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TITLE: The IM ABLE Study: A Cross-Sector, Multisite Initiative to Advance Care for Warriors and Veterans Following Neuromusculoskeletal Injury of the Lower Limb

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14. ABSTRACT An estimated 20,000 military service members sustained extremity injury in the recent wars in Iraq and Afghanistan. This high number of limb injured Service Personnel catalyzed advancements in lower limb bracing technology and a focus on therapy to maximize utilization of these devices. This is a considerable problem in the Veteran and private sectors as well. It is presently unclear whether these newer (i.e. advanced) braces improve comfort and function in those with limb injury compared to bracing options formerly in use. The cost of newer devices and the associated fabrication time is rapidly climbing and some reimbursors are not paying for these newer devices. For instance, a conventional ankle-foot-orthosis has a reimbursable cost of approximately \$1400. Alternatively, newer advanced bracing systems such as the Intrepid Dynamic Exoskeletal Orthosis (IDEO), are approximately twice the cost of conventional devices to fabricate. Reimbursement costs are not yet widely agreed upon, if accepted at all. If the devices truly improve function and comfort, then the initial high costs of provision may be justified. The primary objective of this clinical trial is to determine if different types of leg/foot braces will improve comfort and function in persons who have sustained injury affecting their lower limb.					
15. SUBJECT TERMS None listed.					
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1. INTRODUCTION:

An estimated 20,000 military service members sustained extremity injury in the recent wars in Iraq and Afghanistan. This high number of limb injured Service Personnel catalyzed advancements in lower limb bracing technology and a focus on therapy to maximize utilization of these devices. The primary objective of this clinical trial is to determine if different types of leg/foot braces will improve comfort and function in persons who have sustained injury affecting their lower limb. This is a considerable problem in the Veteran and private sectors as well. It is presently unclear whether these newer (i.e. advanced) braces improve comfort and function in those with limb injury compared to bracing options formerly in use. The cost of newer devices and the associated fabrication time is rapidly climbing and some reimbursors are not paying for these newer devices. For instance, a conventional ankle-foot-orthosis has a reimbursable cost of approximately \$1400. Alternatively, newer advanced bracing systems such as the Intrepid Dynamic Exoskeletal Orthosis (IDEO), are approximately twice the cost of conventional devices to fabricate. Reimbursement costs are not yet widely agreed upon, if accepted at all. If the devices truly improve function and comfort, then the initial high costs of provision may be justified. Further, it is possible that the ability for a brace to enable improved function is partly related to the physical abilities (i.e. functional level) of the user. There is sparse data available to inform clinical providers as it relates to these issues thereby further justifying the conduct of this much needed study. This study will begin to build the evidence to inform clinical decision making about which device, advanced or conventional, maximizes patient comfort and function following extremity injury and identification as someone who could benefit from bracing technology. The study is immediately clinically applicable as it will be conducted within existing bracing clinical infrastructures. It will facilitate a new discussion about evaluating patients who use braces through the lens of an ambulatory functional level. It will also facilitate the use of objective outcome measurements within the participating clinical systems. Upon the conclusion of the study, the use of appropriately selected devices within each of the larger device categories (i.e. traditional or advanced) will yield conclusions regarding which device type optimizes patient performance and comfort within a given ambulatory functional category.

2. KEYWORDS: Provide a brief list of keywords (limit to 20 words).

Limb trauma, limb salvage, orthosis

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goal of this clinical trial is to determine if advanced (ADV) ankle foot orthoses (AFOs) will enable users to achieve greater levels of physical and self-reported function compared with conventional (CONV) AFOs for those ambulating at or above the independent community level of ambulation.

What was accomplished under these goals?

Participant recruitment and enrollment continues. Fifty seven (57) participants have been enrolled to date.

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

Nothing to report at this time.

How were the results disseminated to communities of interest?

Nothing to report at this time.

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

Continue research team teleconferences to ensure recruitment efforts continue to meet recruiting targets.

4. IMPACT:

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

Nothing to report at this time.

What was the impact on other disciplines?

Nothing to report at this time.

What was the impact on technology transfer?

Nothing to report at this time.

What was the impact on society beyond science and technology?

Nothing to report at this time.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report.

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

Enrollment during the final quarter of the reporting period was affected by the COVID-19 pandemic. All sites paused non-critical research. At this time it is likely that any non-critical research pauses will be lifted and sites will be able to resume enrolling participants.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report.

6. PRODUCTS:

• Publications, conference papers, and presentations

Journal publications

Nothing to report at this time.

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

Nothing to report at this time.

Other publications, conference papers, and presentations.

Highsmith MJ, Latlief GA, Kartel M, Ramrattan A et al. Dynamic Response AFO: Prescription, Rehabilitation and Management. Symposium. July 2017. Federal Advanced Amputation Skills Training Conference(FAAST). Uniformed Services University of the Health Sciences. Bethesda, MD.

Latlief G, Highsmith MJ, Ramrattan A, Kartel M. The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance Care for Warriors and Veterans following Neuromusculoskeletal Injury of the Lower Limb. James A Haley VA Hospital Research Poster Day, May 22, 2018, Tampa, FL.

Ramrattan A, Kartel M. The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance Care for Warriors and Veterans following Neuromusculoskeletal Injury of the Lower Limb. James A Haley VA Hospital. Physical Therapy section in-service. August 21, 2018, Tampa, FL.

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

Nothing to report.

• **Technologies or techniques**

Nothing to report.

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

Nothing to report.

• **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

University of South Florida & James A Haley VA

Name: Jason Highsmith

Project Role: Principal Investigator

Researcher Identifier: N/A

Nearest person month worked: 1 calendar month

Contribution to Project: Coordinated and planned project with the members of the research team.

