

AWARD NUMBER: W81XWH-21-2-0013

TITLE: Exoskeletons for Rapid Return to Duty After Tibial Stress Fracture

PRINCIPAL INVESTIGATOR: W. Lee Childers PhD CP

CONTRACTING ORGANIZATION: The Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF), Bethesda, MD

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14. ABSTRACT Military duty involves high impact activities and carrying heavy loads that increases the risk of a Service member to develop a stress fracture in the tibia bone. Stress fractures in the tibia effect about 3100 Service members each year, and 40% of these individuals are separated from service. Treatment after a stress fracture can take several months to a year and typically involves the person to unweight the limb, allow it to heal, and then gradually start bearing more and more weight on it until the bone is able to fully heal. The Service member is not deployable during this time. Therefore, tibial stress fractures represent a significant threat to the readiness of our fighting force. To overcome this threat to military readiness, we will develop a dynamic brace to off-load the facture site while enabling the user to perform high impact activities associated with military service. This will shorten the period of rehabilitation, elevate the military standard of care for tibial stress fractures, enable a Service member to return to duty sooner, and maximize military readiness.					
15. SUBJECT TERMS Operational Readiness, Orthosis, IDEO, Tibial Stress Fracture, Exoskeleton					
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1. INTRODUCTION:

This proposal will develop a device that will facilitate rapid return to duty of a Service member (SM) after developing a tibial stress fracture. The device will offload the tibia while enabling return to high activity and reduce the necessary rehabilitation time for tibial stress fractures. This will maximize readiness by minimizing lost duty days, advance the standard of care for the treatment of tibial stress fractures, and increase evidence-based care of military orthopedic injuries.

2. KEYWORDS:

Operational readiness, orthosis, IDEO

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The major goal of this project is to develop a device that will facilitate rapid return to duty of a Service member (SM) after developing a tibial stress fracture. We will be leveraging our Team's previous work with the Intrepid Dynamic Exoskeleton Orthosis (IDEO) that returned SMs to duty after complex lower limb salvage operations and our ongoing efforts to develop exoskeleton solutions for battlefield care. This goal will be accomplished by: 1) Evaluating the ability of orthoses to transfer energy around a stress fracture site in a cadaveric model, 2) Evaluating the effectiveness of orthoses designed to off-load the shank and enhance user comfort in SMs performing military relevant tasks.

Major Tasks for Specific Aims 1 and 2	Scheduled completion	Percent Completion	Completion date
Major Task 1 – Gain regulatory approvals			
Cadaver testing protocol filed with Lackland Air Force Base	01 DEC 2021	100	01 DEC 2021
Local approvals gained for cadaveric testing	01 MAR 2022	100	06 DEC 2021
Submit cadaveric testing protocol for HRPO approval	01 MAR 2022	100	13 JAN 2022
Milestone Achieved: Regulatory Approval for Cadaveric Testing	01 JUL 2022	100	15 FEB 2022
Human Subject Protocol submitted to BAMC IRB	01 DEC 2021	100	01 DEC 2021
BAMC IRB Approval of Human Subject Protocol	01 JUL 2022	100	21 MAR 2022
Submit for HRPO Approval of Human Subject Protocol	01 AUG 2022	100	22 APR 2022

Milestone Achieved: Regulatory approval for Human Subject Protocol	01 OCT 2022	75	
Major Task 2 – Exoskeleton development			
Build physical surrogates of the lower limb	01 DEC 2021	80	
Develop the soft, outer shell of the fracture management interface prototype that will fit on the lower limb model and contain the inflatable bladders.	01 JUN 2023	10	
Develop inflatable bladders for the fracture management interface prototype capable of stabilizing a stress fracture while also regulating pressure applied across the limb.	01 JUN 2023	10	
Develop the energy storage and return exoskeleton frame that will integrate with the FMI.	01 JUN 2023	40	
Mechanically test SFxO prototypes using human cadavers to determine which design minimizes strain at the distal third of the tibia.	01 OCT 2023	0	
Reduce mechanical testing data and complete statistical analysis	01 OCT 2023	0	
Improve SFxO prototype based on mechanical testing results	01 JUN 2024	0	
Milestone Achieved: SFxO prototype development	01 JUN 2024	0	
Major Task 3 – Evaluate the effectiveness of orthoses to off-load the shank and enhance user comfort during military relevant tasks.			
Collect experimental data on 16 active-duty service members without lower limb pathology after gaining informed consent	01 FEB 2025	0	
Reduce biomechanical and qualitative data	01 APR 2025	0	
Complete statistical analysis	01 MAY 2025	0	
Milestone Achieved: Data collection complete	01 MAY 2025	0	
Major Task 4 – Dissemination			
MHSRS abstract on initial design work	01 JAN 2023	100	14 FEB 2022 (Submitted) 02 May 2022 (Accepted)
MHSRS abstract on cadaveric testing	01 JAN 2024	0	
MHSRS abstract on Hypothesis 2.1	01 JAN 2025	0	
MHSRS abstract on Hypotheses 2.2	01 JAN 2025	0	
Abstract submission to prosthetic and orthotic conference on quasi-static loading	01 MAR 2025	0	
Paper submitted to peer-reviewed journal on mechanical testing	01 FEB 2023	0	

Paper submitted to peer-reviewed journal on Hypotheses 2.1 and 2.2	01 JUL 2025	0	
Milestone Achieved: Abstracts and papers submitted	01 AUG 2025	0	
Major Task 5 – Translation preparation			
Engage with US MRDC Advance Development group for protection of intellectual property and translation planning	01 AUG 2025	0	
Protocol development for clinical trial	01 AUG 2025	10	
Engage with potential industry partners in collaboration with USAMRDC Advance Development	01 AUG 2025	0	
Prepare proposals for clinical trial and facilitate translation	01 AUG 2025	0	
Milestone Achieved: Translation plan complete	01 AUG 2025	0	

What was accomplished under these goals?

Major Activities with Specific objectives

Hiring

- Michael Poppo (Materials Testing Engineer) was onboarded 15 AUG 2021 and is responsible for project management and mechanical design.
- Ciera Price (Research Orthotist Prosthetist) was onboarded 6 JUL 2021 to assist with prototype fabrication.
- Roberto “JR” Cruz (Research Technician) was onboarded 13 JUN 2022 to assist with prototype fabrication.
- Dr. Robert McGrath (Mechanical Engineer) will join our lab on 6 SEP 2022 and will backfill the vacancy left by Dr. McCain.
- Dr. Emily McCain (Mechanical Engineer) left the Henry Jackson Foundation and our lab to pursue another opportunity on 24 JUN 2022.

Regulatory

- Human subjects data collection protocol submitted (1 DEC 2021) and approved (21 MAR 2022) by the San Antonio IRB. Protocol submitted to HRPO on 12 APR 2022.
- Cadaver data collection protocol gained local approval (6 DEC 2021) and HRPO approval (15 FEB 2022). MOU to work with the 59th MDW at Lackland AFB is going through a legal review at the 59th MDW.

Surrogate Development

- Surrogates have been and will be used to help the team rapidly iterate through prototype designs and inform the team on testing protocols for cadaveric testing. The key features of these surrogates are: 1) a resin-filled 3D printed foot, 2) fixed ankle, 3) fixed knee, and 4) strategically placed strain gauges. In general, the fabrication process is:
 1. Obtain negative lower extremity impressions of human models with measurements corresponding to the 5th percentile female, 50th percentile male, and 95th percentile male Army personnel.
 2. Fabricate a negative bi-valve PETG mold.
 3. Assemble a skeletal model with fixed joints and bony landmarks roughly aligned anatomically to the mold.
 4. Suspend the skeletal model in the mold and seal the mold.
 5. Pour 2-part silicone into the mold containing the skeletal model. Allow time to set.
 6. Release the positive silicone surrogate from the mold.
- Composite bones (Sawbones) were on backorder until 14 FEB 2022, when most of the items (excluding the medium femur) shipped. Sawbones were received 21 FEB 2022. This included two pairs of left femurs and tibias at each of the small, medium, and large sizes.
- To overcome the lack of composite bones, lower limb bone models were engineered and used to create a surrogate representative of the 50th percentile male SM. This required:
 1. Scanning display model bones to create a 3D mesh shape.
 2. Using software to convert mesh shape to a hollow bone shell (**Figure 1a**).
 3. 3D printing the bone shells (**Figure 1b**).
 4. Filling the bone shells with a two-part epoxy that approximated the mechanical properties of bone as closely as possible, while ensuring cure temperatures didn't exceed the melting point of the 3D printed material.
 5. Anatomically aligning and secured 3D printed, and epoxy filled bones (**Figure 1c**).
 6. Filling 50th percentile male surrogate mold with silicone (**Figure 1d**).

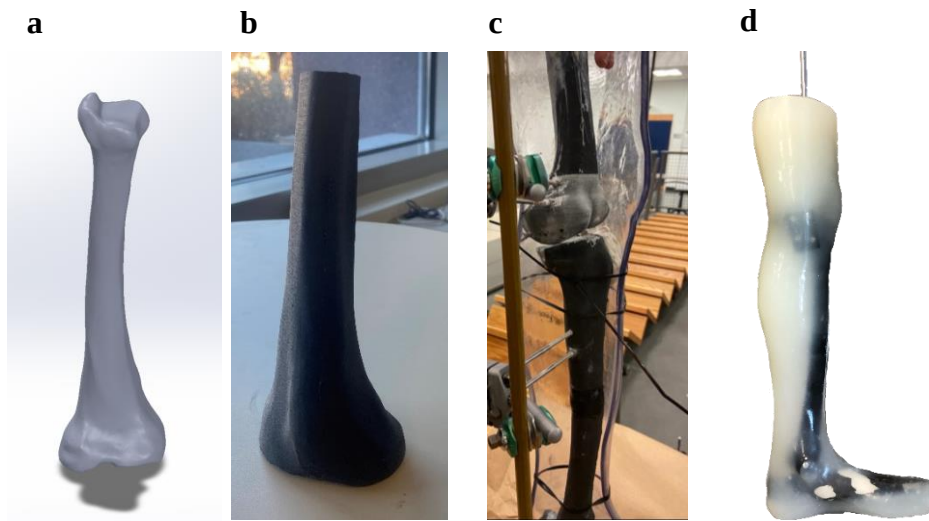


Figure 1: a. 3D part developed from a display model of a human tibia. b. 3D printed tibia half shells c. Aligned 3D printed bones in half of the surrogate mold d. Completed surrogate limb

representing the 50th percentile male SM. This surrogate is now being used for testing and the 5% female and 95% male surrogates will be produced next.

- The development of this surrogate fabricate method is a significant achievement in that it reduces our reliance on external manufacturers, who have been plagued with supply chain issues. Specifically, Sawbones is having major production issues and are not currently accepting orders.
- To develop the fabrication protocol for future surrogates, a set of medium Sawbones were instrumented with linear strain gages (**Figure 2**). This fabrication process taught us:
 1. The use of an external fixator allows for small adjustments to the alignment of the femur and tibia prior to fixing the position of the bones.
 2. The knee can be locked with plates that span the tibial plateau.
 3. A foot can be custom fit to a mold to ensure optimal ground contact. This foot is then scanned, 3D printed hollow, and filled with resin, creating a stable base for the tibia.
 4. Implementing an intact fibula that is not instrumented with strain gauges adds a second pathway to transfer loads and represented a confounding variable for our measurements of offloading on the tibia. The distal/proximal ends of the fibula were retained to best replicate the anatomy, but the shaft removed to eliminate this potential confounding variable in the lower limb surrogate.
 5. Linear strain gauges helped us determine locations for strain gauge rosettes and determine how much loading is needed to see differences in loading patterns. We learned that changes can be seen at lower loads (27 kg or 60 lbs).
 6. The foot-tibia connection utilized an internal pin that caused a high stress concentration and resulted in a distal tibia fracture during angled sine plate testing.

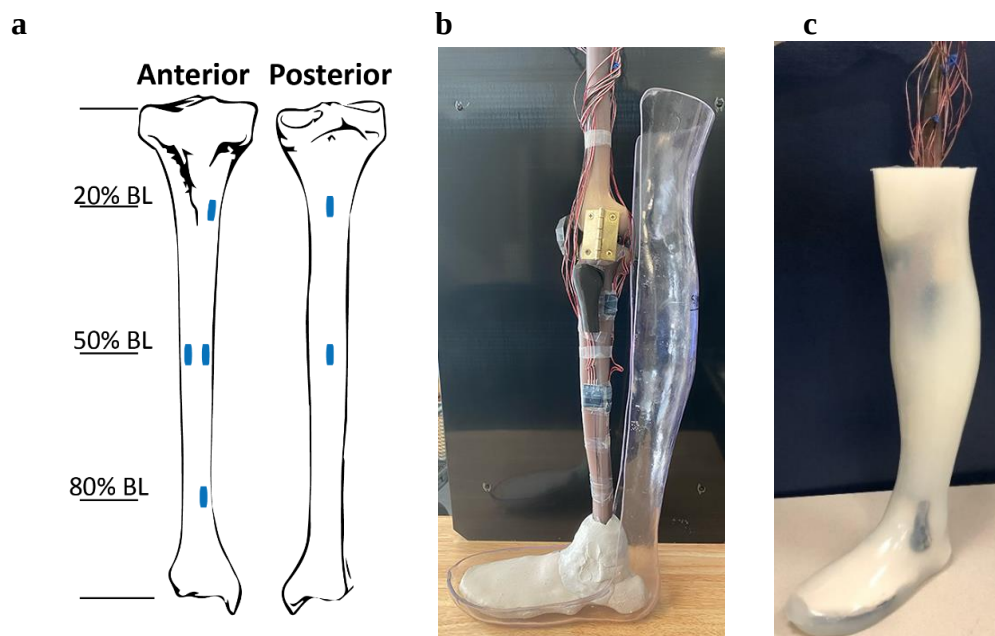


Figure 2: a. Strain gauge rosette locations b. Sawbones skeletal assembly with strain gauge rosettes, hinge-locked ankle, epoxied ankle, and bony landmarks pictured in half of the vivak mold c. final poured surrogate.

- We used these findings to finalize our fabrication procedure for instrumented surrogates which includes the following details:
 1. The surrogate knee is now locked using metal hinges instead of 3D printed plates. This improvement eases installation due to the conforming nature of the hinge to the knee joint. This is also an improvement in strength while reducing bulk.
 2. The ankle joint is now being reinforced with 3-minute putty epoxy to increase the surface area of the locked joint and reduce stress concentrations at the foam-cored heads of the Sawbones.
 3. As previously discussed, the shaft of the fibula has been removed to disallow any load to be borne outside of the tibia where we are measuring strain. The fibular heads were anatomically aligned to provide bony landmarks for fitting the prototypes.
 4. Six strain gauge rosettes were bonded to the tibia in locations noted in **Figure 2a**.

Testing Rig Development

- To quickly test surrogates and prototypes, a testing rig was constructed to vertically load at various conditions. The rig features:
 1. A 7:1 mechanical advantage pulley to allow team members to easily and safely lift the loads being applied during testing. This pulley is attached to the frame to minimize moving parts and allow the rig to be easily and safely operated.
 2. A loading platform to hold the weights and apply them through the line of force.
 3. Two shaft bearings provide stability while allowing the load to be applied straight down. The crossbeam holding these bearings can be moved to allow for different sized surrogates.
 4. A rigid frame with leveling feet to ensure stability during testing.
 5. Enough room at the base to fit around a force plate and allow access for adding testing conditions such as angled sine plates.
 6. The structure stands over 6 feet tall to allow for a wide variety of surrogate sizes to be tested.
- The rig currently allows for consistent loading, more stability, and allows for easy and safe operation (**Figure 3**).

