AWARD NUMBER: W81XWH-21-2-0049

TITLE: Optimizing Ankle-Foot Orthotic Prescription Using an Emulation Test-Drive Strategy

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CONTRACTING ORGANIZATION: Henry M. Jackson Foundation, for the Advancement of Military Medicine, Inc.

REPORT DATE: October 2022

TYPE OF REPORT: Annual Report

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCTOBER 2022	Annual	9/30/2021-09/29/2022

4. TITLE AND SUBTITLE

Optimizing Ankle-Foot Orthotic Prescription Using an Emulation Test-Drive Strategy

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-21-2-0049

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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Bethesda, MD 20817

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

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

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The commercial market for ankle-foot orthoses (AFOs) offers such a broad array of options, yet limited evidence to guide current AFO prescription, which instead relies on clinician intuition, training, experience, and qualitative manufacturer-produced guides. Thus, matching an AFO with optimal mechanical properties to the unique needs and abilities of a given patient is challenging. The inability to test-drive different designs is an unmet need that is holding back patient care, and for which a viable solution is being provided in this proposal. We propose to optimize the process of selecting the optimal AFO for a patient using an AFO emulator to adjust AFO mechanical properties in real-time via software interface, rather than using the resource-intensive trial-and-error approach currently practiced in clinical settings.

15. SUBJECT TERMS
Extremity Trauma, Emulation, Orthosis, Prescription

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	27	19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. INTRODUCTION:

Ankle foot orthoses (AFOs) are often necessary to overcome mobility limitations related to lower limb neuromusculoskeletal injury. While the availability of AFOs for improving function is expanding, options remain limited and especially relative to ankle-foot prostheses. There is a critical need to better optimize AFO designs and provide evidence-based tools to guide their prescription. This study utilizes an exoskeleton capable of emulating AFOs by modulating the magnitude and/or timing of torque. We aim to (1) test the ability of the AFO emulator to reproduce the user experience of wearing commercially available AFOs during different in-lab activities (walking, running, stair climbing; level ground, ramps) in individuals with lower limb musculoskeletal injury. This aim will determine if the proposed AFO emulator framework can provide an option for quickly exploring multiple devices in a short period of time. We aim to (2) test the ability of a short-term, in-laboratory evaluation of function, mobility, and preference with the AFO emulator to predict those same outcomes longer-term (i.e., after 2-week use in the community) in AFO users with lower limb musculoskeletal injury. This aim will determine the predictive ability of a brief test-drive strategy using emulated AFOs to identify function, mobility, satisfaction, and preference at follow-up after two weeks of use in the community environment with corresponding actual AFOs. We aim to (3) allow the user to self-tune AFO emulator stiffness settings while walking and compare function, mobility, preference to the clinically prescribed AFO. This aim will determine if an AFO test drive strategy can be used to better optimize user satisfaction and patient reported outcomes relative to the current standard of care.

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

Extremity Trauma, Emulation, Orthosis, Prescription

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.

Primary Task	Timeline (mo)	Status
Regulatory Approvals	1-6	75%
Equipment Purchases	1-3	0%
Training	ongoing	50%
Data Acquisition	1-36	
Mechanical Testing	1-9	75%
Human Subjects Testing	9-36	0%
Data Analysis	10-36	25%
Dissemination	10-48	10%

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.

Regulatory Approvals: Ongoing at both sites, although we received external IRB approval on 8 OCT (to be officially reported in Y2, Q1). For WRNMMC, IRB pre-review completed on 26 AUG 2022, and submitted to external IRB of record (WCG IRB) on 8 SEP 2022. For VAPSHCS, IRB pre-review documents submitted on 28 SEPT 2022; WCG IRB protocol will be amended for the VAPSHC site once local pre-review complete.

Equipment Purchases: Emulator purchases are still outstanding, pending resolution/finalization of agreements (see section 5 below).

Training: Ongoing

Data Acquisition:

Mechanical Testing: mechanical testing procedures have been developed and implemented. Data collections are ongoing.

Human Subjects Testing: N/A, awaiting full regulatory approvals.

Data Analysis: ongoing (mechanical testing).

Dissemination: initial knowledge dissemination has begun related to mechanical testing (see section 6 and Appendix).

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.

Although not explicitly designed to provide training or professional development, staff at both sites continue to expand skillsets related to the inherent equipment/methodologies and broader research process. And, once primary data are available we expect future opportunities for knowledge translation among numerous key stakeholders (DoD and VA clinical teams), facilitated by the Clinical Affairs Division of the EACE.

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.

Although still early in the larger study timeline, initial (mechanical testing) data has been disseminated through traditional scientific channels (i.e., scientific conferences and peer-reviewed journals); see section 6 below.

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.

In the next reporting period (Y2, Q1), we expect to receive at least IRB approval for activities at WRNMMC, but likely also VAPSHCS, following which we will submit for OHRO acknowledgement to then complete the regulatory task. Related, we hope to resolve ongoing issues with the corresponding agreements such that emulator purchases can occur. In the meantime, we will also register the study on clinicaltrials.gov and seek to publish a protocol paper. Additional mechanical testing is ongoing and expected.

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).

Nothing to report

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:*

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

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.

As noted in prior quarterly reports, there remains confusion surrounding the type/relative timing of agreements vs. purchasing. For example, requiring a signed/executed CRADA before (vs. after) purchase agreements are executed will substantially delay study activities. Our understanding is the concerns are primarily originating from HJF and/or WRNMMC legal review. While this issue remains unresolved, all parties continue to meet and discuss regularly to identify possible solutions that in the end hopefully mitigate further delays. At WRNMMC specifically, we have elevated concerns with the timeliness of agreements to appropriate leadership. While these challenges continue to adversely delay the overall project timeline, in the meantime, we will continue to push forward with other regulatory activities and mechanical testing.

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

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

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

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).*

  Shuman, B.R., Russell Esposito, E. Multiplanar Stiffness of commercial carbon composite ankle- foot orthoses. Journal of Biomechanical Engineering 2022; Jan 144(1): 011004 (online Sept 2021). https://doi.org/10.1115/1.4051845

  Shuman, B.R., Totah, D., Gates, D., Gao, F., Ries, A.J., Russell Esposito, E. Comparison of five different methodologies for evaluating ankle-foot orthosis stiffness. Journal of NeuroEngineering and Rehabilitaion. (In Review)

  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.*

  Shuman, B.R., Russell Esposito, E. Measured Stiffness of Off-the-Shelf Carbon Fiber Ankle Foot Orthoses Depends on Test Alignment. Proceedings of the Military Health System Research Symposium 2022, Sept 12-15, 2022.
  Winner of the 3rd place poster award.

  Nickerson, K., Shuman, B.R., Russell Esposito, E. Transverse alignment impacts AFO stiffness. 48th Academy Annual Meeting & Scientific Symposium, March 2-5, 2022.

  *work form these presentations are being combined with additional analyses into a manuscript

- **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".

Name: Dr. Bradford Hendershot
Project Role: Overall and WRNMMC Site Principal Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Overall project management

Name: Ms. Clare Severe
Project Role: Research Engineer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Support to WRNMMC study preparatory and regulatory activities

Name: Ms. Heidi Mahatan
Project Role: Program/Portfolio Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Support budgetary and regulatory activities

Name: Dr. David Morgenroth
Project Role: VAPSHCS Principal Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: project management for VAPSHCS activities

Name: Dr. Benjamin Shuman
Project Role: VAPSHCS Study Lead
Researcher Identifier (e.g. ORCID ID): 0000-0002-6976-8021
Nearest person month worked: 6
Contribution to Project: Support to VAPSHCS study initiation, regulatory activities, and local study lead

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.*

Seattle Institute for Biomedical and Clinical Research (SIBCR); Seattle, WA
Dr. Morgenroth participates in meetings with Drs. Hendershot (overall project PI) and Shuman to provide input/guidance and discuss project-specific regulatory documents and strategy as well as agreements with Humotech.

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://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) 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.

