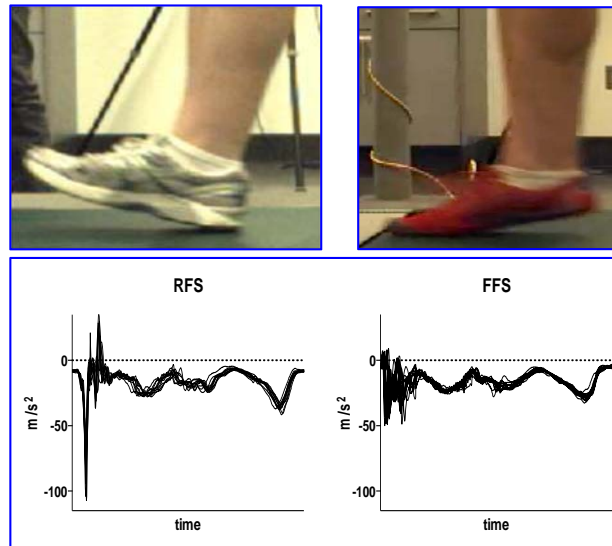
We were successful in developing a mobile monitoring system, in collaboration with IMeasure U of New Zealand, which determines stance time asymmetry during walking using an inertial measurement device. This first required developing the pattern recognition algorithms to robustly and reliably establish stance time using accelerometer data. We then established the validity of measuring stance time of one leg, using force data from an instrument treadmill as the gold standard. Next, two inertial measurement units, each worn on an ankle, had to be synchronized and integrated into the system such that symmetry could be assessed and displayed (Figure 4, Right). We are currently working on validating the stance time symmetry values with those simultaneously collected on the instrumented treadmill. We will then explore the optimal type and frequency of the feedback to be given. Once these aspects of the feedback have been decided, the app will be updated.



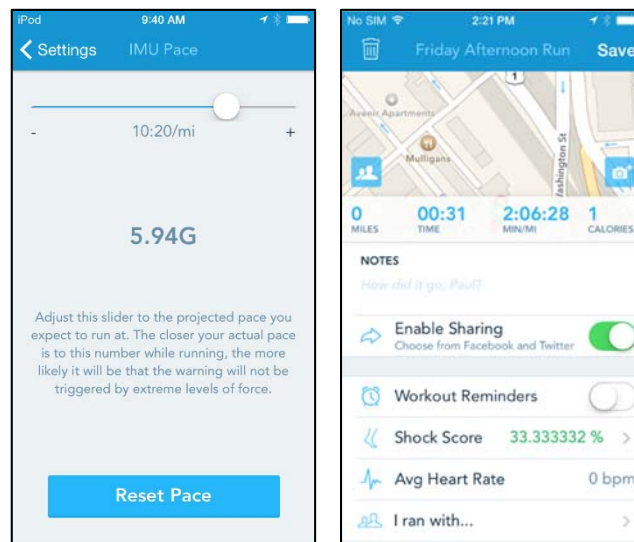
**Figure 4.** Left: Inertial Measurement Device. Middle: Device placed on medial ankle to detect tibial shock. Right: Screenshot of phone screen displaying the symmetry indices calculated from 2 IMU devices.

#### 5. Mobile Monitoring with Realtime Feedback for Running

Using the same IMU device, we were successful in developing the pattern recognition software to determine if one is landing with a rearfoot strike or a forefoot strike pattern during running (Figure 5). We then worked with RunKeeper to develop a mobile application that provided feedback regarding footstrike pattern (and indirectly impacts) (Figure 6). This realtime feedback system is currently being tested in another study at West Point University in runners without amputations. We are also planning on utilizing the device to monitor impacts in runners during the upcoming Boston Marathon.



**Figure 5.** The acceleration traces associated with a rearfoot strike (Left) and forefoot strike (Right) patterns.



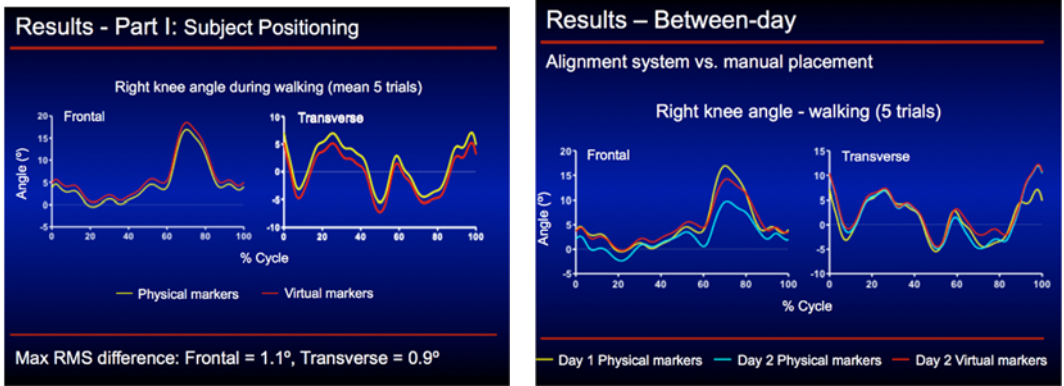
**Figure 6.** Left: Screenshot from iPod app that allows the runner to set their running pace and displays the acceleration threshold that they are to remain below. Right: Screenshot that provides the runner with feedback on the % of footstrike patterns that were RFS. This information is provided to the runner in various increments throughout their run.

## REPORTABLE OUTCOMES:

### 1. Marker Alignment Device (MAD) (Samaan et al, 2013)

Using the MAD, we were able to establish excellent reliability with within-day subject repositioning in the device (**Figure 6**). Additionally, we established excellent day-to-day reliability that was improved over manual placement of markers. This was especially noted in the frontal and transverse plane motions of the hip and knee, which are typically reported to have low day-to-day reliability.

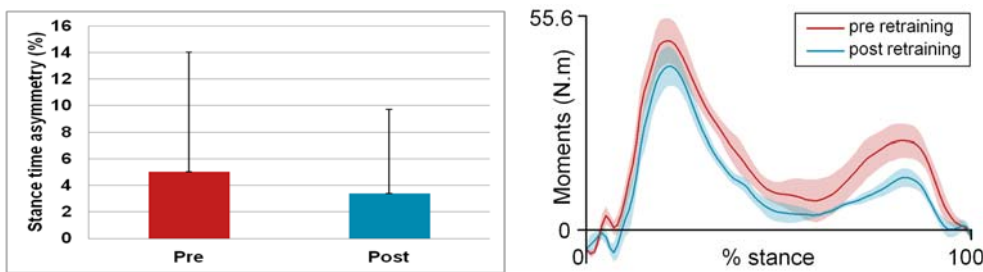




**Figure 6.** Left: Within-day reliability of subject re-positioning in the device. Right: Between-day reliability using the MAD.

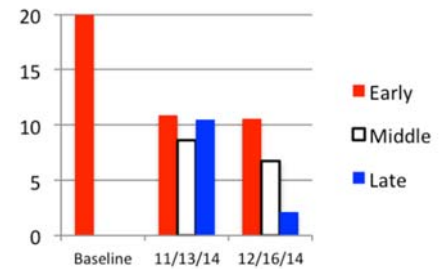
## 2. Walk Retraining (Rice et al, 2015)

The participant was able to improve their stance time symmetry following the retraining (**Figure 7**). In addition, the peak knee adduction moment, associated with the development and progression of knee OA, was also reduced with the retraining. Follow-up data currently being analyzed.



**Figure 7.** Left: Reduction in asymmetry following gait retraining program. Right: Reduction in knee adduction moment, associated with the development and progression of knee OA, also reduced with the retraining.

We have begun to use this feedback system to improve the walking symmetry of individuals who did not meet the inclusion criteria for the study and were seen in our clinic. The results of an individual with a transfemoral amputation who had a 20% asymmetry and baseline and was able to reduce it to an average of 6% during the last session can be seen in **Figure 8**.