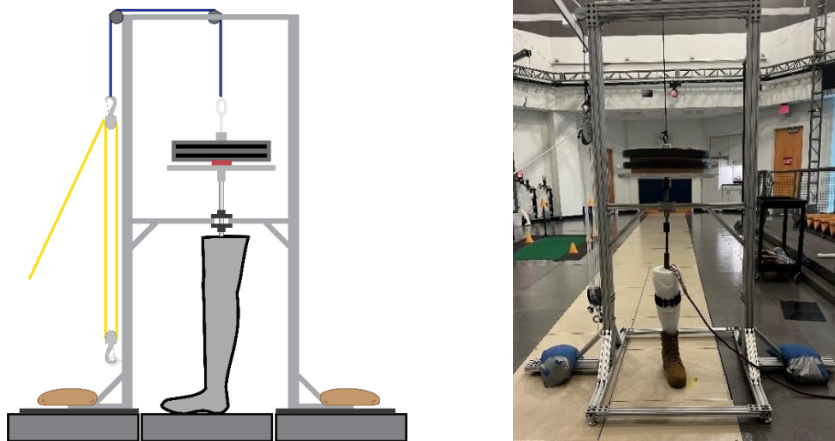


Figure 3: Testing rig schematic and setup under testing conditions with instrumented surrogate

- The testing rig can be used to load surrogates with various loads and an angled sine plate can be used to investigate different loading patterns. Strain patterns and forces have been collected on surrogates using this testing rig.
- We have an Instron Electropulse E3000 materials testing machine on order that is schedule for installation in November this year. Once it is up and running, it will be used in place of this testing setup.

Prototype Development

- The prototype design cycle was started with the aim of producing a design that would provide offloading above the injury site, fit a wide range of anthropometries, and accommodate the active-duty military population uniform requirements.
- Prototype ideas from design sessions were combined into two distinct prototypes (**Figure 4**). A design worn inside of combat boots and a design worn outside of combat boots. These designs feature three main components: 1) proximal patella tendon bearing-inspired cuff to accept the offloading, 2) a modular posterior strut designed to transfer the load proximally, and 3) the shoe wear integration which allows for comfortable fit.
- Several iterations of both prototypes have been fabricated thus far. These prototypes were fabricated from cost-effective thermoplastic material to allow for rapid iteration and preliminary testing of form and fit. Future iterations will be made of a carbon fiber composite. We recently installed a special oven to cure pre-impregnated carbon fiber structures. We are currently building the tooling, fixtures, and molds necessary to manufacture exoskeletons using pre-impregnated carbon fiber.
- The most recent iteration of prototypes (Figure 4) is ready to be tested on our surrogate instrumented with strain gauge rosettes. These tests will determine which device reduces the strain at various locations along the composite tibia and will inform the team for future prototype iterations and designs.



Figure 4: Inside the boot prototype (left) and outside the boot prototype (right)

- Fabrication of these prototypes required advanced manufacturing techniques to eliminate the use of positive plaster molds. All existing molds were scanned to create digital models. Positive foam molds were then produced from an industrial 3D carver. The process of mold digitization has benefitted the fabrication in the following ways:
 - Digital storage provides a safeguard against damage to molds.
 - Ability to easily duplicate molds provide increased efficiency.
 - Use of multiple, identical molds increases consistency in prototyping.
 - Lightweight foam material is physically easier to move and store.
- Existing prefabricated ankle foot orthoses were reviewed to determine trends in sizing and correlation with SM anthropometry. This resulted in the submission of a MHSRS abstract (Appendix A; McCain, E.M., Price, C.A., Dearth, C.L., Farrokhi, S., Johnson, W.B., Mazzone, B.N., Childers, W.L., 2022. Sizing of Novel Stress Fracture Exoskeleton to Encompass Male and Female Service Member Anthropometry, Military Health System Research Symposium)
 - The DJO® ProCare Tibial Fracture Brace best accommodated male and female SM anthropometry (see **Figure 5**). This sizing structure can be expanded to serve our needs and will be used as a basis for the development of the SFxO sizing structure.

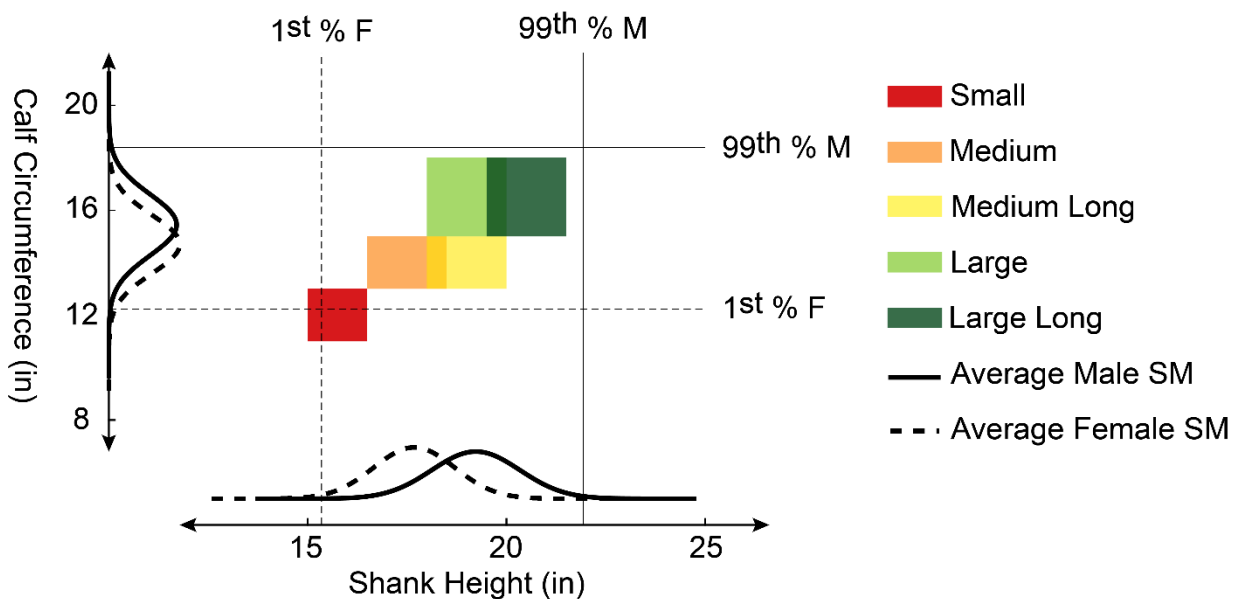


Figure 5: The DJO® ProCare Tibial Fracture Brace is available in 5 sizes and accommodated SM of both sexes from the 1st to 97th percentile or higher for two critical fitting measurements, calf circumference and shank height.

Cadaveric Testing Preparation

- The load cell has been successfully mounted and calibrated on the Instron machine at Lackland AFB. Parts to attach the cadaver to the load cell are being finalized and will then be fabricated.
- The protocol for bonding strain gauges to porous materials has been written and all necessary materials have been procured. Placement of the strain gauge rosettes on the cadavers will be finalized after data from prototype testing is analyzed.

- All walking conditions will be done on the same day in order to minimize any effects of wear and tear or refreezing and rethawing.
- The devices being tested are the baseline condition of no device, the standard of care (Aircast walking boot), an IDEO, the Fabtech Reaktiv brace, and the SFxO prototype. These conditions will be tested in random order, but baseline condition will only be tested at 100% BW (**Figure 6**).

		Walking Conditions (Day 1) % BW			Running conditions (Day 2) % BW
		50%	100%	120%	100%
Gait event or phase	Initial Contact		o,x		o,x
	Mid Stance	x	o,x	x	o,x
	Terminal Contact		o,x		o,x

Figure 6: Testing conditions to include simulations of initial and terminal contact, and device conditions whereas no device will be the baseline (o), and devices (x). Those include the IDEO, Aircast walking boot (standard of care), the SFxO prototype, and the Fabtech Reaktiv brace.

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

Nothing to Report.

How were the results disseminated to communities of interest?

We hosted a laboratory open house to celebrate National Biomechanics Day on 7 APR 2022. This was open to all CFI patients and BAMC/ISR personnel and included demonstrations of our surrogate limbs in our testing apparatus.

The Perry Initiative provides outreach activities to young Women interested in STEM and careers in orthopedics. The CFI hosted the Perry Initiative on 9 APR 2022. Many of our staff were mentors during this event.