TRANSVERSE ALIGNMENT IMPACTS AFO STIFFNESS

Nickerson, K.A. [1,2,3], Shuman, B.S.[1,2], and Russell Esposito, E.[1,3,4]

[1] Center for Limb Loss and Mobility, VA Puget Sound Health Care System, Seattle, WA
[2] The Henry Jackson Foundation for the Advancement of Military Medicine, Bethesda, MD
[3] Department of Mechanical Engineering, University of Washington, Seattle, WA
[4] DOD-VA Extremity Trauma and Amputation Center of Excellence (EACE)

INTRODUCTION

Ankle-foot orthoses (AFO's) are often used stabilize or augment function. The degree to which an AFO can restrict motion is dependent on the mechanical properties of the AFO which are dictated by the geometry and material of the orthosis. Experimental mechanical testing of AFO's often characterizes the rotational stiffness about a defined rotational axis (Shuman 2021, Bregman 2009). Unlike hinged AFOs, which have a defined axis of rotation, off-the-shelf AFO's rely on the deflection of a strut. Thus, the alignment of the AFO must be defined by the testing protocol. The purpose of this study was to evaluate how changes in the transverse alignment of the AFO, corresponding to differences in foot progression (Brockett 2016), impact stiffness measured in the EMPIRE test fixture.

METHOD

Eight commercially available carbon composite AFOs were evaluated (off-the-shelf models, non-articulated, size large, right foot). AFOs were tested in the EMPIRE test fixture (Shuman 2021) through a range of motion from 5 degrees of plantarflexion to 20 degrees of dorsiflexion. Torque and angle data were collected through three cycles. Angular stiffness (measured in Nm/deg) was computed as the slope from the linear fit of the torque-angle curve between 0 and 18 degrees dorsiflexion. Cycles two and three were used in the stiffness calculation. Each AFO was tested twice in each of four different transverse alignments using landmarks on the footplate (Fig 1). The transverse alignments range from a toe-out foot progression to a toe-in foot progression.

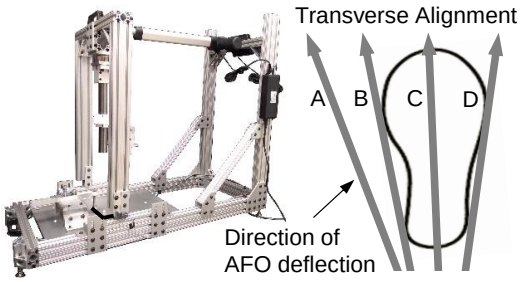


Figure 1. EMPIRE test fixture rotates an AFO about an axis. The AFO (right foot shown) is deflected in the plane perpendicular to the rotation axis, transversely aligned as follows:
A - 5 deg externally rotated from the medial border
B - along the medial border of the AFO
C - bisecting the medial and lateral border
D - along the lateral border of the AFO.

RESULTS

Stiffnesses varied by transverse alignment between 0.08 Nm/deg (SpryStep Max) and 0.69 Nm/deg (WalkOn Reaction). Three AFOs had changes of less than 5% relative to the bisected alignment (Blue Rocker, ToeOff 2.5 and SpryStep Max). The remaining AFOs changed by 8% (ToeOff), 13% (Matrix Max), 17% Matrix SuperMax, 17% SpryStep, and 24% (WalkOn Reaction).

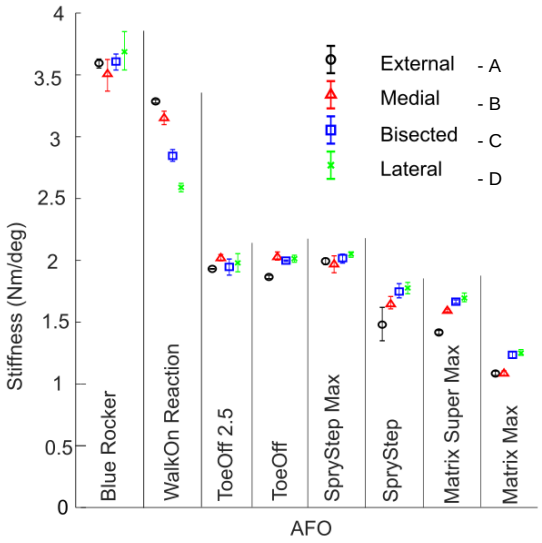


Figure 2. AFO stiffness by transverse alignment

DISCUSSION & CONCLUSION

AFOs with a lateral strut became stiffer when more internally rotated, while the AFO with a medial strut (WalkOn Reaction) became stiffer when externally rotated. This is similar to the preferred direction of AFO flexion previously reported in spiral lateral leaf AFOs (Cappa 2005).

CLINICAL APPLICATIONS

Foot progression angle may change the stiffness experienced by a user of an AFO.