Name: Rebecca Miro

Project Role: Research Coordinator

Researcher Identifier: N/A

Nearest person month worked: 1 calendar month

Contribution to Project: Managed set-up and execution of 4 study subcontracts. Submitted USF IRB applications and ClinicalTrials.gov registry.

Name: Anita Ramrattan

Project Role: Research Assistant, James A. Haley VA

Researcher Identifier: N/A

Nearest person month worked: 6 calendar months

Contribution to project: Responsible for assisting study PI in preparing and routing the regulatory documents through the Central VA IRB. Serves as main liaison between PI and Central VA IRB.

Hanger Prosthetics

Name: Phil Stevens

Project Role: Site PI (Hanger Prosthetics)

Researcher Identifier: N/A

Nearest person month worked: 0.4 calendar months

Contribution to project: Direct study activities, including regulatory approvals, at the Hanger Site.

New York VA

Name: Jason Maikos, PhD

Project Role: Site-PI

Nearest person month worked: 1

Contribution to project: Oversees integrity of the study at the local VANYHHS site. Supervises study staff. Coordinates recruitment efforts at local site. Contributed to LSI application forms to cIRB.

Name: Jonathan Glasberg, DPT

Project Role: Co-I

Nearest person month worked: 1

Contribution to project: Coordinates physical therapy study assessments. Assists with study protocol activities at the local VANYHHS site.

Name: Kenneth Breuer, CP, BOCO

Project Role: Orthotist

Nearest person month worked: 1

Contribution to project: Manages the orthotics lab at the local site and fits the study participants with the orthotics.

Name: Michael Hyre, MS

Project Role: Coordinator

Nearest person month worked: 1

Contribution to project: Coordinates recruitment efforts at local site. Maintains regulatory documentation and storage of study materials at the local site.

Name: Hannah Tadley

Project Role: Coordinator

Nearest person month worked: 1

Contribution to project: Coordinates recruitment efforts at local site. Maintains regulatory documentation and storage of study materials at the local site.

Name: Michael Poppo, MS

Project Role: RA

Nearest person month worked: 1

Contribution to project: Helps with recruitment and maintains communication with the orthotic clinic locally. Will obtain informed consent and help guide data collection.

Name: Ellen Godwin, PT, PhD

Project Role: Research PT

Nearest person month worked: 1

Contribution to project: Communicates with the local orthotic clinic. Will help perform PT outcome measures and any assessments as necessary. Assists with completing data collection forms.

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

No.

What other organizations were involved as partners?

Organization Name: James A Haley Veterans Hospital
Location: Tampa, FL
Financial Support: (years 1 & 2)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Hanger Prosthetics
Location: Houston, TX and Tucson, AZ
Financial Support: (Years 1 & 2, Houston location); (Years 1 & 2, Tucson location)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: New York HHS VA
Location: New York, NY
Financial Support: Years 1 & 2)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

8. SPECIAL REPORTING REQUIREMENTS: None

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and

See updated Quad Chart on the following page

The IM ABLE Study: A Cross-Sector, Multi-Site Initiative to Advance care for Warriors and Veterans following Neuromusculoskeletal Injury of the Lower Limb

W81XWH-16-1-0738

Log No: OP150089



PI: CPT M. Jason Highsmith, PhD, DPT, CP, FAAOP Org: USF & VA/DOD EACE (Tampa-Lead sites) Award Amount:\$

Study/Product Aim(s)

Advanced orthotic technologies will enable Service Members, Veterans and other orthotic users to achieve greater levels of self-reported and physical function compared with traditional orthotic devices regardless of ambulatory level. IM ABLE: a multi-site/sector initiative to study efficacy of advanced orthotics for limb injury below, or above the knee that is indicated for external bracing support. Included sectors: the VA, Military, academic medical centers, private sector.

Approach

This is Funding Level 2 (3y) study is a randomized, multi-site cross-over design. Subjects using LE orthoses will be recruited and either continue using their established orthosis or cross-over to the alternative. Physical therapy will be provided along with accommodation. Following the first data collection, subjects will cross-over into the alternate device and the process repeated. Following the second data collection, subjects will be given whichever orthosis they prefer and surveyed a final time.

Subject Ambulatory Functional Levels:

1. Ambulation with human assist
2. Limited household ambulation/limited community ambulation
3. Unlimited household ambulation/limited community ambulation
4. Unlimited household ambulation/unlimited community ambulation
5. Activities, such as exercise, that extend beyond basic ambulation

Subject Eligibility Criteria:

1. 18 to 68yo
2. Any gender & race
3. Lower extremity trauma or injury indicating use of an orthosis
4. Use of an orthosis for at least 60 days

SAMPLE ORTHOSES C.

Conventional

Advanced

A.

B.

A. Sample below the knee orthotic comparison. B. Sample above the knee orthotic comparison. C. Sample orthotic alternatives.

Timeline and Cost

Activities	CY	16-17	17-18	18-19
Regulatory approvals, begin recruitment		■		
Ongoing recruitment & data collection. Begin data analysis			■	
Complete data collection & analysis. Dissemination				■
Estimated Budget				

*Total Costs

Updated: Tampa, FL 9/28/2020

Goals/Milestones

CY16 Goals – Regulatory approvals underway.

CY17 Goal – Complete regulatory approvals; Initiate inter-site training; begin recruitment and data collection.

CY18 Goal – Complete data collection and data analysis. Disseminate study findings.

CY19 Goal – Continue data collection.

CY20 Goal - Complete data collection and data analysis.

Comments/Challenges/Issues/Concerns

- None

Budget

Total Expenditures to Date: