AWARD NUMBER: W81XWH-18-2-0073

TITLE: Comparative Effect of Commercially Available Custom Dynamic Orthoses (CDOs)

PRINCIPAL INVESTIGATOR: Jason Wilken

CONTRACTING ORGANIZATION: University of Iowa

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6. AUTHOR(S)
Jason Wilken, Molly Pacha

E-Mail:Jason-Wilken@uiowa.edu; Molly-Pacha@uiowa.edu

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Iowa, The
105 Jessup Hall
Iowa City, IA 52242-1316

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The objective of this research is to provide first-of-its-kind comparative effectiveness data for commercially and clinically available CDOs, and identify factors most strongly associated with device preference and function. Our efforts primarily focus on outcomes associated with the form, fit, and resulting function with the devices. The project's specific aims are to (1) determine the comparative effect of custom dynamic orthosis type in individuals with limb impairment resulting from traumatic limb injury; (2) determine if study-provided custom dynamic orthoses improve function relative to no-device and standard-of-care conditions in individuals with impairment resulting from traumatic limb injury; and (3) identify factors that are associated with device preference and function. A multicenter, prospective, randomized, crossover, controlled clinical trial will be conducted to determine the effect of device type on patient outcomes. Study staff have been hired, the project sites have received local IRB approval and are awaiting HRPO approval prior to initiating collection.

15. SUBJECT TERMS

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

Page

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The objective of this research is to provide first-of-its-kind comparative effectiveness data for commercially and clinically available CDOs, and identify factors most strongly associated with device preference and function. Our efforts primarily focus on outcomes associated with the form, fit, and resulting function with the devices. The project's specific aims are to (1) determine the comparative effect of custom dynamic orthosis type in individuals with limb impairment resulting from traumatic limb injury; (2) determine if study-provided custom dynamic orthoses improve function relative to no-device and standard-of-care conditions in individuals with impairment resulting from traumatic limb injury; and (3) identify factors that are associated with device preference and function. A multicenter, prospective, randomized, crossover, controlled clinical trial will be conducted to determine the effect of device type on patient outcomes. The trial will compare two commercially available devices. The devices will also be compared to standard-of-care (SOC) and no-device (NONE) conditions to examine the effect on limb function. Physical performance measures, patient-reported outcomes, and biomechanical testing data will be used to fully evaluate device function and participant outcomes. The PI proposes that the data from this study will inform clinical care decisions in both military and civilian settings by improving the understanding of the benefits and limitation of available devices and the factors that contribute to patient satisfaction and dissatisfaction.

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

Orthosis, Custom, Dynamic, Limb Trauma, Outcomes, Biomechanics, Gait, Physical Performance

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

	Months
Major Task 1: Overarching Project Activities	
Subtask 1: Identify, hire and retain top quality staff and students	0-48
Subtask 2: Obtain and maintain local IRB and HRPO regulatory approvals	0-48
Subtask 3: Project team teleconferences	0-48
Subtask 4: Complete study reports, presentations, publish and disseminate study results	10-48+
Milestone: Timely submission of progress reports	3-48
Milestone: Submission of continuing review documents	12-48
Milestone: Local IRB and HRPO approval at all sites	6
Milestone: Submission of final report	48
Major Task 2: Project Standup	
Subtask 1: Establish CRADA and other required agreement	0-6