REFERENCES

Shuman, BR. J Biomech Eng. 144(1) 01104, 2021
Bregman, DJJ. Gait Posture. 30 144-149, 2009
Brockett, CL. Orthop Trauma. 30(3) 232-238, 2016
Cappa, P. J Biomech Eng. 127 1025-1029, 2005

American Academy of Orthotists & Prosthetists
48th Academy Annual Meeting
& Scientific Symposium
March 2-5, 2022

Measured Stiffness of Off-the-Shelf Carbon Fiber Ankle Foot Orthoses Depends on Test Alignment

Shuman, B.S.[1,2,3], and Russell Esposito, E.[1,2,4]

[1]RR&D Center for Limb Loss and Mobility, VA Puget Sound Health Care System, Seattle, WA
[2] DOD-VA Extremity Trauma and Amputation Center of Excellence
[3] The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc.
[4] Department of Mechanical Engineering, University of Washington, Seattle, WA

BACKGROUND

Ankle-foot orthoses (AFOs) are intended to support or augment the ankle joint. A wide variety of custom and commercial AFOs are available with different geometry and mechanical properties. Ideally an AFO can be selected based upon mechanical properties of the device and the individual needs of the user (1). The most common mechanical property to measure is the rotational stiffness about an ankle joint which relates changes in the resistive moment produced by the AFO to angular position. Unlike hinged AFOs, which are designed to rotate about a defined axis, many off-the-shelf AFOs rely on the deflection of a strut to support the ankle. Thus the alignment and positioning of an AFO must be defined by the test set-up. However, unlike prosthetics, no standards exist to guide the measurement of AFO stiffness, making it impossible to directly compare across sizes and manufacturers. Thus, the purpose of this study was to examine sensitivity of AFO stiffness to two alignment decisions: the height of the rotational axis and the transverse alignment of the AFO corresponding to foot progression angle (2).

METHOD

Rotational stiffness data were collected on eight, size large, right footed, off-the-shelf carbon composite AFOs (Blue Rocker, ToeOff, and ToeOff 2.5 from Allard; WalkOn Reaction from Ottobock; SpryStep and SpryStep Max from Thuasne; and Matrix Super Max and Matrix Max from Trulife). AFO stiffness was evaluated using the EMPIRE (Evaluating Mechanical Properties in Rotating Exoskeletons), a custom designed fixture capable of rotating an AFO about a defined ankle axis (3). Torque and angular position data were collected while the AFOs were rotated from 5 degrees of plantarflexion to 20 degrees of dorsiflexion through three cycles. Rotational stiffness (measured in Nm/deg) is computed as the linear fit of the torque angle curve computed from 0 to 18 degrees of dorsiflexion of the second and third cycle.

Each AFO was tested twice in six total configurations changing the height of the rotation axis and the transverse alignment. Ankle axis heights were determined based on anthropometric data (4) and transverse alignments were defined by footplate landmarks. We tested three ankle heights of 60 mm, 69 mm, and 81 mm which would approximately correspond to foot lengths of 229, 246, and 275 mm (roughly men's shoe size U.S. 5.0, 7.0, and 10.5), with the AFO aligned along the medial border. Next, transverse alignments were tested at the 81 mm ankle height and AFOs were rotated to align the direction of rotation with 1. the lateral border of the footplate, 2. the bisecting angle of the medial and lateral border, and 3. 5 degrees of external rotation from the medial border of the footplate.

RESULTS

Measured AFO stiffness varied by 0.30 Nm/deg (Matrix Max) and 0.92 Nm/deg (WalkOn Reaction) corresponding to between 14% (Blue Rocker) and 29% (WalkOn Reaction) of the average stiffness across all test conditions. Lowering the bending axis height resulted in an average of 0.31 Nm/deg greater measured stiffness's. In AFOs with an external strut (all except the WalkOn Reaction) internally rotating the AFO increased measured stiffnesses by an average of 0.24 Nm/deg compared to the most externally rotated condition. Similarly, the WalkOn Reaction, which had a medial strut increased it stiffness by 0.69 Nm/deg by externally rotating the AFO compared to the most internally rotated condition.

CONCLUSION

No standards exist to guide mechanical tests of AFOs, making robust comparisons across makes and models difficult. Our team is systematically evaluating the range of methodological considerations that must be accounted for when determining the mechanical properties of AFOs. This analysis sheds new light onto the sensitivity of AFO stiffness to testing set-up and alignment of both bending axis height and transverse alignment. These results also have a direct clinical relevance, as AFO bending axis height can be impacted

both by an individual's anatomical geometry and in-shoe orthotics or insoles which are often worn on top of the AFO footplate. The sensitivity to transverse alignment suggests a preferred direction of deflection similar to that reported in spiral lateral leaf AFOs (5), which may impact an AFO user's gait. These results add to the sparse literature on the evaluation of AFO design properties and, combined with our prior and ongoing work, is intended to provide key information towards the development of testing standards.

DISCLAIMER

Funding provided by CDMRP award W81XWH2120049. The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, Department of Defence, Department of Veterans Affairs, or the U.S. Government.

REFERENCES

1. Totah, D. Gait Posture. 69 101-111, 2019

2. Brockett, CL. Orthop Trauma. 30(3) 232-238, 2016

3. Shuman, BR. J Biomech Eng. 144(1) 01104, 2021Parham

4. Parham, K.R. US Army Natick Research 1992.

5. Cappa, P. J Biomech Eng. 127 1025-1029, 2005

LEARNING OBJECTIVES

1) Describe how AFO mechanical properties can vary across different test conditions.
2) Consider how differences in an individual's anatomy and gait my influence their experience in an AFO.
3) Discuss whether AFO mechanical properties should be available for comparison to improve device prescription.

INTRODUCTION

- The rotational stiffness of ankle-foot orthoses (AFOs) directly impacts a user's gait by changing how much the device stabilizes, restricts, or augments movement [1].
- Understanding AFO stiffness may be useful for AFO prescription to improve function.
- Problem: Comparisons across makes and models is challenging because no testing standard exist for AFOs.
- We are currently evaluating how different testing frameworks and methodological considerations affect stiffness outcomes [2]. The overarching goal is to provide information to guide the mechanical evaluation of AFOs.

Purpose: To evaluate the impact of transverse plane alignment and rotation axis height on rotational stiffness of commercially available, off-the-shelf AFOs using the EMPIRE test fixture [2].

METHODS

AFOs Tested: 8 Off-the-shelf AFOs
- Allard Blue Rocker, Toe Off, and Toe Off 2.5
- Ottobock Walk-On Reaction
- Thusane SpryStep and SpryStep Max
- Thusane Trulife Matrix SuperMax and Matrix Max

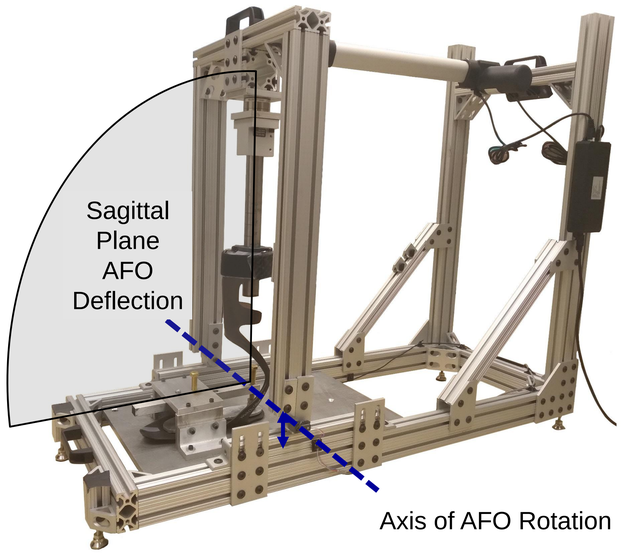
Testing Method: EMPIRE

- Transverse Alignment: Four transverse alignments based on AFO landmarks (Tested at 81mm rotation height)
- Rotation Axis Height: Three heights based on anthropometric data and CT data [2,3] for men's shoes sizes 5 (60mm), size 7 (69 mm), and size 10.5 (81mm). (Medial Border Alignment)
- Range of motion: 5 deg plantarflexion to 20 deg dorsiflexion

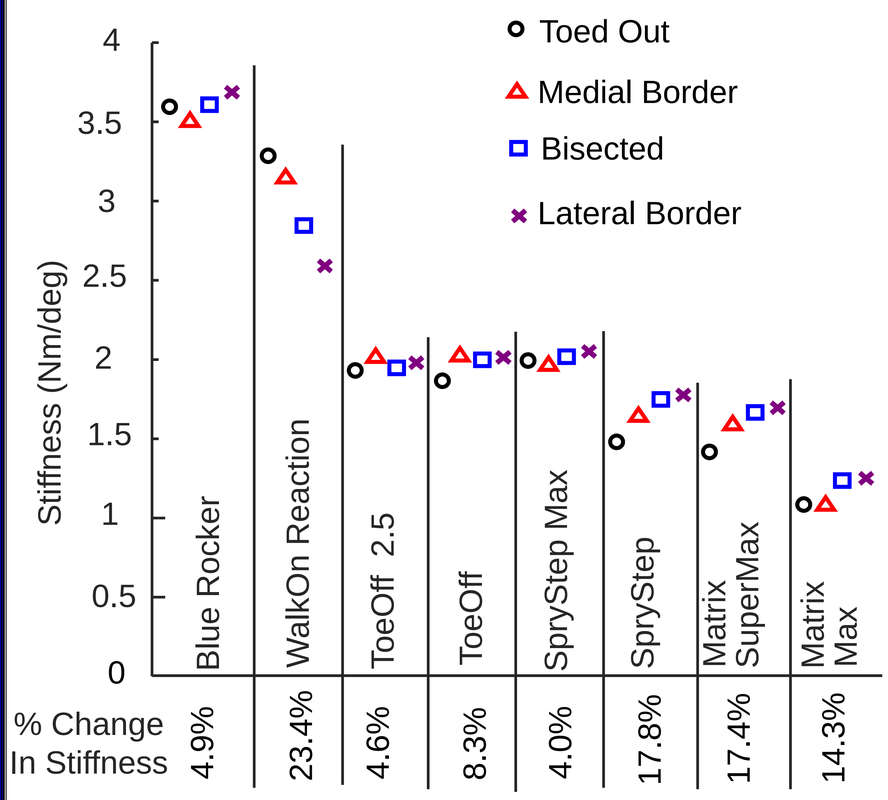
Outcomes: AFO Stiffness = Linear fit between AFO torque and angle in the sagittal plane

EMPIRE

Evaluating Mechanical Properties In Rotating Exoskeletons

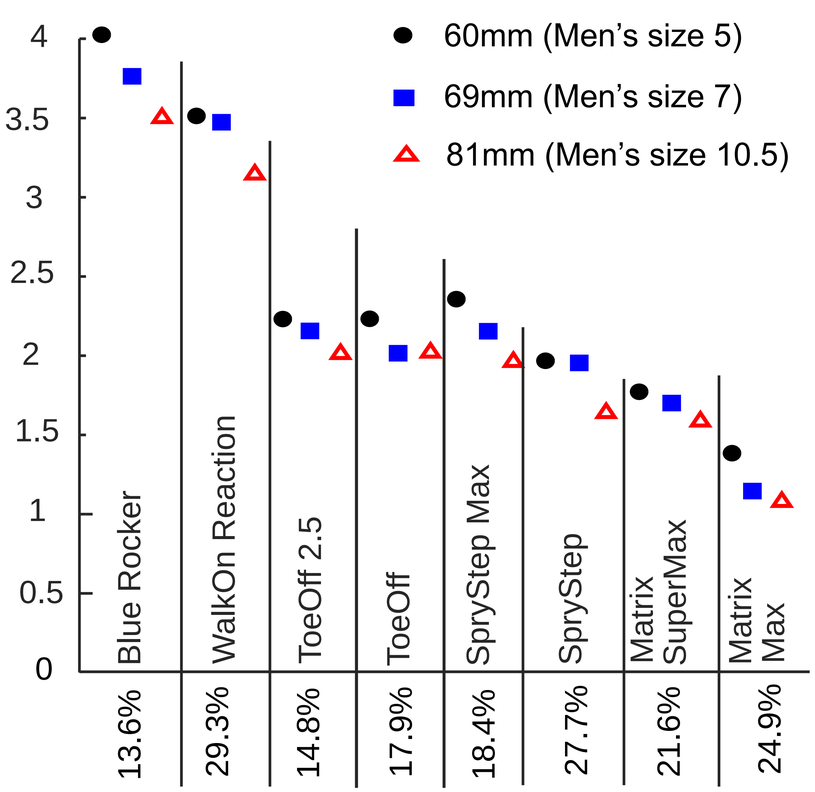


Transverse Alignment Adjustments



Stiffness changed by an average of 10.2% based upon the AFO Transverse Alignment

Rotation Axis Height Adjustments



Stiffness changed by an average of 21.0% based upon the AFO Rotation (Ankle) Axis Height