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

We plan to fill our Mechanical Engineering II position on 6 SEP 2022 when we onboard Dr. Robert McGrath. We are prepared to test our two current prototypes on a surrogate instrumented with strain gauge rosettes. This will inform the team on the internal and external prototype designs and provide valuable information on the required number and placement of strain gauges for cadaveric testing. We will continue fabricating surrogates using Sawbones for the small and large sizes to allow to test designs that will fit to the extremes of fitting conditions. Future prototypes will be fabricated using prepreg carbon methodology. Finally, the testing protocols for the Instron will be generated to prepare the team to start cadaveric testing as soon as possible although it is scheduled to begin MAY 2023.

4. IMPACT:

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

The findings from our MHSRS abstract is relevant for off-the-shelf orthosis design beyond the Service member population and should help orthotic manufactures optimize their sizing options within their product line.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to Report at this time. We will be preparing invention disclosures for DHA T2 office this coming quarter.

What was the impact on society beyond science and technology?

Nothing to Report.

5. CHANGES/PROBLEMS:

Global supply chain issues have delayed the receipt of many materials/supplies necessary. We continue to overcome these challenges by ordering as soon as possible or finding similar items that can be used in place of the original item.

Changes in approach and reasons for change

We have moved away from inflatable bladders as we have learned during a parallel development effort that they do not provide enough fracture stability relative to more traditional means in a way that would justify the additional systems. We are now focused on creating designs that are equally or more effective than bladder-based systems. We presented our work on the relationship between fracture stabilization and interface design at the American Academy of Orthotists and Prosthetists annual meeting in Atlanta, GA on 3 MAR 2022.

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

Placing strain gauges on the posterior section of the cadaver would require extensive soft tissue removal that will alter the fit of the device and could change the properties of the cadaveric model. To plan for this, we are testing various locations on the surrogates to determine the optimal placement in cadavers. Also, we anticipate Sawbones acquisition being an issue in the future and we are prepared to use the alternate surrogate fabrication technique using 3D printed bones.

We continue to have delays attaining supplies. We also continue to improvise and develop alternatives (e.g., 3D printed bones, building a surrogate testing apparatus until our Instron E3000 can be installed, use of plastic for prototypes until the pre-preg carbon fiber fabrication process is brought online, etc.) to keep the project as close to on track as possible.

Changes that had a significant impact on expenditures

We hired a full-time fabricator to keep up with our prototyping demands and build the items that we cannot acquire in time. These expenses were offset by reducing the %effort by the prosthetist that were performing those duties and we will now be able to make the IDEOs in house vs. central fabrication as laid on in the original proposal.

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

NA

Significant changes in use or care of human subjects

NA

Significant changes in use or care of vertebrate animals

NA

Significant changes in use of biohazards and/or select agents

NA

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

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

The August 2021 issue of the O&P Almanac (a trade magazine) published a spotlight on Dr. Childers in which this project was highlighted. <https://www.aopanet.org/publications/op-almanac-magazine/>

Other publications, conference papers and presentations.

McCain, E.M., Price, C.A., Dearth, C.L., Farrokhi, S., Johnson, W.B., Mazzone, B.N., Childers, W.L., 2022. Sizing of Novel Stress Fracture Exoskeleton to Encompass Male and Female Service Member Anthropometry. Abstract and Poster to be presented at Military Health System Research Symposium, Kissimmee, FL, Sept 2022. **(Appendix A & B)**

- **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?

<i>Name:</i>	Lee Childers, PhD
<i>Project Role:</i>	PI – Senior Scientist
<i>Researcher Identifier (ORCID ID):</i>	0000-0002-6119-983X
<i>Nearest person month worked:</i>	1.9
<i>Contribution to Project:</i>	Coordinates the project, communicating regularly with on study-related issues
 <i>Name:</i>	 Brett Johnson, PhD
<i>Project Role:</i>	AI – Biomedical Engineer
<i>Researcher Identifier (ORCID ID):</i>	0000-0002-6119-983X
<i>Nearest person month worked:</i>	4
<i>Contribution to Project:</i>	Coordinates with PI and research staff

Name: Emily McCain, PhD
Project Role: AI – Mechanical Engineer
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 12
Contribution to Project: Project management, mechanical design, manages IRB and other administrative issues

Name: Michael Poppo
Project Role: Materials Testing Engineer
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 6
Contribution to Project: Project management and mechanical design

Name: Sarah Pesquera
Project Role: Biomedical Engineer
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 4
Contribution to Project: Human Cadaver protocol and equipment maintenance

Name: Ciera Price
Project Role: Research Orthotist Prosthetist
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 5
Contribution to Project: Fabrication and Design

Name: Roberto “JR” Cruz
Project Role: Research Technician
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 2
Contribution to Project: Fabrication and Design

Name: Alyssa Salazar
Project Role: Research Assistant
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 2
Contribution to Project: Assists with research activities.

Name: Noel Guerrero
Project Role: Research Coordinator
Researcher Identifier (ORCID ID): 0000-0002-5129-1763
Nearest person month worked: 4
Contribution to Project: Manages IRB and other administrative issues

Name: Sarah Pierrie, MD
Project Role: Orthopedic Surgeon
Researcher Identifier (ORCID ID): 0000

Nearest person month worked: 0.1
Contribution to Project: Co-Investigator and will assist with protocol development, data interpretation, and results dissemination

Name: Christopher Dearth, PhD
Project Role: Chief R&S Division
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 0.4
Contribution to Project: Co-Investigator and will be working closely with Dr. Childers during all related activities throughout the period of performance

Name: Tim Mauntel, PhD
Project Role: Musculoskeletal Health Researcher
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 0.4
Contribution to Project: Co-Investigator and will be leveraging his background to assist with protocol development, data interpretation, and results dissemination.

Name: Mary Boussein, PhD
Project Role: Professor
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 0.1
Contribution to Project: Co-Investigator and will assist with protocol development, data interpretation, and results dissemination.

Name: Kristy Popp, PhD
Project Role: Researcher
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 0.4
Contribution to Project: Co-Investigator and will assist with protocol development, data interpretation, and results dissemination.

Name: Shawn Farrokhi PT, PHD
Project Role: Musculoskeletal Health Researcher
Researcher Identifier (ORCID ID): 0000
Nearest person month worked: 0.4
Contribution to Project: Co-Investigator and will be leveraging his background to assist with protocol development, data interpretation, and results dissemination.

<i>Name:</i>	Brittney Gunterstockman PT, DPT
<i>Project Role:</i>	Research Physical Therapist
<i>Researcher Identifier (ORCID ID):</i>	0000
<i>Nearest person month worked:</i>	0.3
<i>Contribution to Project:</i>	Co-Investigator and will ensure the development of this stress fracture orthotic device could be applied in a rehabilitation setting

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

Yes, Dr. W. Lee Childers is lowering his time commitment slightly. Updated PCPS attached.
(Appendix C)

What other organizations were involved as partners?

Name: Air Force

Location: San Antonio, TX (Lackland Air Force Base)

Contribution: Assisted with cadaver storage and testing

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: QUAD CHARTS:

9. APPENDICES:

Attached as PDF's.

Appendix A: MHSRS Abstract

Appendix B: MHSRS Poster

Appendix C: Childers updated funding support

Appendix A

Sizing of a Novel Stress Fracture Exoskeleton to Encompass Male and Female Service Member Anthropometry

McCain, EM^{1,2}, Price, CA^{1,2}, Dearth, CL^{3,4}, Farrokhi, S^{3,5}, Johnson, WB^{1,3}, Mazzone, BN^{2,6}, Childers, WL^{1,3}

1. Center for the Intrepid, Brooke Army Medical Center, JBSA Ft. Sam Houston, TX. 2. Henry M. Jackson Foundation for the Advancement of Military Medicine Inc., Bethesda, MD. 3. Extremity Trauma and Amputation Center of Excellence, JBSA Ft. Sam Houston, TX. 4. Department of Surgery, Uniformed Services University of the Health Sciences, Bethesda, MD, 5. Naval Medical Center San Diego, San Diego, CA, 6. San Diego State University, San Diego, CA

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INTRODUCTION

Service members (SM) are at a particularly high risk for tibial stress fracture (SFx) due to repetitive high impact activity and the load carrying requirements of military training and duty [1]. The greatest risk for SFx in SM occurs during basic combat training and initial entry-level training [1, 2]. Common treatment of tibial SFx includes rest and activity modification, characterized by a period of offloading followed by slow and deliberate increases in weight bearing [3]. Return to duty (RTD) can take up to six months [2]. Dated evidence suggests that a pneumatic leg brace can facilitate return to sport and avoidance of surgical intervention in athletes with a tibial SFx [4, 5]; however this has not become the standard of care for the management of tibial SFx. An off-the-shelf SFx orthosis (SFxO) capable of offloading the fracture site and enabling RTD earlier could prevent prolonged inactivity and expedite rehabilitation, improving injury treatment and bolstering military readiness.