**Figure 8.** Asymmetry (in %) in an individual with a unilateral transfemoral amputation who underwent the feedback training (early, middle and late refer to time frames within the training session day).

### 3. Run Retraining (Husson et al, 2015)

The participant was able to reduce the number of his footsteps that exhibited impact transients from 100% at baseline to 3% after 12 sessions of retraining (Figure 9). He was also able to maintain this at his one month follow-up. While the peak vertical force remains higher on the intact side, the peak force has not been related to injuries in runners. The impact transient is associated high rates of loading (associated with injuries) while the peak force is not. This was the motivation for focusing on this aspect of the ground reaction force. However, peak force may be important in individuals with amputations. Therefore, future studies should explore the ability/benefit of retraining to reduce the peak force as well.

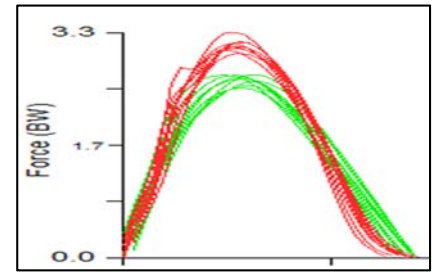


Figure 9. Vertical ground reaction forces after 12 sessions of retraining in a subject who exhibited consistent impact transients at baseline. Red: Intact side, Green: prosthetic side.

### 4. Mobile Monitoring Device – Walking (Jamison et al, 2015)

We have developed robust algorithms to determine stance times using the IMU devices (Figure 10, left) and have established strong correlations between stance times determined using the accelerometer data versus the instrumented treadmill data (figure 12, Right).

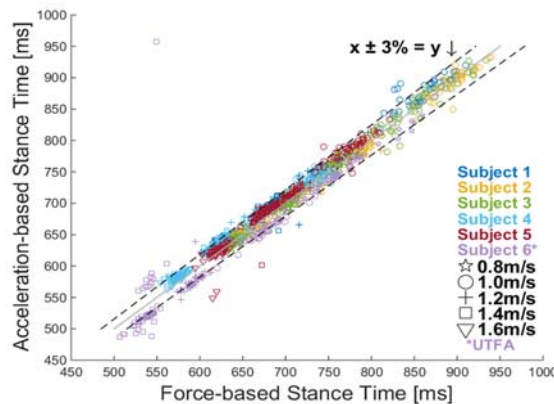
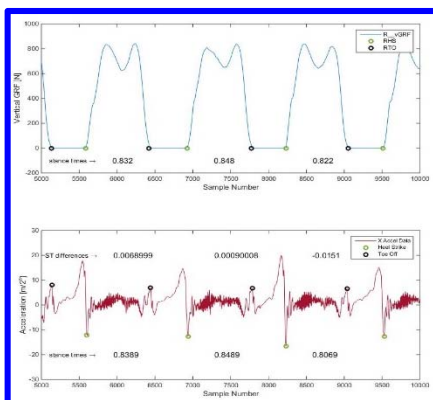


Figure 10. Left: Use of pattern recognition software to determine stance time from acceleration data (bottom left panel). Right: Strong correlation between stance time determined from the force (gold standard) and accelerometry data.

### 5. Mobile Monitoring Running

We used the mobile monitoring device to collect 1029 running footsteps that were stratified into heel strikes (rearfoot strikes) and toe strikes (forefoot strikes). Based upon these data, we were able to determine a functional cut-off value of 6 gs, below which delineated those with a rearfoot strike pattern, above which determined a forefoot strike pattern for a speed of 6 mph (Figure 11). We have since developed these cutoffs for a range of speeds.

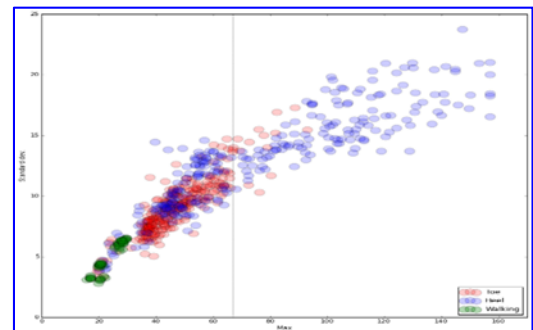


Figure 11. Delineation of the RFS (> 6 gs) from the FFS (< 6 gs) based upon accelerometry data

## **CONCLUSIONS:**

Overall, we were successful in developing proof-of-concept cases in both the walk and run retraining programs. However, we were unable to recruit the number of individuals with unilateral transtibial amputations that we had proposed at both the Spaulding National Running Center and the Walter Reed National Medical Military Center. We believe this was due, in part, to the de-escalation of the war conflicts, as well as the commitment necessary by the individuals to complete the training study. This commitment has not been an issue with similar retraining studies conducted by the Principal Investigator on individuals without amputations. However, individuals with amputations have additional challenges that interfere with their ability to participate in studies requiring multiple visits. This includes issues such as difficulty with transportation and complications with their residual limb and their prosthetic fit.

However, much work has been done to develop and test both the lab-based and mobile-based systems. The combination of these systems for both walking and running, will provide a very powerful tool for retraining faulty gait patterns. Future studies are planned, whereby the participant will undergo a baseline assessment and initial training (1-2 sessions) using the more complete, lab-based system. They would then be given the mobile feedback system as training during their community walking and/or running. Their gait data will be stored on an SD card, and could also be transferred via Bluetooth back to the study coordinator. Their gait would then be re-assessed in the lab following the training. This would require far fewer lab visits, and be more attractive to this population. Based upon the simplicity and low cost of the mobile feedback system, this approach will easily be translated to the clinical environment. Additionally, this system has broad applicability to other patient populations. Examples include improving symmetry of gait in individuals with limb salvage or with joint replacements.

Therefore, despite the difficulties with recruitment, this study has yielded important information regarding the potential to improve walking and running gait patterns in this population in a way that should reduce their injury risk. The work done to develop the mobile monitoring platforms to extend this work into the community has been critical to set the stage for more practical and ecologically valid studies in the future.

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

We are currently working on four manuscripts.

1. Improving Day-to-Day Reliability in Kinematic Measures Using a Marker Alignment Device
2. Case Report on Gait Retraining to Improve Symmetry during Walking in an Individual with a Unilateral Transtibial Amputation
3. Case Report on Gait Retraining to Reducing Impacts in an Individual with a Unilateral Transtibial Amputation
4. Validation of Stance Time Asymmetry Measured during Community Walking with a Mobile Device

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

Samaan, C, Schwartz, J, Graf, E, Davis, IS and Rainbow, MJ. A standing alignment system improves between-session repeatability in gait kinematics: a preliminary study. Presented at the American Society of Biomechanics Meeting, Omaha, Nebraska, Sept 2013.

Rice, H., Jamison, S.T., Pruziner, A.L., and Davis, I.S. 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.T., Pruziner, A.L., and Davis, I.S. 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.

Husson EM, Wolf EJ, Wingate AF, Davis IS, Pruziner AL. 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, ST and Davis, IS. Validation of stance determination using accelerometer data. Presented at the American Society of Biomechanics Meeting, Columbus, OH, Aug. 2015.

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

***“Trauma Outcomes”***

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 Tulsy, PhD	New York University
Collaborators:	Erik Wolf, PhD	WRNMMC
	Marilynn Wyatt, MPT	NMCS D
	Jason Wilken, PhD	BAMC/CFI
Accruals	No patients yet enrolled	
IRB Approvals:	NMCS D IRB approval received (August 21, 2013). HRPO Approval received March 2014. HRPO Log Number A-17117.5	

**Details of this project can be found under Research Outcomes Measurement Core Statement of Work, Task 2**

**2013.1: Prosthetic Leg Prescription (ProLegRx): What is the optimal stiffness and height of a running-specific prosthesis?**  
***“The ProLegRx Study”***

**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: 40 Potential subjects screened: 30 Subjects enrolled: 28	
IRB Approvals:	COMIRB: September 3, 2016	
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 Spent to date: \$413,124 % spent to date: 50% Project dates: 10/01/2013 – 09/30/2016 % complete: 67%

**Research Progress Update:**

**Specific Aim 1:** Quantify the biomechanics, metabolic demands, and socket pistoning of subjects with transtibial amputations using distance-running running-specific prostheses (RSPs) of different stiffness and height. *Number of Research Subjects:* 15 subjects will be recruited to participate in a clinical research study, 10 Service Members with unilateral and 5 Service Members with bilateral transtibial amputations that have prior experience with distance-running RSPs.

