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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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13. SUPPLEMENTARY NOTES

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 provided

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	8	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
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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?
No data collection has begun. Hanger Prosthetics received Western IRB approval. VA Central IRB regulatory approvals for the James A Haley VA and New York VA is pending. Once VA Central IRB approval is received, the University of South Florida IRB will review the data coordinating center's application. Subsequently, USF will submit to DOD HRPO.

What opportunities for training and professional development has the project provided?
Nothing to Report.

How were the results disseminated to communities of interest?
Nothing to report at this time.

What do you plan to do during the next reporting period to accomplish the goals?
Once regulatory approvals are in place, study recruitment will begin.

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
Nothing to report.

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.
Nothing to report at this time.

• Website(s) or other Internet site(s)
Nothing to report.

• Technologies or techniques
Nothing to report.

• Inventions, patent applications, and/or licenses
Nothing to report.

• Other Products
Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Name: 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.

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: $141,594 (year 1 subcontract amount)
In-Kind Support: None
Facilities: None
Collaboration: None
Personnel Exchanges: None

Organization Name: Hanger Prosthetics
Location: Houston, TX and Tucson, AZ
Financial Support: $67,623 (Year 1 for Houston location); $65,148 (Year 1 for 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: $117,622 (Year 1 subcontract amount)
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

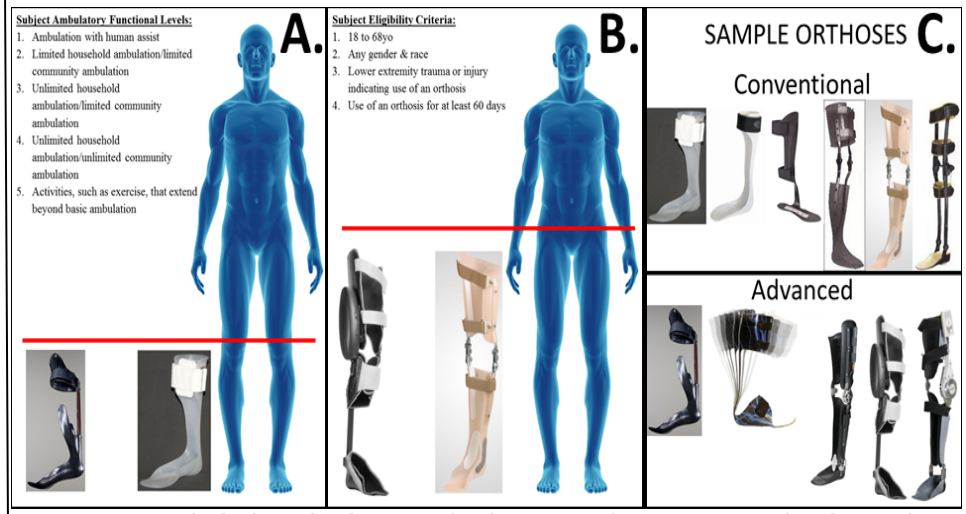
PI: CPT M. Jason Highsmith, PhD, DPT, CP, FAAOP **Org:** USF & VA/DOD EACE (Tampa-Lead sites) **Award Amount:$1,227,333**

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.



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 ($1.22M)	**$453K**	**$433K**	**$342k**

***Total Costs**

Updated: Tampa, FL 9/18/2017

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 – Complete data analysis.

Comments/Challenges/Issues/Concerns

- None

Budget

Total Expenditures to Date: $1,218,278