To maximize the benefit of the SFxO, the range of sizes available should encompass the full anthropometry of SM. While some insight can be drawn from the sizing of existing off-the-shelf ankle foot orthoses (AFOs), these devices were developed for the general population and it is unclear whether the range of sizes would encompass SM anthropometry. The objective of this work is to evaluate whether the range of sizes for existing off-the-shelf lower limb orthoses could be expanded to encompass male and female SM anthropometric measurements. This preliminary study will inform the future development of a SFxO to meet the needs of SM.

MATERIALS AND METHODS

We examined the manufacturer sizing recommendations of eleven prefabricated AFOs selected by a certified orthotist experienced with providing and fitting off-the-shelf AFOs for the treatment of diverse clinical presentations in adult populations. We used this information to identify patterns in available sizes and required measurements relevant to the sizing of a novel SFxO. AFO types included orthoses described as the Sarmiento patellar tendon bearing (PTB), pneumatic controlled ankle motion (CAM), ankle gauntlet, static night splint, thermoplastic solid ankle, and carbon composite with rigid anterior panel. Although these devices are for a more diverse set of clinical indications than tibial SFx, they all need to fit a human shank and foot, thus are relevant from a sizing standpoint. We focused on shank height and calf circumference measurements due to their relevance to future SFxO designs.

Each AFO was analyzed to determine the available sizes, the measurement(s) required for fitting, and the range of SM that could be accommodated by each size according to an anthropometric survey database [6]. Out of the eleven devices originally considered, six devices listed measurements of calf circumference, and three listed a measurement of shank height (midpatella or tibial height) [6]. The remaining devices providing measurements that did not correspond to the anthropometric survey results in a way that would permit further analysis and were excluded. AFOs were evaluated based on the range of measurements that the device could accommodate by either calf circumference (Alimed Miami Tibial Fracture PTB Brace, DJO ProCare Tibial Fracture Brace, OPTEC Solid Ankle AFO, Orthomerica AFO, RCAI Rigid AFO, and OCSI DynaPro ® AFO) or shank height (DJO ProCare Tibial Fracture Brace, Allard BlueROCKER ® 2.0, and Trulife Matrix Max) as characterized by stratified percentile of SM measurements [6].

RESULTS

Of the six devices that provided measurements for calf circumference, only the Alimed Miami Tibial Fracture PTB Brace, DJO ProCare Tibial Fracture Brace, and OCSI DynaPro ® AFO included sizes that would accommodate SM of both sexes from the 1st to 98th percentile or higher. Alimed Miami Tibial Fracture PTB Brace and DJO ProCare Tibial Fracture Brace provided three different sizes: small, medium, and large. OCSI DynaPro ® AFO provided these three sizes in addition to a youth size which accommodated up to the 10th and 25th percentile of male and female SM, respectively.

Only the DJO ProCare Tibial Fracture Brace included sizes that would accommodate a wide (1st-99th) range of SM shank height. The range of sizes available for the Allard BlueROCKER ® 2.0 corresponded to shank heights between the 1st and 70th percentile female SM and the 1st and 25th percentile male SM. The Trulife Matrix Max size range was slightly more expansive, with shank heights between the 3rd and 80th percentile female and the 1st and 35th percentile male. The DJO ProCare Tibial Fracture Brace encompassed the largest range of shank height accommodating SM of both sexes from the 1st to the 98th percentile. The DJO ProCare Tibial Fracture Brace comes in sizes of small, medium, and large with two additional sizes of medium long and large long to account for variation in shank length.

CONCLUSIONS

Initial results demonstrate several readily available prefabricated AFOs do provide sizing inclusive of a wide range of SM based on calf circumference. However, only one of the devices included sizes that would accommodate the wide range in SM shank heights. Of the devices considered, the DJO ProCare Tibial Fracture Brace best represented the range of shank height sizes needed. These sizing criteria can be improved and adapted to encompass the full anthropometry of SM with minor modifications. The same sizing structure will be used as a basis for the development of the SFxO with consideration for designs that allow for height adjustability. Incorporating more adaptability in device height would result in a reduction in the number of sizes that would also decrease the logistical barrier for deployment of a future SFxO design.

Learning Objectives

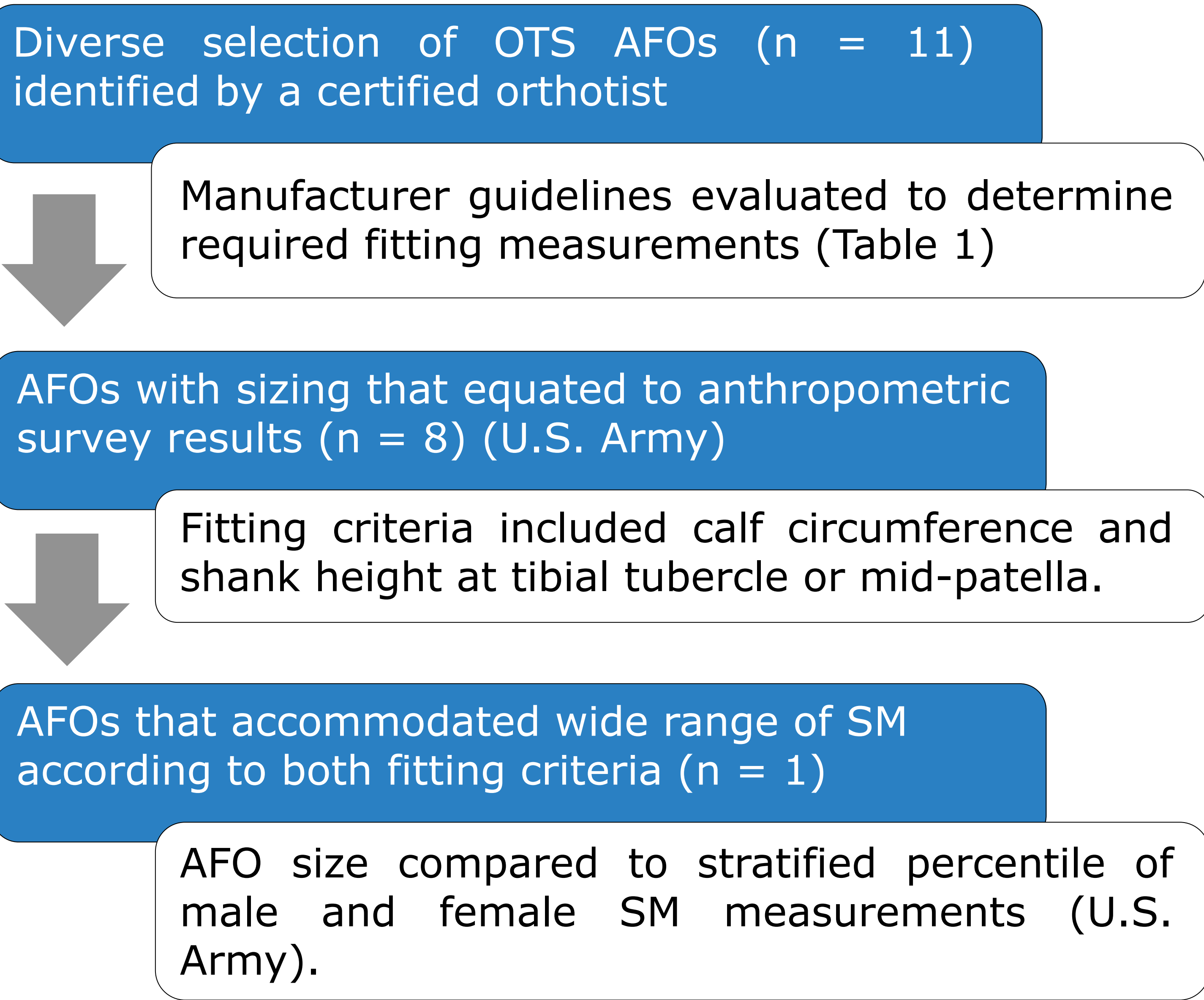
1. Discuss the necessity for expedited rehabilitation of tibial stress fractures.
2. Describe how the range of sizes of off-the-shelf ankle foot orthoses corresponds to Service member anthropometry.
3. Discuss how the results of this study can be used to define sizing of a novel stress fracture orthosis.