**Specific Aim 2:** Quantify the biomechanics, performance, and socket pistoning of subjects with transtibial amputations using sprint-running RSPs of different stiffness and height. *Number of Research Subjects:* 15 subjects will be recruited to participate in a clinical research study, 10 Service Members with unilateral and 5 Service Members with bilateral transtibial amputations that have prior experience with sprint-running RSPs.

**Specific Aim 3:** Develop a clinically relevant, quantitative algorithm for RSP stiffness and height prescription based on a subject's weight, level of amputation, limb segment lengths, and desired running speed.

***SA 1 and 2, Task 1:***

- (a) We obtained IRB approval from the Colorado Multiple Institutional Board Review (COMIRB) for the human experimental studies in Specific Aims 1 and 2. The University of Colorado Boulder IRB ceded to COMIRB. We have obtained review and approval of approved IRB documents by the USAMRMC Office of Research Protections (ORP).

***SA 1 and 2, Task 2:***

- (a) Otto Bock, Ossur, and Freedom Innovations have provided over 60 prostheses to accommodate our subjects. We used a mechanical testing machine (MTS) within the Department of Mechanical Engineering at the University of Colorado Boulder to quantify the stiffness of each running-specific prosthesis (RSP).
- (b) We quantified the stiffness of each prosthesis and are compiling the results of the stiffness tests into a manuscript that we intend to publish.
- (c) We needed to build a test jig and determine the angle to test each prosthesis.
- (d) We built a test jig, measured stiffness at different angles and have established a prosthetic testing protocol we intend to publish.

***SA 1 and 2, Task 3:***

- (a) For the running protocol, we have recruited 15 participants and 15 have completed the study. For the sprinting protocol, we have recruited 15 participants and 11 have completed the study.

- (b) We have networked with the community to establish a subject pool. We were invited to attend the USOC Paralympic Track and Field research clinic in Chula Vista, CA, and have attended the Hanger Running Clinic in Golden, CO, and the 5480 Challenge Paralympic Track and Field meet in Cherry Creek, CO. We organized a research team meeting that included: the prosthetist that is building the sockets, the prosthetist that is fitting and aligning participants, and a prosthetist from the USOC.
- (c) Because each athlete with an amputation has a different build height, we recruited participants in a specific order.
- (d) We have obtained measurements from about 23 athletes with leg amputations and recruited athletes with the tallest build height first and then with shorter build heights so that we could re-use each RSP.

**SA 1, Task 4:**

- (a) A certified prosthetist from our research team has fit and aligned subjects to each distance-running RSP brand during an accommodation session. Subjects then ran on a treadmill to accommodate to each of these distance-running RSPs. The height of each RSP was adjusted for each subject prior to the experiment so that they could use each RSP brand with different stiffness and height characteristics without destroying the RSP. Following the accommodation session, subjects came into the lab for three experimental data collection sessions. During these experimental sessions, we measured their biomechanics, metabolic demands, and socket pistoning while they ran with different stiffness and height distance-running RSPs on an instrumented treadmill.
- (b) We have recruited and completed data collection of all the subjects for the running protocol.
- (c) We calculated the average required speed for the Physical Fitness Test (PFT) 2 mile run for all participants and found that it is nearly the same as our standardized speed of 3.0 m/s.
- (d) We decided to reduce the number of running trials so that athletes ran at 3 m/s with all of the different prosthetic configurations.

**SA 2, Task 6:**

- (a) A certified prosthetist from our research team has fit and aligned subjects to each sprint-running RSP brand during an accommodation session. Subjects will then run on a treadmill to accommodate to each of these sprint-running RSPs. The height of each RSP was adjusted for each subject prior to the experiment so that they could use each RSP brand with different stiffness and height characteristics without destroying the RSP. Following the accommodation session, subjects came into the lab for six experimental data collection sessions. During these experimental sessions, we measured their biomechanics, top speeds, and socket pistoning while they ran with different stiffness and height sprint-running RSPs on an instrumented treadmill.
- (b) We have recruited all subjects for the sprinting protocol.
- (c) One of our subjects had bilateral leg amputations and bilateral arm amputations, which presented a challenge for dismounting the treadmill at top speed.
- (d) We built custom hand-rails that allowed this participant to achieve his top speed and dismount the treadmill safely.

**SA 1, Task 5:**

- (a) Analyze the data from Task 4 to determine the optimal stiffness and height of a distance-running RSP for each individual. Prepare a manuscript and publish the results of our study in a peer-reviewed scientific journal.
- (b) We submitted four abstracts to the American Society of Biomechanics (ASB) and the Rocky Mountain ASB (RMASB) meetings.
- (c) We have presented a talk and/or a poster for each meeting.
- (d) Mr. Beck presented a poster and podium talk at the RMASB and presented two thematic posters at the ASB meetings.

**SA 2, Task 7:**



- (a) Analyze the data from Task 6 to determine the optimal stiffness and height of a sprint-running RSP for each individual. Prepare a manuscript and publish the results of our study in a peer-reviewed scientific journal.
- (b) We submitted four abstracts to the American Society of Biomechanics (ASB) and the Rocky Mountain ASB meetings.
- (c) We have presented a talk and/or a poster for each meeting.
- (d) Dr. Taboga presented two posters at the RMASB and presented two posters at the ASB meetings.

**The following tasks will begin shortly:**

**SA 3, Task 8:**

- (a) Combine the results from Specific Aims 1 and 2 to create a comprehensive, user-friendly algorithm for prosthetists and clinicians to use so that they can make optimal RSP prescriptions. Prepare a manuscript and publish our algorithm in a free public access peer-reviewed journal. Distribute our algorithm to clinicians through VA education programs and conferences such as the American Academy of Orthotists and Prosthetists (AOPA) annual meeting and the American Orthotic and Prosthetic Association (AOPA) World Congress. Distribute our height-adjustment bracket to clinicians through VA education programs and conferences such as the American Academy of Orthotists and Prosthetists (AOPA) annual meeting and the American Orthotic and Prosthetic Association (AOPA) World Congress.

**Plans for seeking other or continued support when current funding for this research expires:**

We submitted a pre-proposal to the Defense Health Program Defense Medical Research and Development Program Department of Defense Clinical and Rehabilitative Medicine Research Program Joint Program Committee 8 Orthotics and Prosthetics Outcomes Research Program Orthotics and Prosthetics Outcomes Research Award Funding Opportunity Number: W81XWH-14-OPORP-OPORA, but were not invited to submit a full proposal.

**Presentations (BADER-related only):** Quarterly report meeting: 2/2014, 2/2015, Rocky Mountain American Society of Biomechanics meeting

**1. Preliminary results:**

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

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

Beck, ON, Taboga, P, and Grabowski, AM. 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, ON, Taboga, P, and Grabowski, AM. 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.*

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

Taboga, P, Beck, ON, and Grabowski, AM. Optimal Running Prostheses for Sprinters with Bilateral Leg Amputations. *American Society of Biomechanics Annual Meeting, OH, 2015.*

Taboga, P, Beck, ON, and Grabowski , AM. Optimal Running Prostheses for Sprinters with Unilateral Leg Amputations. *Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015.*

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

## **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 MFCL 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.

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. Linberg, DPT	Walter Reed National Military Medical Center
Collaborators:	Erik J. Wolf, PhD	Walter Reed National Military Medical Center
	Joseph B. Webster, MD	Hunter Holmes McGuire VA Medical Center
	David S. Tulskey, PhD	University of Delaware
IRB Approvals:	Expires May 6, 2016	
Amendments:	None reported	
Adverse events:	None reported	
Serious adverse events:	None reported	
Problems or barriers to research:	None reported	
Finances:	Award amount: \$1,529,718 Spent to date: \$409,017	

	% spent to date: 27% Project dates: 03/01/2014 – 09/30/2016 % complete: 50%
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**Research Progress Update:**

The first and third subjects have completed data collection. The third subject was required to withdraw due to health concerns that arose on the residual limb. The team is meeting to address if this type of situation can be prevented in the future. The second subject is still completing data collection. Multiple potential subjects have recently reached out which the team is following up with to determine potential for enrollment. The second subject is in process of completing data collection. The research team is working to schedule his final appointment. A fourth participant initiated data collection this quarter and is scheduled for his 4<sup>th</sup> visit next week. One additional interested participant has contacted us, but we are awaiting this potential participant to be fit with a comfortable socket to screen him. Recruitment efforts will continue at local VAs and at local prosthetist offices. We do not foresee any additional challenges at the moment.

Accruals (number of subjects enrolled in the study): 4

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

GSC Meeting 19 February 2014  
GSC Meeting 20 February 2015  
MHSRS: 19 August 2015

**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 was slated to begin October 1, 2013. At this time, we have not received funding approval from the Contract Specialist.***

**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:	\$1,999,969	
Principal Investigator:	David Tulsy, PhD	University of Delaware
Collaborators:	Erik Wolf, PhD	WRNMMC
	Jason Wilken, PhD	BAMC/CFI
	Marilynn Wyatt, MPT	NMCSO
	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
	Pamela Kisala, MA	University of Delaware

The Toolbox project was approved at the beginning of May, 2015 and we have been very active initiating start up activities for this project.

1. Established subcontracts with Tampa VA, Henry H. Jackson Foundation, Geneva Foundation, Oceanside, University of Michigan, and working on final subcontract with New York University.
2. We have hired personnel at University of Delaware to work on the Toolbox and other BADER projects including: Jerry Slotkin, Ph.D. started on September 28, 2015. Dr. Slotkin will serve as a co-investigator and project manager for the grant. He will work closely with other recently hired personnel (Jim Holdnack, Ph.D., Matt Cohen, Ph.D., and Deborah Micklos, MA). Each of these individuals has extensive experience in research and outcomes and these investigator additions will greatly enhance our ability to meet project deliverables.
3. We have met in person with Alison Pruziner at WRNMMC and Jason Wilken at SAMMC and discussed revised timelines and project goals.
4. A project kickoff meeting has been scheduled for November 18-19 in Chicago, with all key BADER Toolbox Co-Investigators and stakeholders.

5. Conducted focus groups at WRNMMC, Center For the Intrepid, and NMCSO. Preliminary qualitative analyses are being conducted on these data. Additional focus groups will be conducted at Tampa VA with possible second round of focus group data collection at MTFs if it is determined that saturation has not been reached.
6. Pam Kisala, Matt Cohen, Jerry Slotkin, and Deborah Micklos have been meeting and have conducted a substantial amount of the qualitative work. The following work has been completed:
  - a. Transcription of focus group meetings
  - b. "Chunking" of focus group transcripts
  - c. Creation of a codebook
  - d. Codebook review by project co-investigators
  - e. Identification, hiring, and training of coders
  - f. Initiation of coding process and achievement of inter-rater reliability target
7. Initial round of coding is anticipated to be completed, along with qualitative analyses, by the November kickoff meeting. Preliminary data will be prepared.
8. Work on systematic literature reviews is in process for this study. A review of community reintegration has been drafted; a review for upper extremity is in process; some additional methodological clarification is required for the completion of lower extremity. The final domain will focus on quality of life. A quality of life review team has now been organized and will include Claire Kalpakjian (lead), Hilary Bertisch, Jim Holdnack, and Matt Cohen. The goal will be to complete all reviews by April 2016.
9. Revised timelines for the project have been drafted and are in review. The timelines will be shared at the November kickoff meeting. We will aim to have a consensus meeting no later than early fall, 2016.

## **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.



**Research Progress Update:**

Title:	2014.1: Maximizing Outpatient Rehabilitation Effectiveness (MORE)	
Funded Amount:		
Principal Investigator:	Jason Wilken, PhD	Brooke Army Medical Center, Center for the Intrepid
Collaborators:	David Tulsy, PhD	University of Delaware
	COL Scott Shaffer, PhD	US Army Baylor University
	LTC Kevin Houck, PT, DPT	Darnall Army Medical Center, Ft. Hood
	MAJ Owen T. Hill, PhD	Center for the Intrepid, Joint Base San Antonio

**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) Multiple activities have been completed prior to receipt of funds. This includes IRB submission, receipt of updated quotes and preparation of position descriptions. We have coordinated with the clinic sites to identify locations for staff, the clinics have added and rearranged working spaces, presentations have been provided to site staff, and we worked with the local information management divisions to ensure access to the BADER CTDB for data entry. Methods of dissemination of data collected to therapists for clinical care have been established, within limits set forth in the protocol and ICD. All measures have been selected and forms for collection have been created in both the Assessment Center (for NIH PROMIS Data) and the CTDB (all other data). Additionally, with the recent release of funds, equipment purchases have been initiated and standardization of all collection procedures is being established for all dependent measures. One of the study positions was filled and in processing and initial training has been completed for that individual.
- b) Additional study staff will be hired and trained on data collection and recording methods. Positions for study staff have been posted and we currently have multiple resumes that are being reviewed in an effort to rapidly fill the additional positions. Upon HRPO approval, we will begin an initial gradual enrollment of participants.
- c) Due to a miscommunication at our local IRB, they provided IRB approval and signed consent documents in 2014, without the study having been approved by HRPO. This issue was recently identified and is currently being resolved. Resolution is anticipated in less than 1 month. Additionally, significant delay in the release of funding slowed the process of acquiring equipment needed for collection.
- d) As stated above, efforts are already underway to ensure timely study execution, to include purchasing, hiring and regulatory.

**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 covary 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 Aim1 a.
- b) Awaiting enrollment and collection of data to begin this aim.
- c) See above Aim1c.
- d) Awaiting Data Collection

**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) Awaiting enrollment and collection of data to begin this aim.
- c) See above Aim1c.
- d) Awaiting Data Collection

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

**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:		
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 8 2016	
Accruals	Patients contacted: 3 Patients screened: 3 Patients enrolled: 3	

**Research Progress Update:**

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

Progress to date: HRPO approval received; enrollment initiated.

Next steps: Testing Aim 1 pending.

Challenges: The original budget for this project included funds to purchase a small number prosthetic feet for Specific Aim 1; however funds to purchase the prosthetic feet for the second phase of this study were inadvertently omitted. Thus, additional monies are required to purchase the prosthetic feet for the human subject testing to be conducted at WRNMMC (Specific Aim 2). We have estimated the budget shortfall to be

~\$65k (~\$2,500/foot x 2 feet/subject x 12 subjects + HJF IDC). To this end, Dr. Dearth has corresponded with Dr. Stanhope regarding the possibility of BADER supporting these additional costs.

**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.

Progress to date: Obtained SRC approval at Walter Reed. Completed sub-award and SOW documentation for HJF.

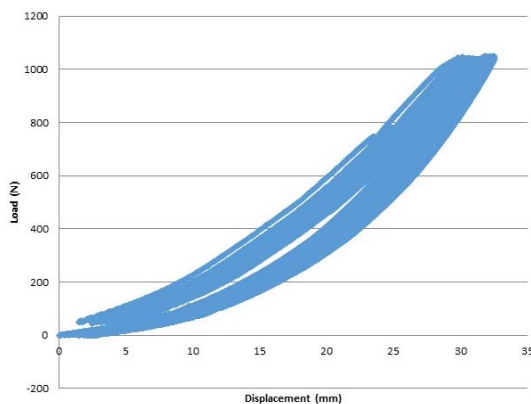
Next steps: Preparing consent form for WRNMMC IRB submission.