Subtask 2: Finalize collection procedures and REDCap data management	0-6
Subtask 3: Fabricate and distribute device mechanical testing systems	0-6
Subtask 4: Staff training and collection procedure refinement	3-6
Milestone: All approvals and agreements in place	6
Milestone: Ready to initiate recruitment and collection	6
Major Task 3: Patient Fittings	
Subtask 1: Work with vendors to finalize distribution and training plan	0-3
Subtask 2: Inter-site coordination of fitting processes and CPO training	0-12
Subtask 3: Completion of study fitting manual describing procedures	0-12
Milestone: Ready to initiate fittings	6
Milestone: Patient fittings ongoing and logistics resolved	12
Major Task 4: Participant Testing	
Subtask 1: Staff training and methods verification	3-45
Subtask 2: Ongoing data quality checks	9-42
Subtask 3: Recruitment, enrollment and collection (31 Patients)	7-40
Subtask 4: Recruitment, enrollment and collection (25 Patients)	7-40
Subtask 5: Recruitment, enrollment and collection (15 Patients)	12-40
Milestone: Enrollment complete	33
Milestone: Collection complete	40
Major Task 4: Data Analysis and Publication	
Subtask 1: Data Analysis- Patient reported and performance measures	14-45
Subtask 2: Data Analysis- Biomechanical and mechanical measures	14-45
Subtask 3: Finalize and implement statistical analysis plan	40-45
Subtask 4: Interpretation of results and manuscript preparation	40-45
Milestone: Analysis complete	45
Milestone: Initial manuscripts	48
Specific Aim 1: Determine the comparative effect of custom dynamic orthosis type in individuals with limb impairment resulting from traumatic limb injury	
Specific Aim 2: Determine if study-provided custom dynamic orthoses improved function relative to no device, and standard of care conditions, in individuals with impairment resulting from traumatic limb injury	
Specific Aim 3: Identify factors that are associated with device preference and function	

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Major Task 1
Study standup activities continue across all three sites. The University of Iowa (UIA) site hired a full-time Research Associate. The Minneapolis VA Health Care System (MVAHCS) identified and hired one Research Study Coordinator and one Research Prosthetist Orthotist that contributed to the preparation of the project protocol submission to the local IRB. MVAHCS has been preparing their gait laboratory in the prosthetics department where data collection will take place. Existing staff continue to contribute to the project at all sites. Project coordination is ongoing between sites. The UIA IRB reviewed and approved the new project application on 06/25/2019. The project has been determined to be minimal risk. Minneapolis VA IRB reviewed and approved the new project application on 05/10/2019. The project has been determined to be minimal risk. Walter Reed National Military Medical Center (WRNMMC) submitted the protocol to their local IRB and responded to stipulations. WRNMMC's subaward has been fully executed. After additional coordination with the UIA IRB, the HRPO protocol submission form and supporting documentation were submitted on 7/23/2019 and is currently still under review. The submission form will serve as the master protocol for all participating sites. Multiple project teleconferences have been held to ensure consistency of study documents.

Major Task 2
Collection procedures were agreed upon and the study collection manual has been developed. An amendment was submitted and approved on 10/10/2019 to UIA IRB to update collection forms and modify study procedures. MVAHCS and WRNMMC will update changes to their local IRB. CDO fitting training sessions took place in April of 2019 with practitioners at the Minneapolis VA Health Care system (MVAHCS) and American Prosthetics and Orthotics (APO), who will be doing the device fittings at the University of Iowa (UIA). The sessions included training directly from the clinical subject matter experts from the commercial vendors. IAROM devices were designed and fabricated by Special Designs and shipped to UIA and MVAHCS. The devices have been received. Staff training at UIA for subject evaluation was completed. A Data Sharing Agreement (DSA) was developed between WRNMMC and UIA and submitted locally. The CRADA application has been developed at WRNMMC and will be processed upon receiving IRB approval. The statistician generated and uploaded the randomization table with defined parameters to the REDCap randomization module which will assign participants to a condition.

Major Task 3
The device distribution and training plans for UIA and MVAHCS have been established. Device fitting training was conducted for both devices in April of 2019. Development of the fitting manual was initiated in conjunction with the UIA and MVAHCS training sessions. Additional refinement will take place during the initial few fittings as questions arise. WRNMMC will most likely complete training during the next reporting period. CDO device testing took place at the University of Delaware using a 3-D print custom cuff insert for every AFO to facilitate stiffness testing. The University of Delaware is nearly finished constructing the CDO mechanical testing device and will shipped them to each site upon completion.

Major Task 4
Collection has not been initiated. Staff training and methods verification are ongoing. Methods refresher training will take place prior to the initiation of collection at the respective study sites.