REFERENCES

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- Heavy load carriage
- Treatment often involves offloading the injured site, an extended rest period, and activity modification with progressive increases in weight bearing (Warden, 2014).
- Return to duty (RTD) can take up to six months.
 - Developing a novel off-the-shelf (OTS) stress fracture orthosis (SFxO) could enable earlier RTD.
- SFxO sizing must encompass the full SM anthropometry, and it is unclear whether existing OTS ankle foot orthosis (AFO) sizing sufficiently accommodates SM.
- **Objective:** Evaluate existing OTS AFO sizing and determine how to expand those ranges to fit most SMs

Methods



Device Name	Required Fitting Measurement		
	Calf Circumference	Shank Height	Other
Alimed® Miami Tibial Fracture PTB Brace	X		
Allard BlueROCKER® 2.0		X	
DJO® Aircast® AirSelect™ Elite			X
DJO® ProCare Tibial Fracture Brace	X	X	
OCSI DynaPro® AFO	X		
OPTEC Solid Ankle AFO	X		
Orthomerica® AFO	X		
Orthotronix Air Cam Walker Boot			X
Ossur Formfit® Ankle			X
RCAI Rigid AFO	X		
Trulife Matrix Max		X	

DJO® ProCare Tibial Fracture Brace vs SM Anthropometry

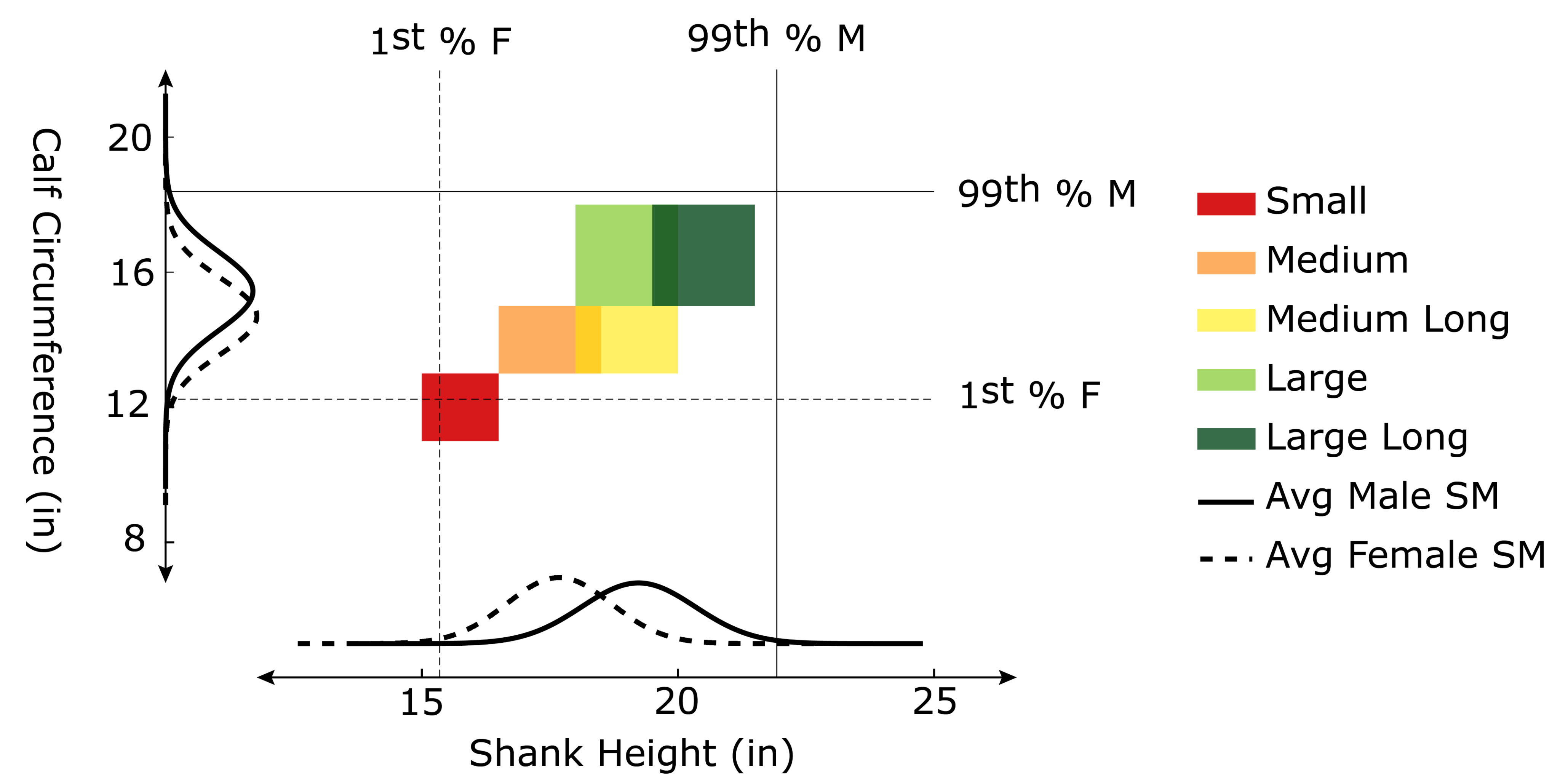


Figure 1: The DJO® ProCare Tibial Fracture Brace accommodates SM of both sexes from the 1st to the 97th percentile or higher for both required fitting measurements.

Appendix C

Previous, Current, and Pending Support

Walter Lee Childers, PhD, CP

Previous (Past Five Years') Support:

Title:	User-independent Intent Recognition on a Powered Transfemoral Prosthesis
Time Commitments (Cal. months):	0.25 months (2%) as Co-I
Supporting Agency:	Dept. of Defense, Congressionally Directed Medical Research Programs; W81XWH-17-1-0031(Young)
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Jessica Clement, MS Science Officer Ripple Effect Communications in support of Congressionally Directed Medical Research Programs (CDMRP) 1053 Patchel Street, Fort Detrick, MD 21702 Jessica.e.clement.ctr@mail.mil,
Performance Period:	1/15/17-1/15/20
Level Of Funding (Direct):	
Brief Description of Project's Goals:	We will recruit and train 7 transfemoral amputees on a powered knee/ankle prosthesis and collect from this group a set of sensor data as they ambulate over a locomotion circuit including level walking, stairs and ramps. We will implement our intent recognition systems on the powered prosthesis and test them in real-time and measure metabolic cost of walking, completion time, and user biomechanics.
List of The Specific Aims:	1. Compare intent recognition accuracy of the user- independent system to the user-dependent system in real-time as amputees ambulate over different locomotion modes. 2. Quantify the metabolic cost of walking, amputee biomechanics of motion and completion time and compare between user dependent and user- independent intent recognition. Quantify clinical outcome measures of powered prosthesis with the developed active intent recognition module
Overlap:	None

Title:	NRI:INT:COLLAB: Accelerating large-scale adoption of robotic lower-limb prostheses through personalized prosthesis controller adaptation
Time Commitments (Cal. months):	1.0 months (8%) as co-PI until 1/8/2018
Supporting Agency:	National Science Foundation NRI 2.0; NRI 2.0 1734416
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Kishan Baheti Energy, Power, Control and Networks Division of Electrical, Communications, and Cyber Systems National Science Foundation
Performance Period:	9/1/2017 – 8/30/2021
Level Of Funding (Direct):	(sub-award from Univ. of Alabama)