Challenges: None reported.

Plans to overcome challenges: n/a

**Preliminary results:**

See below image and plot depicting initial testing at the Minneapolis VA regarding stiffness characterization of a prosthetic foot (+ boot).



**KEY RESEARCH ACCOMPLISHMENTS**  
**FOR THE PERIOD**  
**SEPTEMBER 30, 2011 – SEPTEMBER 29, 2015**

## BADER Consortium

W81-XWH-11-2-0222

Annual Report – Year 4

### Key Research Accomplishments

#### 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 Tulsky 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**  
**for the period**  
**September 30, 2011 – September 29, 2015:**

## **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. Start date: September 2012.

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. Start date: October 2012.

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. Start date: October 2013.

Pruziner, A., Wolf, E., Webster, J., Tulsy, 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. Start date: March 2014.

Tulsy, D., Wolf, E., 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.”** \$1,999,969. 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. Start date: Pending.

Wilken, J., Tulsy, 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. Start date: Pending.

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. Start date: Pending.

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

Tulsy, 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:**

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”** Proposal to CDMRP/PRORP, July 2013. Recommended for funding, awaiting subcontract. This is a METRC/BADER Collaboration.

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. Recommended for funding, awaiting subcontract. Sites: NMCP, NYU.

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

Whittelsey, S., Selbie, W.S. **“Development of a Low Cost, Real-time Biofeedback Gait Retraining System”** \$149,995. Funded by: NIH, Phase I – SBIR. Sites: C-Motion, LLC

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. Sites: Mayo Clinic, MTFs

Deluzio, K. J., Selbie, W.S., **“Statistical Models for Establishing a Control Data Set for Biomechanical Gait Analysis”** \$25,000. Natural Sciences and Engineering Research Council of Canada.

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

None at this time.

#### **Research Proposals - BADER Supported**

Ziemke, G. **“Rate of Surgical Revision in Active Duty Service Members After Anterior Cervical Disc Arthroplasty or Fusion for Spinal Post-Traumatic Osteoarthritis”**. CDMRP/PRORP pre-application, not invited for full submission.

Ziemke, G. **“Identifying Obstacles and Facilitators of Work Re-Integration in Active Duty Sailors and Marines with Deployment and/or Combat-Related Musculoskeletal Injuries.”** CDMRP/PRORP pre-application, not invited for full submission.

Stanhope, S. **“BADER Consortium – A Five Year Budget Projection”** proposal for sustaining Consortium Operations. Submitted July 16, 2014 to the Health Care Delivery Subcommittee of the Defense Health Board.

Buchanan, T. **“OA study.”** CDMRP/PRORP pre-application, not invited for full submission.

The BADER Consortium Administrative Core supported, at their request, the VA with planning the upcoming, DEKA arm multi-center clinical trial.

The MTF/BADER Consortium limb salvage team submitted an unfunded pre-proposal to the PRORP TRPA program.

Dr. Tim Judkins with Intelligent Automation, Inc. has completed a DoD funded Phase I SBIR, Virtual Therapist PTSD, project and wishes to develop and execute the Phase II, clinical trial effort, through the BADER Consortium.

## Manuscripts, abstracts, presentations

### BADER Funded Projects

#### **Publications:**

Dingwell, J.B., and Cusumano, J.P. (2015) "Identifying Stride-To-Stride Control Strategies in Human Treadmill Walking" *PLoS ONE*, 10(4): e0124879. (Published on line 04/24/15: <http://dx.doi.org/10.1371/journal.pone.0124879>).

#### **Abstracts:**

JB Dingwell\*, JH Rylander, JP Cusumano, & JM Wilken (2015) "Control Models of Lateral Stepping in Human Walking," *Proceedings of the 2015 Dynamic Walking Meeting*, Columbus, OH, July 20-24, 2015. (Podium Presentation).

JH Rylander\*, JP Cusumano, JM Wilken, & JB Dingwell (2015) "Frontal Plane Stepping Control in Persons with Transtibial Amputation," *Proceedings of the 39<sup>th</sup> Annual Meeting of the American Society of Biomechanics*, Columbus, OH, Aug. 5-8, 2015. (Accepted).

RC Sheehan\*, JH Rylander, JM Wilken, & JB Dingwell (2015) "Lower Limb Trauma Impairs Lateral Walking Transitions in a Virtual Obstacle Course," *Proceedings of the 39<sup>th</sup> Annual Meeting of the American Society of Biomechanics*, Columbus, OH, Aug. 5-8, 2015. (Accepted).

MM Salinas\*, JM Wilken, & JB Dingwell (2015) "How Humans Use Visual Optic Flow to Regulate Stepping Movements," *Proceedings of the 39<sup>th</sup> Annual Meeting of the American Society of Biomechanics*, Columbus, OH, Aug. 5-8, 2015. (Accepted).

Cusumano, J.P. and Dingwell, J.B. (Submitted) "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.

Rylander, J.H., Wilken, J.M., Cusumano, J.P. and Dingwell, J.B. (2013) "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.

Dingwell, J.B. and Cusumano, J.P. (2013) "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.

Rylander, J.H., Beltran, E.J., Wilken, J.M., and Dingwell, J.B. (2014) "Healthy Persons with Unilateral Amputation and Able Bodied Controls Respond Similarly To Visual Field Perturbations While Walking," *Proceedings of the 60<sup>th</sup> Annual Meeting of the Orthopaedic Research Society*, New Orleans, LA, March 15-18, 2014.

Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (Submitted) "Able Bodied Persons and Individuals with Transtibial Amputation Employ Similar Control Strategies in the Frontal Plane during Treadmill Walking," *Proceedings of the 7<sup>th</sup> World Congress of Biomechanics*, Boston, MA, July 6-11, 2014.

Dingwell, J.B. and Wilken, J.M. (Submitted) "Integrating Virtual Reality and Motion Capture for Clinical Assessment and Rehabilitation," *Invited Symposium Presentation, Proceedings of the 7<sup>th</sup> World Congress of Biomechanics*, Boston, MA, July 6-11, 2014.

Salinas, M.M. and Dingwell, J.B. (2014) "How Humans Use Visual Optic Flow To Regulate Stepping Movements During Walking," *Proceedings of the 7<sup>th</sup> World Congress of Biomechanics*, Boston, MA, July 6-11, 2014.

Rylander, J.H., Wilken, J.M., Cusumano, J.P., and Dingwell, J.B. (2014) "Strategies for controlling lateral stepping movements in human walking," *Proceedings of the 2014 Society for Neuroscience Annual Meeting*, Washington, DC, Nov. 15-19, 2014.

Sheehan, R.C., Rylander, J.H., Wilken, J.M., and Dingwell, J.B. (2014) "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.

Rylander JH, Wilken JM, Cusumano JP, and Dingwell JB. "Strategies for Controlling Lateral Stepping Movements in Human Walking," [Abstract # 2014-S-10710-SfN].

Sheehan RC, Rylander JH, Wilken JM, and Dingwell JB. "A Virtual Reality Obstacle Course to Improve Lateral Balance Control in Lower Limb Trauma Patients," [Abstract # 2014-S-4958-SfN].

Samaan, C, Schwartz, J, Graf, E, Davis, IS and Rainbow, MJ. A standing alignment system improves between-session repeatability in gait kinematics: a preliminary study. Presented at the American Society of Biomechanics Meeting, Omaha, Nebraska, Sept 2013.

Rice, H., Jamison, S.T., Pruziner, A.L., and Davis, I.S. 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.T., Pruziner, A.L., and Davis, I.S. 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.

