

AWARD NUMBER: W81XWH-22-1-0464

TITLE: Carbon Fiber Orthosis Cuff Design

PRINCIPAL INVESTIGATOR: Dr. Jason Wilken, PT, PhD

CONTRACTING ORGANIZATION: The University of Iowa

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PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

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| 14. ABSTRACT Traumatic lower limb injuries often result in poor functional outcomes with long-term negative effects. Carbon fiber custom dynamic orthoses (CDOs) increase mobility, improve quality of life, and improve function following injury by reducing pain, supporting the limb, and transferring forces around the limb through the CDO. CDOs consist of a proximal cuff that wraps around the leg just below the knee, a posterior carbon fiber strut that stores and returns energy during gait, and a carbon fiber foot plate that supports the foot and allows bending of the posterior strut. The proximal cuff is a primary interface between the patient and the CDO and may influence comfort, preference, limb mechanics and loading, and effective stiffness of the CDO. Although CDOs are becoming more commonly prescribed following injury the evidence available to guide clinical practice remains limited and the important role of the proximal cuff has not been examined. The purpose of this study is to determine the effects of CDO proximal cuff design on patient reported outcomes, limb mechanics and loading, and CDO mechanical characteristics. | | | | | |
| 15. SUBJECT TERMS Carbon Fiber Orthosis, Post-Traumatic Osteoarthritis, Lower Limb Injury, Healthy | | | | | |
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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose, and scope of the research.*

Traumatic lower limb injuries often result in poor functional outcomes with long-term negative effects. Carbon fiber custom dynamic orthoses (CDOs) increase mobility, improve quality of life, and improve function following injury by reducing pain, supporting the limb, and transferring forces around the limb through the CDO. CDOs consist of a proximal cuff that wraps around the leg just below the knee, a posterior carbon fiber strut that stores and returns energy during gait, and a carbon fiber foot plate that supports the foot and allows bending of the posterior strut. The proximal cuff is a primary interface between the patient and the CDO and may influence comfort, preference, limb mechanics and loading, and effective stiffness of the CDO. Although CDOs are becoming more commonly prescribed following injury the evidence available to guide clinical practice remains limited and the important role of the proximal cuff has not been examined.

The purpose of this study is to determine the effects of CDO proximal cuff design on patient reported outcomes, limb mechanics and loading, and CDO mechanical characteristics. Two groups of individuals will participate: individuals with post-traumatic osteoarthritis (PTOA) in the ankle and healthy individuals. Testing will occur without an orthosis and while wearing orthoses with four proximal cuff designs representative of currently available devices: CUFF-A) a rigid patellar tendon bearing (PTB) clamshell cuff secured using a mechanical ratcheting system, CUFF-B) a PTB shell with a fixed pivot point secured with Velcro, CUFF-C) a rigid clamshell cuff secured with Velcro, and CUFF-D) a semi-rigid cuff with a flexible outer layer secured with Velcro. Participants will provide demographic and anthropometric information, be cast and fit for the study CDOs, undergo full biomechanical gait analysis and passive ankle joint stiffness testing, will complete questionnaires concerning device comfort and smoothness, pain, preference, physical function, and pain interference, and will complete a semi-structured interview.

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

Carbon Fiber Orthosis, Post-Traumatic Osteoarthritis, Lower Limb Injury, Healthy

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

- o **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.*

| Activity | Months | Progress |
|--|--------|----------|
| Major Task 1: Overarching project activities | | |
| Subtask 1: Identify, hire, and retain top quality staff and students | Pre-24 | 45% |
| Subtask 2: Obtain and maintain IRB and HRPO regulatory approvals | Pre-24 | 65% |
| Subtask 3: Project team teleconferences | 0-24 | 25% |
| Subtask 4: Reports, presentations, publish and disseminate study results | 10-24+ | 20% |
| <i>Milestone Achieved: Timely submission of progress reports</i> | 3-24 | 12% |
| <i>Milestone Achieved: Submission of continuing review documents</i> | 12-24 | 20% |
| <i>Milestone Achieved: Local IRB and HRPO approval</i> | 4 | 100% |
| <i>Milestone Achieved: Submission of final report</i> | 24 | 0% |
| Major Task 2: Project Standup | | |
| Subtask 1: Establish required agreements | Pre-3 | 95% |
| Subtask 2: Finalize collection procedures and REDCap data management | 0-3 | 100% |
| Subtask 3: Staff training and collection procedure refinement | 2-3 | 95% |
| <i>Milestone Achieved: All approvals and agreements in place</i> | 3 | 95% |