Brief Description of Project's Goals:	This project will utilize wearable inertial sensors to automate the tuning process of a powered knee and ankle prosthesis.
List of The Specific Aims:	1. Develop an IMU based trunk sensor to measure human movement. 2. Develop a learning algorithm to characterize gait events and tuning parameters for a knee/ankle prosthesis.
Overlap:	None

Title:	Development of an Engaging Training Tool to Provide Superior Muscle Computer Interfaces for Rehabilitation of Neuromusculoskeletal Injuries
Time Commitments (Cal. months):	0.9 months (7.5%) as site-PI
Supporting Agency:	Clinical and Rehabilitative Medicine Research Program, W81XWH15-2-0035
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	USAMRAA 820 Chandler St. Ft Detrick, MD 21702
Performance Period:	8/15/2015 – 8/14/2021
Level Of Funding (Direct):	
Brief Description of Project's Goals:	To increase the functional abilities of upper-extremity amputees and improve myoelectric prostheses utilization by developing a virtual reality-based, pre-prosthetic training program (Virtual Coach).
List of The Specific Aims:	1. To conduct rehabilitative needs assessment focus groups to determine clinician and amputee preferences for game design and hardware usability. 2. To conduct iterative usability testing to assess the release of each playable version of the Virtual Coach by clinicians and amputees. 3. To compare the relative efficacy of Virtual Coach and conventional pre-prosthesis training in improving an amputees' control of myoelectric prostheses.
Overlap:	None

Title:	Automated Assessment of Rehabilitation Outcomes
Time Commitments (Cal. months):	0.9 months (7.5%) as site PI
Supporting Agency:	Telemedicine and Advanced Technology Research Center, W911QY-16-A-0013
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Holly H. Pavliscsak TATRC USAMRMC Ft Detrick, MD 21702
Performance Period:	9/25/2017 – 5/3/2021
Level Of Funding (Direct):	
Brief Description of Project's Goals:	To determine the feasibility and reliability of assessing the physical performance of participants with lower extremity injuries using a novel wearable sensor (ALEKSIS) system.

List of The Specific Aims:	1. To perform a clinical needs assessment which will allow the research team to make changes to software or reporting features of the ALEKSIS system. 2. To determine the usability of instructional videos for outcome measures. 3. To determine if the ALEKSIS system is equivalent to current practices by comparing the results from using the ALEKSIS to traditional clinical outcomes assessments. 4. To perform reliability testing and calculate minimal detectable change values for outcome measures collected with the ALEKSIS system.
Overlap:	None

Title:	A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations
Time Commitments (Cal. months):	0.45 months (3.75%) as site PI
Supporting Agency:	Dept. of Defense, Congressionally Directed Medical Research Programs
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Christopher Meinberg Phone: Email: christopher.l.meinberg.civ@mail.mil 820 Chandler St Fort Detrick MD 21702-5014
Performance Period:	8/1/2017 – 7/31/2021
Level Of Funding (Direct):	
Brief Description of Project's Goals:	This project will optimize functional outcomes and user satisfaction for Service members and Veterans with lower limb amputation using a Prosthetic Foot Emulator that can mimic the characteristics of different types of prosthetic feet.
List of The Specific Aims:	1. Determine whether a prosthetic foot emulator can be used to predict foot preference and mobility outcomes with corresponding commercial prosthetic feet in individuals with TTA. 1. Determine whether a brief trial of commercial prosthetic feet can predict longer-term preference and mobility outcomes with prosthetic feet in individuals with TTA.
Overlap:	None

Title:	Assessing Rehabilitation Outcomes after Severe Neuromusculoskeletal Injury
Time Commitments (Cal. months):	.9 Months (7.5%) as site-PI
Supporting Agency:	US Army Medical Research and Materiel Command, W81XWH-16R-BAA1

Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Laura Peller Business Administrator Center on Assessment Research & Translation University of Delaware STAR Campus 540 S. College Avenue STAR Annex Room 111 Newark, Delaware 19713
Performance Period:	8/1/2017-9/30/22
Level Of Funding (Direct):	
Brief Description of Project's Goals:	To examine the way that outcomes are assessed in injured service members and make recommendations for change
List of The Specific Aims:	1. Recruit participants and conduct cognitive interviews 2. Conduct medical record abstraction for consented participants (to include relatively basic information such as date of injury, mechanism of injury, ICD-10 diagnosis code(s), height, weight, limb(s) affected, injury severity score (ISS)) 3. Recruit clinicians to participate in cognitive debriefing interviews about the content of score reports
Overlap:	None

Current Support:

Title:	Multi-center phase 2 trial to test ability for stem cell therapy to induce palmo-plantar skin at the stump site of amputees
Time Commitments (Cal. months):	0.9 Month (7.5%) as site PI
Supporting Agency:	USAMRMC Broad Agency Announcement BAA W81XWH-18-20055 (Garza)
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Jenifer, Ojeda US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	9/30/2018-9/29/2022
Level Of Funding (Direct):	(sub-award to the CFI)
Brief Description of Project's Goals:	The goal of this proposal is to make the placement of a prosthetic at a stump site analogous to the placement of a shoe on a foot. We hope to achieve the rarity of skin break- down at the soles of our feet for stump sites in amputation victims. Therefore, we propose to convert stump skin to volar type skin with its attendant friction-resistant, irritant-resistant and weight bearing properties.
List of The Specific Aims:	1. To evaluate the safety of small injections of autologous volar fibroblasts (6mm in diameter) in the stump site of transtibial amputee. 2. To evaluate the efficacy of small injections of autologous volar fibroblasts (6mm in diameter) in the stump site of transtibial amputees. 3. To evaluate the effect of autologous volar fibroblast injections to the entire area of the stump on prosthesis use and quality of life.
Overlap:	None

Title:	Do Adaptable Sockets Improve Military Performance?
Time Commitments (Cal. months):	1.35 Months (11.25%) as Site-PI
Supporting Agency:	CDMRP Orthotics and Prosthetics Outcomes Research Program
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	Jason D. Kuhns US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	10/1/2019-9/30/2023
Level Of Funding (Direct):	(sub-award to the CFI)
Brief Description of Project's Goals:	The purpose of the proposed research is to evaluate adaptable sockets during Military specific tasks consistent with return- to-duty assessments for Service members with transtibial amputation.
List of The Specific Aims:	1. Recruit participants, and fabricate microprocessor- adjusting sockets for Service members and Veterans conducting intense physical activities 2. Test participants in the CAREN, a return to duty assessment simulator using three socket configurations: microprocessoradjusting, user- adjusting, and static 3. Test participants in a military function test, the Functional Capacity Evaluation–Military (FCE-M) using three socket configurations: microprocessor- adjusting, user-adjusting, and static
Overlap:	None

Title:	Development of ambulatory external fixation device for lower extremity combat injuries
Time Commitments (Cal. months):	0.9 Months (7.5%) as PI
Supporting Agency:	Army and Defense Health Program, Combat Casualty Care Research Program, W81XWH-21-CCCRP-AD
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	10/1/2020-9/30/2023
Level Of Funding (Direct):	
Brief Description of Project's Goals:	Develop a proof-of-concept prototype of an unpowered exoskeleton solution to be utilized by Service Members with an open tibia fracture in prolonged field care scenarios
List of The Specific Aims:	1. Evaluate the ability of a non-invasive fracture orthosis system to stabilize an open tibia fracture. 2. Define the effectiveness of non-invasive methods to transfer weight bearing loads to proximal segment s to off-load the fracture site. 3. Develop an exoskeleton frame that will integrate with the fracture orthosis prototype and off-load the fracture. 4. Integrate all sub-components into a proof-of- concept prototype.
Overlap:	The current proposal is the next stage in development from this proposal.