Husson EM, Wolf EJ, Wingate AF, Davis IS, Pruziner AL. 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, ST and Davis, IS. Validation of stance determination using accelerometer data. Presented at the American Society of Biomechanics Meeting, Columbus, OH, Aug. 2015.

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

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

Beck, ON, Taboga, P, and Grabowski , AM. 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, ON, Taboga, P, and Grabowski , AM. 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.*

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

Taboga, P, Beck, ON, and Grabowski , AM. Optimal Running Prostheses for Sprinters with Bilateral Leg Amputations. *American Society of Biomechanics Annual Meeting, OH, 2015.*

Taboga, P, Beck, ON, and Grabowski , AM. Optimal Running Prostheses for Sprinters with Unilateral Leg Amputations. *Rocky Mountain Regional American Society of Biomechanics Annual Meeting, CO, 2015.*

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

**Patents:**

None at this time

**BADER Supported Projects**

**Publications:** None at this time.

**Abstracts:** None at this time.

**Patents:** None at this time.

**BADER Related Projects**

**Publications:**

Takahashi KZ, Kepple TM, Stanhope SJ. 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

Schrank E and Stanhope SJ. Dimensional accuracy of ankle-foot orthoses constructed by an automated fit customization and rapid manufacturing framework. *Journal of Rehabilitation Research & Development* 2011;48(1):31-42. PMID:21328161

Schrank ES, Stanhope SJ. Orthotic Device Research. In *Full Stride: The Past, Present, and Future of Lower Extremity Gait Systems*. Springer Publishing. *in preparation.*

### **Abstracts and Presentations:**

- 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
- 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
- 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
- Schrank ES, Higginson JS, Stanhope SJ. 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
- 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.
- 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.
- 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.
- 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.

### **Patents:**

None at this time.

**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.

**Funding applied for based on work supported by this award:**

Morshed, S., Kaufman, K. **“The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees”** Proposal to CDMRP/PRORP, July 2013.

Judkins, T. **“Development of a Mobile Advanced Real-Time Kinetic System (MARKS) for Balance Rehabilitation.”** Proposal to Department of Defense SBIR, June 2013.

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.

Van Citters, D. **“Active Implant”** Proposal to CDMRP/PRORP, July 2013.

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

John David Collins, a biomechanist in the gait analysis laboratory at NMCS D has been accepted in to the University of Delaware Biomechanics and Movement Sciences PhD program under the BADER Consortium waived tuition program.



## CONCLUSION

As we complete year 4, efforts continue to be focused on the “Engagement” phase of the Consortium and working toward the “Sustainability” phase. BADER is actively working on the successful accomplishment of tasks as outlined in the proposed statement of work.

The Consortium has experienced a number of successes over the first four years. The partnerships with the MTFs are strengthening, the relationship with EACE is strong and the VA is actively engaged with the Consortium. We have eight research projects underway – meeting the proposed 6-8 during the period of performance. In addition, plans for establishing administrative, personnel, IT and support infrastructures have been fully realized.

BADER Continues progress in the following areas:

Defense Health Board: The Defense Health Board report “Sustainment and Advance of Amputee Care” was released on April 8, 2015. The BADER Consortium is mentioned (<http://www.health.mil/About-MHS/Other-MHS-Organizations/Defense-Health-Board/Reports> p30):

#### THE BADER CONSORTIUM

*As previously discussed, DoD’s research is often conducted in partnership with and complemented by other agencies conducting research in various fields related to amputee care. The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium is central to the ARCs’ research capabilities and current efforts. The BADER Consortium is a non-profit organization funded primarily by the Congressionally Directed Medical Research Program (CDMRP), as well as Orthopaedic Research Clinical Consortium Award (ORCCA) and Peer Reviewed Orthopaedic Research Program (PRORP), to work with the three ARCs and the Naval Medical Center Portsmouth “to strengthen and support evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for each Wounded Warrior.”<sup>88</sup> The sole mission of the BADER Consortium is to establish, foster the development of, and achieve sustainability of robust research capabilities within the ARCs. To this end, it establishes partnerships with research leaders such as the Mayo Clinic, Spaulding Harvard, and the University of Delaware, and facilitates the establishment of research partnerships between the ARCs and public and private institutions.<sup>89</sup> The Consortium also aids the ARCs in identifying research funding opportunities and grant proposal development and provides the ARCs with staff augmentation as well as technical support.<sup>90</sup>*

*Although the ARCs’ research capabilities are significantly enhanced and facilitated by the BADER Consortium, the Consortium must be self-sustainable by September 2016, as it was established with five-year funding in September 2011. Additionally, fiscal constraints and the drawdown of troops from the recent conflicts threaten to diminish medical research funding.<sup>91</sup> Thus, research initiatives that have made significant strides in advancing the field are at risk of being halted mid-course before new advances make it to market or implementation.*

MTF Team Building: Regular monthly meeting 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.

### Sustainability:

At the request of a MTF representative, BADER leadership is actively working to implement a policy allowing non-University personnel to be Principal Investigators on research projects submitted through UD. As part of this policy, the University would return a portion of the F&A recovered back to the program. This contribution of F&A back into the research would make the UD F&A profile similar to that of Henry Jackson and Geneva Foundations. Furthermore, At the request of a Consortium member, the University of Delaware has established an account to receive charitable donations directed to support and conduct specific research projects. This fund will not carry indirect costs, making it highly attractive to individual donors wishing to fund research.

At the time of this report, BADER staff are actively responding to PA W81XWH-15-PRORP-OCRCA.

BADER is currently exploring numerous proposal opportunities including the Medical Technology Enterprise Consortium (MTEC), the NIH Medical Rehabilitation Research Resource R24, and the BAA for additional funding opportunities. We also look to fully leverage our IDIQ relationship with Leidos.

Having obtained over \$4 million in additional external funding and initiated four BADER related, but not BADER funded projects, our omnibus Consortium model is rapidly gaining evidence of success.

Over the next several quarters, working toward sustainability efforts, we will continue to engage BADER Consortium Affiliates into forming large research teams to compete for large scale, impactful clinical studies. BADER will effectively leverage existing networks and establish new partnerships to identify research teams to seek external funding opportunities for sustainability of the Consortium.

### 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.

EACE: CAPT Lanny Boswell participated in BADER Consortium Committee monthly meetings until announcing his departure from EACE. Dr. Stanhope and CAPT Boswell have discussed synergies between EACE and BADER and how both programs can support each other and we will be keeping the relationship in tact with his replacement. Dr. Stanhope has been invited to participate in the EACE meetings. Continuing to strengthen ties with EACE is critical. BADER and EACE bring unique resources to amputee rehabilitation care across the Department of Defense and working in partnership toward well-established goals will achieve great success.

METRC: The first BADER-METRC collaboration “The PROFIT Study: Prosthetic Fit Assessment in Traumatic Trans-tibial Amputees” has been funded and the subcontract was received at the end of the quarter. We look forward to engaging METRC in future collaborations.

Veteran’s Affairs (VA): BADER leadership continues to engage the VA. A strong partnership with the VA will be essential for sustainability efforts of the Consortium. BADER looks forward to establishing a strong relationship with Dr. Brian Schulz as he replaces Dr. Jaeger on the GSC.

National Institutes of Health (NIH): The Consortium 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 Collaboration Agreement was renewed for an additional two years in December 2014. This unique partnership is supported by leadership at both NIH and UD and brings substantial opportunities to both parties for future development.

Post baccalaureate training: John David Collins (NMCSO) continues to progress toward his PhD in Biomechanics and Movement Sciences at the University of Delaware and is preparing to return to NMCSO in January 2016 to continue his research to complete his degree requirements. We are working with potential PhD candidates from across the Consortium for program enrollment.

We look forward to continuing our work in strengthening orthopaedic rehabilitation research to bring all Wounded Warriors back to optimal function.