All indications continue to be that we should be able to complete our remaining major tasks in a manner similar to initially planned over the next and future quarters.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

CDO fitting training sessions took place in April of 2019 with practitioners at the Minneapolis VA Health Care system (MVAHCS) and American Prosthetics and Orthotics (APO), who will be doing the device fittings at the University of Iowa. The sessions included training directly from the clinical subject matter experts from the commercial vendors. WRNMMC will complete training at a later time that more closely aligns with implementation.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

During the next reporting period, we anticipate the study will receive HRPO approval and Walter Reed National Military Medical Center (WRNMMC) will receive local IRB approval. MVAHCS and WRNMMC will mirror the UIA amendment to update collection forms and modify study procedures with their local IRB. These modifications to the research protocol and collection forms do not increase risk to subjects or meet other requirements for HRPO submission.

The University of Delaware will ship the CDO mechanical testing devices to each site. We will coordinate and schedule CDO device training with practitioners at Walter Reed National Military Medical Center (WRNMMC). Additional staff training and methods verification will take place with the UIA and MVAHCS teams. We intend to begin recruitment, enrollment and collection at UIA and MVAHCS.

All indications continue to be that we should be able to proceed with our remaining major tasks as planned over the next and future quarters.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

The ongoing discussions between the study team members and industry have advanced the way team members think about CDO fitting. These discussions have the potential to advance both industry and clinical practice in the future and will likely result in a future related grant submission.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:
- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to Report

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

The regulatory review process has taken longer than anticipated, however, expenses have been in line with progress, and we anticipate we will be able to complete the project in the proposed timeline.

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Delays in regulatory approvals and subsequent study activities has resulted in a decreased rate of expenditure during the first year for the study. The resources will be required in subsequent years to complete the project in a timely manner.

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

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

List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**

Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

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

Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**

Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Name: *Jason Wilken, PhD*
Project Role: *Overall Award Principal Investigator; UI Site Principal Investigator*
Researcher Identifier (ORCID ID): *0000-0002-5556-7667*
Nearest person month worked: *2*
Contribution to Project: *Study direction, site management, regulatory approvals, review of patient fitting methods, work with vendors to finalize distribution and training plan*

Name: *Molly Pacha*
Project Role: *Research Associate*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *3*
Contribution to Project: *Data collection procedure refinement, regulatory approvals, technical report preparation and submission.*

Name: *Madison Chrisman*
Project Role: *Research Assistant*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Preparation of project protocol submission to local IRB*

Name: *Natalie Glass*
Project Role: *Statistician*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Preparation of study documentation in REDCap*

Name: *Michael Willey*
Project Role: *Co-Investigator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Study direction, data collection, procedure refinement*

Name: *Andrew H. Hansen, PhD*
Project Role: *MVAHCS Site Principal Investigator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Site PI, Study standup activities*

Name: *Kimberly Behrens, BA*
Project Role: *MVAHCS Research Study Coordinator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *3*
Contribution to Project: *Data collection procedure refinement, regulatory approvals, technical report preparation and submission*

Name: *Nicole Walker, MS*
Project Role: *MVAHCS Research Prosthetist Orthotist*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *3*
Contribution to Project: *Study standup activities, technical report preparation and submission*

Name: *Christopher L Dearth, PhD*
Project Role: *WRNMMC Site Principal Investigator, Co-Investigator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Site PI, Study standup activities*

Name: *Jenny Nguyen*
Project Role: *Protocol Coordinator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Study standup activities, Regulatory approvals*

Name: *Elisa Arch, PhD*
Project Role: *UD Site/Subaward Principal Investigator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Subaward PI, Study standup activities - CDO Testing Device*

Name: *Ellen MacKenzie, PhD*
Project Role: *JHU Site/Subaward Principal Investigator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Subaward PI, Study standup activities*

Name: *Daniel J. Stinner, MD*
Project Role: *BAMC Site Principal Investigator, Subject Matter Expert*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *1*
Contribution to Project: *Subaward PI, Study standup activities*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to report beyond the team initially described in the grant proposal

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

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 surveys, etc.