Title:	Rapidly Deployable Exoskeletons for Prolonged Field Care Scenarios in Austere Environments
Time Commitments (Cal. months):	0.9 Months (7.5%) as PI
Supporting Agency:	CRM RP BAA W81XWH18SBAA1
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	4/15/2021-4/14/2025
Level Of Funding (Direct):	
Brief Description of Project's Goals:	This proposal will develop exoskeleton solutions that will enhance Service Member lethality after lower or upper limb trauma as they are called to fight outside of the traditional "Golden Hour" of evacuation.
List of The Specific Aims:	1. Determine what materials, equipment, and historical field improvised designs are available to a Tactical Medical Practitioner. 2. Determine Field Improvised Exoskeleton solutions that may be constructed from materials and equipment currently available to a Tactical Medical Practitioner. 3. Determine Field Improvised Exoskeleton solutions that are based on materials and components likely available to a Tactical Medical Practitioner in a prolonged field care environment.
Overlap:	None

Title:	Clinical translatability of reactive hyperemia measurements that can monitor adaptation of residual limb skin to socket wear
Time Commitments (Cal. months):	1.2 Months (10%) as PI
Supporting Agency:	CDMRP OPOP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	8/1/2021 – 7/31/2025
Level Of Funding (Direct):	
Brief Description of Project's Goals:	The objective of this proposal is to define how measurements of reactive hyperemia are indicative of residual limb health and we will provide the setup for potential clinical translation.
List of The Specific Aims:	1. Define the relationship between skin temperature and microvascular response during reactive hyperemia. 2. Determine differences in reactive hyperemia between normal skin and skin exposed to long term mechanical loading via transtibial and transfemoral prosthesis use. 3. Reactive Hyperemia response will be associated with prosthetic socket use.
Overlap:	None

Title:	Exoskeletons for rapid return to duty after tibial stress fracture
Time Commitments (Cal. months):	1.2 Months (10%) as PI
Supporting Agency:	CDMRP PRORP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	08/01/2021-08/01/2025
Level Of Funding (Direct):	
Brief Description of Project's Goals:	The primary objective of this study is to develop a novel orthotic device designed to enhance whole person performance and decrease pain in patients with impairment due to tibial stress fracture.
List of The Specific Aims:	1. Evaluate the ability of an energy storage and return exoskeleton system to transfer energy around a stress fracture site. 2. Evaluate the effectiveness of orthoses designed to off-load the shank and enhance user comfort during military relevant tasks.
Overlap:	None

Title:	Validation of military-relevant assessments to predict successful return to duty following lower limb injury
Time Commitments (Cal. months):	0.45 Months (3.75%) as Co-Investigator
Supporting Agency:	CDMRP OPORP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	08/01/2022-07/31/2023
Level Of Funding (Direct):	
Brief Description of Project's Goals:	The objective of the proposed study is to develop a RTD decision tree through the validation of military-relevant assessments to predict successful RTD in Military personnel that use of O&P.
List of The Specific Aims:	1. Determine what factors and assessments predict successful RTD following lower limb injury. 2. Refine and validate the decision tree's ability to predict successful RTD following lower limb injury.
Overlap:	None

Title:	Personalizing MPK Prescription for Individuals With Transfemoral Amputation
Time Commitments (Cal. months):	0.3 Months (2.5%) as consultant
Supporting Agency:	CDMRP OPORP

Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	US Army Medical Research Acquisition Activity 820 Chandler St. Fort Detrick, MD 21701-5014
Performance Period:	TBD
Level Of Funding (Direct):	
Brief Description of Project's Goals:	Our objective is to create a clinical decision algorithm for selection of an ideal MPK for an individual with TFA based off of objective and subjective data collected from the individual patient
List of The Specific Aims:	1. Determine functional performance associated with three commercially available microprocessor knees and an opensource research grade powered prosthesis. 2. Assess patient reported outcomes for each prosthesis type 3. Create a clinical decision algorithm for the 3 commercially available MPK prostheses which will allow clinicians to make a logical, structured decision on the best MPK to provide to their patient
Overlap:	None

Title:	Development of the Intrepid Battlefield Exoskeleton to enable continued battlefield lethality during prolonged field care scenarios
Time Commitments (Cal. months):	1.2 Months (10%) as Site PI
Supporting Agency:	US Army Medical Research and Development Command, Combat Casualty Care Research Program W81XWH-23-CCCRP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	US Army Medical Research and Development Command 1520 Freedman Drive, Suite 227 Fort Detrick, MD 21702-5012
Performance Period:	10/01/2022-09/30/2024
Level Of Funding (Direct):	
Brief Description of Project's Goals:	To design and demonstrate extremity stabilization and fixation while enabling mobility and lethality using the Intrepid Battlefield Exoskeleton (IBEX).
List of The Specific Aims:	1. Define the key mechanical loading requirements the IBEX device will endure during Military relevant tasks. 2. Refine device design requirements and design features through engagement with field medical providers. 3. Evaluate IBEX prototype performance in a simulated environment.
Overlap:	The current proposal is the next stage in development from this proposal.

Title:	The relationship between residual limb skin health measurements and clinical outcomes
Time Commitments (Cal. months):	0.6 Months (5%) as Principal Investigator

Supporting Agency:	CDMRP OPORP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	N/A
Performance Period:	8/1/2022 – 7/31/2024
Level Of Funding (Direct):	
Brief Description of Project's Goals:	The objective of this proposal is to determine how different measures of residual limb skin health relate to skin adaptation and continued socket use.
List of The Specific Aims:	1. Define residual limb skin adaptations to socket wear after amputation 2. Define the relationship between skin health measurements and long-term clinical outcomes and continued prosthetic socket use.
Overlap:	None

Title:	Impact of Technologies that Personalize Robotic Leg Prostheses for Individuals with Transfemoral Amputation of Varying Mobility
Time Commitments (Cal. months):	0.6 Months (5%) as Co-Investigator
Supporting Agency:	CDMRP PRORP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	N/A
Performance Period:	8/1/2023 – 7/31/2027
Level Of Funding (Direct):	
Brief Description of Project's Goals:	The objective of this proposal is to develop personalized prosthesis control that scales robotic knee and ankle assistance to each person.
List of The Specific Aims:	1. Enable User-Independent Control Systems of Robotic Leg Prostheses that Continuously Recognize. 2. Deliver Personalized Assistance to Individuals with Transfemoral Amputation by Seeding Terrain and User States to Modulate Prosthetic Knee-Ankle Impedance. 3. Evaluate Novel Personalized Controllers of Robotic Knee-Ankle Prosthesis Relative to Passive Prostheses and Evaluate Multimodal Outcomes for Patients of Varying Mobility.
Overlap:	None

Pending Support:

Title:	The Impact of Prosthetic Frontal Plane Compliance to Residual Limb Health
Time Commitments (Cal. months):	0.6 Months (5%) as Principal Investigator
Supporting Agency:	CDMRP OPORP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	N/A
Performance Period:	8/1/2022 – 7/31/2025
Level Of Funding (Direct):	
Brief Description of Project's Goals:	The objective of this proposal is to assess how prosthetic foot compliance changes mechanical loads on the residual limb and the relationship of those loads to residual limb health.
List of The Specific Aims:	1. Define the relationship between prosthetic foot design and frontal plane compliance. 2. Define the relationship between prosthetic foot frontal plane compliance and residual limb health, loading, and dynamic balance over variable terrain after short-term use. 3. Determine the long-term effects of prosthetic foot frontal plane compliance on residual limb health and user experience.
Overlap:	None

Title:	Development and Validation of SUPORT (Sprayable Universal Polyurethane Orthosis for Rapid Treatment) for More Severe Injuries
Time Commitments (Cal. months):	0.6 Months (5%) as Co-Investigator
Supporting Agency:	CDMRP PRORP
Name And Address of the Funding Agency's Procuring Contracting/Grants Officer:	N/A
Performance Period:	TBD
Level Of Funding (Direct):	
Brief Description of Project's Goals:	The objective for this proposal is to validate the injury stabilization and gait characteristics of an enhanced prototype of the SUPORT splinting system that could enable rapid independent mobility and return to combat effectiveness, even after an open tibia fracture.
List of The Specific Aims:	1. Validate fracture stabilization performance of SUPORT Gen III (Weber C Focused) device relative to comparable devices during simulated gait using a limb surrogate model. 2. Refine device design requirements, advance the SUPORT TRL, and expand capabilities to include treatment of an Open Tibia Fracture (SUPORT Gen IV). 3. Determine prototype performance device in vivo and in silico relative to comparable devices.
Overlap:	None