## APPENDICES

## **APPENDIX A:**

### ***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

#### 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
- 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***

Total as of September 30, 2015: 98

<b>Aldridge, Jennifer</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Anne Andrews, LTC, PhD, RD, CSSD, CSCS</b>	BADER Consortium Affiliate, Director of Othopaedic Rehabilitation Research	Walter Reed National Military Medical Center (WRNMMC)
<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>Cesario, Erin</b>	CRC Staff BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS D)
<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>DeMaio, Marlene, CAPT</b>	BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
<b>Dingwell, Jonathan B., PhD</b>	BADER Consortium Affiliate	University of Texas at Austin
<b>Dromsky, David</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS)
<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>Faulkner, Danielle</b>	CRC Staff BADER Consortium Affiliate	Naval Medical Center Portsmouth (NMCP)
<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	Massachusetts Institute of Technology
<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>Hiebert, Rudi</b>	BADER Consortium Affiliate	New York University
<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>Jamison, Steve, PhD</b>	CRC Staff 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 (NMCS)
<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>Linberg, Alison</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Logerstedt, David, PT, PhD, MPT, SCS</b>	BADER Consortium Affiliate	University of Delaware
<b>Ludwig, Paula M.</b>	BADER Consortium Affiliate	University of Minnesota

<b>Metzger-Abamukong, Melinda</b>	CRC Staff BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Milbourne, Suzanne A., PhD</b>	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>Myers, Grant</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS)
<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 (NMCS)
<b>Royer, Todd, PhD</b>	BADER Consortium Affiliate	University of Delaware
<b>Sacher, Richard S</b>	BADER Consortium Affiliate	University of Delaware

<b>Saha, Devjani, PhD</b>	CRC Staff BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<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 (NMCS)
<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	North Carolina State University
<b>Thesing, Nancy</b>	BADER Consortium Affiliate	Naval Medical Center San Diego (NMCS)
<b>Tulsky, David, PhD</b>	BADER Consortium Affiliate, Director, Outcome Measures Core	University of Michigan Medical School
<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	San Antonio Military Medical Center (SAMMC)

<b>Wingate, Amanda</b>	CRC Staff BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Wolf, Erik, PhD</b>	BADER Consortium Affiliate	Walter Reed National Military Medical Center (WRNMMC)
<b>Wyatt, Marilyn</b>	MTF Representative	Naval Medical Center San Diego (NMCS)
<b>Yack, John</b>	BADER Consortium Affiliate	San Antonio Military Medical Center (SAMMC)
<b>Ziemke, Gregg, CAPT</b>	MTF Representative	Naval Medical Center Portsmouth (NMCP)

APPENDIX C

Government Steering Committee Meeting – February 20 2015

Agenda:

US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

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**CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS (CDMRP)**

***PEER REVIEWED ORTHOPAEDIC RESEARCH PROGRAM (PRORP) FISCAL YEAR 2010 (FY10)***

***THE BADER CONSORTIUM***

***GOVERNMENT STEERING COMMITTEE (GSC) MEETING***

**20 February 2015**

**AGENDA**

Teleconference numbers:

<https://connect.dco.dod.mil/bader-gsc/>

DCO Connect:

1-855-462-5367 Conference code: 9321352

8:00 a.m. – 8:05 a.m.	Welcome	CDMRP Leadership
8:05 a.m. – 8:10 a.m.	Moment of silence	TBD
8:10 a.m. – 8:20 a.m.	Introductions Purpose of GSC meeting	Dr. Darnell
8:20 a.m. – 9:00 a.m.	<u>Progress Report</u> <ul style="list-style-type: none"><li>• Brief background</li><li>• Consortium Cores/Infrastructure</li><li>• Resources</li><li>• Activities</li><li>• Initiatives</li></ul>	Dr. Stanhope
9:00 a.m. – 10:00 a.m.	<u>Current Studies</u> <ul style="list-style-type: none"><li>• Introduction of projects (Dr. Davis)</li><li>• RETRAIN clinical trial update (Dr. Davis)</li><li>• STEP2STEP clinical trial update (Dr. Dingwell)</li><li>• ProLegRX clinical trial update (Dr. Grabowski)</li><li>• K2Power clinical trial update (Dr. Pruziner)</li></ul>	Project PIs
10:00 a.m. – 10:15 a.m.	Break	All Participants
10:15 a.m. – 11:00 a.m.	<u>Current Studies (con't)</u> <ul style="list-style-type: none"><li>• QOL Toolbox clinical trial update (Dr. Tulsy)</li></ul>	Project PIs

	<ul style="list-style-type: none"> <li>• ROM Focus Group Study (Dr. Tulskey)</li> <li>• MORE clinical trial update (Dr. Wilken)</li> <li>• RuckFoot clinical trial update (Dr. Schnall)</li> </ul>	
<i>11:00 a.m. – 12:00 p.m.</i>	<u>MTF site reports</u> <ul style="list-style-type: none"> <li>• Research initiatives</li> <li>• Consortium resources</li> <li>• MTF research progress</li> </ul>	MTF representatives
<i>12:00 p.m. – 1:00 p.m.</i>	Lunch on your own. NCI Cafeteria available	All participants
<i>1:00 p.m. – 1:45 p.m.</i>	Future directions and sustainability	Dr. Stanhope
<i>1:45p.m. – 2:00 p.m.</i>	Break Release Project PIs and MTF representatives	All participants
<i>2:00p.m. –4:00 p.m.</i>	GSC Executive Session	GSC

## APPENDIX D

### BADER Consortium Committee Memberships

#### BADER Consortium Coordinating Center (B3C) Committee

Steven J. Stanhope, PhD - University of Delaware  
Irene Davis, PhD - Spaulding Rehabilitation Hospital  
Kenton Kaufman, PhD – Mayo Clinic  
Suzanne Milbourne, PhD – University of Delaware  
Rachel Strickland – University of Delaware

#### BADER Consortium Committee (BCC)

Steven J. Stanhope, PhD – University of Delaware  
Irene Davis, PhD – Spaulding Rehabilitation Hospital  
Kenton Kaufman, PhD – Mayo Clinic  
Suzanne Milbourne, PhD – University of Delaware  
Rachel Strickland – University of Delaware  
Jason Wilken, PhD – BAMC/CFI  
Shawn Farrokhi, PhD - NMCS D  
Marilynn Wyatt - NMCS D  
Gregg Ziemke - NMCP  
Alison Pruziner, DPT - WRNMMC  
Scott Selbie, PhD – C-Motion  
David Tulskey, PhD – University of Delaware  
Paul Kolm, PhD – Christiana Care Health System  
  
Chris Dearth, PhD – WRNMMC  
  
Jason Highsmith, PhD – EACE

**APPENDIX E: BADER Staff Participation in non-BADER Funded Studies**

	<b>TITLE</b>	<b>STAFF</b>	<b>ROLE</b>	<b>PI Name</b>	<b>PI Institution</b>	<b>Project cycle (e.g., Jan 2014 - Dec 2017)</b>	<b>Funding? (Y/N)</b>	<b>Funding source</b>	<b>Study SITE (s)</b>
	<b>NOTE: rows 1 and 2 cover multiple research studies as noted for each</b>								
1	Recruitment for Studies (span 4 projects)	Brown	Research Support						
2	Regulatory Admin for all CFI-MPL studies (span an average of 25 studies)	Brown	Admin support	Jason Wilken	BAMC CFI				
3	Physical Therapy Spine Research Department	Faulkner	Department Admin Reviewer	Gregg Ziemke	NMCP	on-going	N	N/A	NMCP
4	A Pilot Study to Test the Efficacy of Psychologically Based Physical Therapy Training for Treating Deployed U.S. Sailors and Marines with Musculoskeletal Injuries	Faulkner and Hiebert	Associate Investigator	Sherri Weiser, CO-PI Marco Campello and Gregg Ziemke	NYU		Y	CMDRP	NMCP
5	Retrospective Administrative Limited Duty Outcomes follow-up	Faulkner and Hiebert	Associate Investigator	Gregg Ziemke	NMCP			N/A	NMCP