| | | |
|--|-------|------|
| <i>Milestone Achieved: Ready to initiate recruitment and collection</i> | 3 | 100% |
| Major Task 3: Patient Fittings | | |
| Subtask 1: Work with vendors to finalize distribution and training plan | Pre-4 | 90% |
| Subtask 2: Coordination of fitting processes and CPO training | 0-6 | 90% |
| Subtask 3: Completion of study fitting manual describing procedures | 0-6 | 90% |
| <i>Milestone Achieved: Ready to initiate fittings</i> | 3 | 100% |
| <i>Milestone Achieved: Patient fittings ongoing and logistics resolved</i> | 6 | 25% |
| Major Task 4: Participant Testing | | |
| Subtask 1: Staff training and methods verification | 2-21 | 60% |
| Subtask 2: Ongoing data quality checks | 4-21 | 5% |
| Subtask 3: Recruitment, enrollment, and collection (Healthy individuals) | 4-15 | 5% |
| Subtask 4: Recruitment, enrollment, and collection (Individuals with PTOA) | 6-21 | 0% |
| <i>Milestone Achieved: Enrollment complete</i> | 19 | 0% |
| <i>Milestone Achieved: Collection complete</i> | 21 | 0% |
| Major Task 5: Data Analysis and Publication | | |
| Subtask 1: Data analysis – Patient reported outcomes | 5-22 | 0% |
| Subtask 2: Data analysis – Biomechanical gait data | 5-22 | 0% |
| Subtask 3: Data analysis – Mechanical testing data | 5-22 | 0% |
| Subtask 4: Finalize and implement statistical analysis plan | 18-22 | 0% |
| Subtask 5: Interpretation of results and manuscript preparation | 20-23 | 0% |
| <i>Milestone Achieved: Analysis complete</i> | 23 | 0% |
| <i>Milestone Achieved: Initial manuscripts submitted</i> | 24 | 0% |

- **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: In the first calendar year study standup efforts have continued and one Graduate Research Assistant (Mrs. Kirsten Anderson) and additional Undergraduate Research Assistants at the University of Iowa were identified. The project protocol was submitted to the local IRB and was approved on July 25th, 2022, and subsequently submitted to the Office of Human Research Oversight (OHRO) and approved on September 19th, 2022. Continuing review documents were also submitted to and approved by both University of Iowa IRB and OHRO offices. Project teleconferences with the study team have been held to discuss regulatory strategy, study measures, CDO casting and fitting procedures, participant recruitment, regulatory strategy, and study measures.

Major Task 2: Collection procedures were planned, study team members were trained, and the Research Electric Data Capture (REDCap) was used to create and refine study documentation and questionnaires during the first calendar year. Additionally, a strategy was developed to address CDO casting and fabrication procedures, and the first study CDO was fabricated.

Major Task 3: In the first calendar year the study PI coordinated with the vendors to ensure they are included in the University of Iowa procurement system. American Prosthetics and Orthotics was acquired by Hanger Clinic and project meetings were conducted to ensure that ongoing

study procedures will continue as planned. Study CPOs were trained to cast and fit the study CDOs, and the study fitting manual will be available for reference. The first participant was cast for the study CDO, the device was fabricated, and the participant was fit with study CDO.

Major Task 4: In the first calendar year, the research team has started training study staff on collection procedures. The first study participant was enrolled and completed study activities.

Major Task 5: Data analysis and publication has not been initiated in the first calendar year.

- **Describe the Regulatory Protocol and Activity Status (if applicable).** *Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state "Nothing to Report."*

- **Human Use Regulatory Protocols**

- **TOTAL PROTOCOLS:** *State the total number of human use protocols required to complete this project (e.g., 5 human subject research protocols will be required to complete the Statement of Work.). If not applicable, write "No human subjects research will be performed to complete the Statement of Work."*

One human subject research protocol will be required to complete the study activities. The protocol has been submitted to, and approved by, the local IRB at the University of Iowa. The study protocol has also been submitted to and approved by the OHRO.

- **PROTOCOL(S):** *List the identifier and title for all human use protocols needed to complete the project. Include information about the approved target number for clinical significance, type of submission, type of approval with associated dates, and performance status.*

Protocol (1 of 1 total):

Protocol [OHRO Assigned Number]: Protocol E03038.1a (University of Iowa), E03038.1a-1 (Hanger Clinics).