	<b>TITLE</b>	<b>STAFF</b>	<b>ROLE</b>	<b>PI Name</b>	<b>PI Institution</b>	<b>Project cycle (e.g., Jan 2014 - Dec 2017)</b>	<b>Funding? (Y/N)</b>	<b>Funding source</b>	<b>Study SITE (s)</b>
6	Rate of Surgical Revision in Active Duty Service Members After Anterior Cervical Disc Arthroplasty or Fusion.	Faulkner and Hiebert	Associate Investigator	Gregg Zieke, CO-PI Dennis Rivet	NMCP			Identifying potential funding sources	NMCP
7	Obstacles and Facilitators of Work Reintegration in Military Members with Deployment Related Musculoskeletal Injuries	Faulkner and Hiebert	Associate Investigator	Marco Campello, Gregg Ziemke co-PI; NAVY POC CDR Brian Iveson	NMCP			CMDRP	NMCP
8	Clinical and Radiographic Outcomes Following Anterior Cervical Discectomy and Fusion Versus Anterior Cervical Discectomy and Arthroplasty in Active Duty Service Members.	Faulkner and Hiebert	Associate Investigator	change PI to Iveson (Gregg Ziemke)	NMCP			BUMED	NMCP
9	Brace comparison case study	Husson	research support	Alison Pruzner	WRNMMC	N/A	n	N/A	WRNMMC
10	Split-belt Treadmill Adaptation for Service Members with Unilateral	Husson	AI	Devjani Saha, PhD	WRNMMC C - BADER	2014-2015	N	N/A	WRNMMC

	TITLE	STAFF	ROLE	PI Name	PI Institution	Project cycle (e.g., Jan 2014 - Dec 2017)	Funding? (Y/N)	Funding source	Study SITE (s)
	Lower Extremity Amputation								
11	OA Protocol	Husson	AI	Alison Pruzner	WRNMM C	?	y	CRSR	WRNMMC
12	Summer 2015 Intern supervision	Husson	Co-supervisor	N/A	WRNMM C	May - Aug 2015	n	N/A	WRNMMC
13	Support Tasks (e.g. literature searches)	Jahelka	Research Support						BAMC/CFI
14	OA Fxn	Jahelka	Research Support	Jason Wilken	BAMC CFI				
15	MORE	Jahelka	Research Associate, Project Point Lead	Jason Wilken	CFI	12/2014-11/2017	y	BADER	Ft Hood, JBSA, CFI
16	Summer 2015 Interns supervision	Jahelka	Co-supervisor	NA	BAMC CFI				BAMC/CFI
17	FAI (Femoral Acetabular Impingement)	Jahelka	Research Support	Dr. Sheean	CRC BAMC				CRC BAMC
18	Differences in biomechanics during barefoot running with altered plantar cutaneous sensation by foot sole tape [BF Sense]	Jamison	Associate Investigator	Irene Davis	Harvard	Aug2013-	N	N/A	SNRC
19	Investigation of Running Mechanics in Healthy Runners [Normative Database]	Jamison	Associate Investigator	Irene Davis	Harvard	Nov2012	Y	Dept Funds	SNRC

	TITLE	STAFF	ROLE	PI Name	PI Institution	Project cycle (e.g., Jan 2014 - Dec 2017)	Funding? (Y/N)	Funding source	Study SITE (s)
20	Investigation of Loading Mechanics Experienced While Racing a Marathon	Jamison	Associate Investigator	Irene Davis	Harvard	April2015-	Y	Industry Partner	SNRC
21	Walk to Run Training with Realtime Kinetic Feedback	Jamison	Associate Investigator	Irene Davis	SNRC	June2013-	Y	BADER	SNRC/WRNMMC
22	Mobile Monitoring of Gait [place holder as studies are developed] These are now listed (amputees and runners)	Jamison	Investigator - Leading initiatives - PI?	TBD	TBD	Jan2014	TBD	TBD	SNRC
23	Gait Retraining for Individuals with Unilateral Lower Extremity Amputation Using a Mobile Device to Provide Real-time Feedback	Jamison	PI	Jamison	UDel	June2014-?	TBD	TBD	SNRC
38	Level Belt Validation	Jamison	Lead Investigator (PI for all intents and purposes outside of IRB paperwork)	Jimmy Onate	Ohio State	Jan2012-	N	N/A	OSU - data collection

	TITLE	STAFF	ROLE	PI Name	PI Institution	Project cycle (e.g., Jan 2014 - Dec 2017)	Funding? (Y/N)	Funding source	Study SITE (s)
39	Efficacy of a real-time feedback intervention to correct seated posture	Jamison	Associate Investigator	Debbie Givens	Creighton	Aug2013-	N	N/A	ASB 2013 meeting - Omaha, NE
40	Pelvic Obliquity Gait Retraining of Individuals with Unilateral Lower Extremity Amputation Using a Mobile Device (title in draft form)	Jamison	PI	Jamison	UDel	Nov2014-?	TBD	TBD	SNRC
24	WRNMMC Dept of Rehab and EACE	Wingate	Admin Support	NA	WRNMMC				WRNMMC
25	BADER Focus Group	Wingate	Associate Investigator, Admin Support	Wyatt	NMCSD				
26	Biomechanical Variability with Changes in Cognitive Demand during Ambulation for Service Members with Lower Limb Amputations	Wingate	Associate Investigator, Admin Support	Alison PRuziner, DPT, ATC	WRNMMC				WRNMMC
27	Verint Software	Wingate	Admin Support	NA	WRNMMC				WRNMMC

	<b>TITLE</b>	<b>STAFF</b>	<b>ROLE</b>	<b>PI Name</b>	<b>PI Institution</b>	<b>Project cycle (e.g., Jan 2014 - Dec 2017)</b>	<b>Funding? (Y/N)</b>	<b>Funding source</b>	<b>Study SITE (s)</b>
28	Dpt of Orthopaedic, Rehab and Pain	Wingate	Department Admin Reviewer	NA	WRNMMC	on-going	N	N/A	WRNMMC
29	Blanket Protocol (data registry)	Wingate	Associate Investigator, Admin Support	Erik Wolf, PhD	WRNMMC	?	N	N/A	WRNMMC
30	Software development for generation of clinical gait reports	Yoder	Clinical support	Marilynn Wyatt	NMCSD	N/A	N/A	N/A	N/A
31	Development of a Gait Quality Index to be Utilized Across the Department of Defense	Yoder	Associate Investigator	Marilynn Wyatt	NMCSD	Apr2015- ?	Y	CRSR	NMCSD-CFI-WRNMMC
32	Verification and validation of IMU system for dynamic pose measurement	Yoder	Research support	Marilynn Wyatt	NMCSD	N/A	N/A	N/A	N/A
33	High Level Functional Activities for Patients with Amputations	Yoder	Associate Investigator	Marilynn Wyatt	NMCSD	Jan2013 - ?	Y	BUMED	NMCSD
34	Comparison of Transtibial and limb salvage functional outcomes	Yoder	Associate Investigator	Marilynn Wyatt	NMCSD	Sept2014 - ?	N	N/A	NMCSD
35	Naval Medical Center Gait Lab Registry	Yoder	Associate Investigator	Marilynn Wyatt	NMCSD	June2015 - ?	N	N/A	NMCSD

	TITLE	STAFF	ROLE	PI Name	PI Institution	Project cycle (e.g., Jan 2014 - Dec 2017)	Funding? (Y/N)	Funding source	Study SITE (s)
36	Summer 2015 Intern supervision	Yoder	Co-supervisor	N/A	N/A	May - Aug 2015	N	N/A	NMCS D
37	Normative gait database for NMCS D clinical gait analyses	Yoder	Clinical support	Marilynn Wyatt	NMCS D	N/A	N/A	N/A	N/A
<b>64</b>	<b>TOTAL (37+3+24)</b>								