Title: Comparative Effect of Carbon Fiber Orthosis Cuff Design on Preference, Comfort, and Mechanics

Target required for clinical significance: 34 (17 healthy, 17 with PTOA)

Target approved for clinical significance: 34 (17 healthy, 17 with PTOA)

Submitted to and approved by:

New Protocol IRB Submission: Approved on 07/25/2022

New Protocol OHRO Submission: Approved on 09/13/2022

Status:

Recruitment/Screening/Enrollment/Completion:

Number of subjects recruited/original planned target: 1/34

Number of subjects screened/original planned target: 2/34

Number of patients enrolled/original planned target: 1/34

Number of patients completed/original planned target: 1/34

Amendments submitted to the IRB and USAMRMC OHRO for review:

| Submitted | Approved | Notes |
|------------|------------|--------------|
| 08/14/23 | pending | Modification |
| 07/31/23 | 08/02/23 | Modification |
| 05/23/2023 | 05/23/2023 | Modification |
| 05/15/2023 | 05/15/2023 | Modification |
| 05/11/2023 | 05/12/2023 | Modification |

| | | |
|------------|------------|---|
| 05/05/2023 | 05/09/2023 | Modification and Continuing Review |
| 05/02/2023 | 05/05/2023 | Modification |
| 05/01/2023 | 05/02/2023 | Modification |
| 12/05/2022 | 12/05/2022 | Modification |
| 09/21/2022 | 09/21/2022 | Modification |
| 05/10/2022 | 07/25/2022 | Initial submission of full project protocol |

Any adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

N/A

○ **Use of Human Cadavers for Research Development Test & Evaluation (RDT&E), Education or Training**

No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW).

○ **Animal Use Regulatory Protocols**

No animal use research will be performed to complete the Statement of Work.

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

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.

Nothing to report this year.

○ **How were the results disseminated to communities of interest?** *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 this year.

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

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

During the next reporting period recruitment will continue and additional healthy participants will be enrolled in the study. Individuals with PTOA will be enrolled and tested. Recruitment materials, including informational emails, flyers, and letters will continue to be distributed. 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:** *Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about because of the project relative to:*

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

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).

Nothing to report this year.

○ **What was the impact on other disciplines?** *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 this year.

- **What was the impact on technology transfer?** *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 this year.

- **What was the impact on society beyond science and technology?** *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 this year.

5. **CHANGES/PROBLEMS:** *The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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:*

- **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.*

Nothing to report this year.

- **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.*

American Prosthetics and Orthotics (APO) was acquired by Hanger Clinic in the first calendar year. Project meetings have continued to ensure that ongoing collaborations will proceed as planned and additional meetings have been planned to ensure strong collaboration moving forward.

- **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.*

Nothing to report this year.

- **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.*

Nothing to report this year.

6. **PRODUCTS:** *List any products resulting from the project during the reporting period.*

- **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 this year.

- **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 this year.

- **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 this year.

- **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 this year.

- **Technologies or techniques** *Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.*

Nothing to report this year.

- **Inventions, patent applications, and/or licenses** *Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. 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 this year.

- **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; biospecimen 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 this year.

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."*

| | |
|------------------------------|--|
| Name: | Jason Wilken, PT, PhD |
| Project Role: | Overall Award PI |
| Researcher ID (ORCID ID): | 0000-0002-5556-7667 |
| Nearest Person Month Worked: | 1 |
| Contribution to Project: | Study direction, site management, regulatory approvals, review of patient fittings, work with vendors to finalize distribution and training plans. |

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| | |
|------------------------------|--|
| Name: | Molly Pacha, MS |
| Project Role: | Research Associate |
| Researcher ID (ORCID ID): | N/A |
| Nearest Person Month Worked: | 0 |
| Contribution to Project: | Data collection procedure refinement, regulatory approvals, technical report preparation and submission. |

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Name: Patrick Ten Eyck, PhD
Project Role: Co-Investigator/Lead Biostatistician
Researcher ID (ORCID ID): N/A
Nearest Person Month Worked: 1
Contribution to Project: Preparation of data collection forms in REDCap, data quality checks, statistical analysis.

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Name: Kirsten Anderson, BSE
Project Role: Graduate Research Associate
Researcher ID (ORCID ID): 0000-0003-4282-5038
Nearest Person Month Worked: 1
Contribution to Project: Data collection procedure refinement, regulatory approvals, report preparation and submission

- **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 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 this year.

- **What other organizations were involved as partners?** *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.*

Organization Name: The University of Iowa
Location of Organization: Iowa City, IA
Contribution to Project: Facilities, collaboration

8. SPECIAL REPORTING REQUIREMENTS

- **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. Reminder: Pages shall be consecutively numbered throughout the report. **DO NOT RENUMBER PAGES IN THE APPENDICES.***

Nothing to report this year.