CONCLUS

- Alignment and test set-up both affect
- AFOs with lateral struts are stiffer w rotated position, and medial struts (e when more externally rotated, **indic deflection [4].**
- Lower rotation axis heights were stiffe

Standardized testing practices mu clinician comparison of stiffness acr

Patient specific anatomy and w progression angle [5]) may impact t [6].

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The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, Department of Defens Extremity Trauma and Amputation Center of Excellence (EACE), the U.S. Government, or the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. Funding provided by CDMRP award W81XW

Multiplanar Stiffness of Commercial Carbon Composite Ankle-Foot Orthoses

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The mechanical properties of an ankle-foot orthosis (AFO) can impact how a user's movement is either restricted or augmented by the device. However, standardized methods for assessing stiffness properties of AFOs are lacking, posing a challenge for comparing between devices and across vendors. Therefore, the purpose of this study was to quantify the rotational stiffness of thirteen commercial, nonarticulated, carbon composite ankle-foot orthoses. A custom, instrumented test fixture, for evaluating mechanical properties in rotating exoskeletons (EMPIRE), deflected an AFO through 20 deg of plantar/dorsiflexion motion about a specified, but adjustable, ankle axis. Sagittal, frontal, and transverse plane rotational stiffness were calculated, and reliability was assessed between cycles, sessions, and testers. The EMPIRE demonstrated good-to-excellent reliability between testers, sessions, and cycles (intraclass correlation coefficients all $\geq$0.95 for sagittal plane stiffness measures). Sagittal plane AFO stiffness ranged from 0.58 N·m/deg to 3.66 N·m/deg. AFOs with a lateral strut demonstrated frontal plane stiffnesses up to 0.71 N·m/deg of eversion while those with a medial strut demonstrated frontal plane stiffnesses up to 0.53 N·m/deg of inversion. Transverse plane stiffnesses were less than 0.30 N·m/deg of internal or external rotation. These results directly compare AFOs of different models and from different manufacturers using consistent methodology and are intended as a resource for clinicians in identifying a device with stiffness properties for individual patients. [DOI: 10.1115/1.4051845]

Keywords: ankle-foot orthosis, rotational stiffness, reliability testing, ankle axis

Introduction

Ankle foot orthoses (AFOs) are often necessary to overcome a variety of mobility limitations during gait. The mechanical properties of the AFO largely determine the degree to which an individual's movement is either restricted or augmented. [1–5], and are related to the AFO material, proprietary geometry, and fabrication practices [6]. Broadly, AFOs have been shown to restrict ankle kinematics and alter gait timings, with secondary changes at the knee [7]. It has been suggested that the mechanical properties of an AFO can be matched to an individual's specific impairments and thus should be tailored to the individual [1,8,9]. As such, the reporting of mechanical properties has been suggested as a best practice in studies involving AFO interventions [10] and the importance of understanding the mechanical characteristics of AFOs has received increasing attention in the literature [7,11,12].

Given the interest in AFO design properties, a number of different methods for evaluating the mechanical properties of an AFO have been developed. Some investigators examine linear stiffness [13–17] while others examine the rotational stiffness about the ankle measured as the change in resistive torque versus ankle angle [1,9,18–22]. However, nonstandardized test methodologies [12,23] and differences in outcome variables [7] pose a challenge for comparing outcomes across the literature. In addition, limited, if any, information is provided on the reliability of many of these testing methods. Those studies which do provide reliability analyses focused on the rotational stiffness of an AFO about a defined axis (as in an ankle joint) and evaluated intracycle variability [18–20,24], intersession variability [3,18,19,24,25], and/or intertester variability [18,19,24]. Intracycle, intersession and intertester variability are all important to report in characterizing AFO properties.

The sagittal plane stiffness of an AFO is widely recognized as an important component in the design and prescription of a device. However, many AFOs, including those with a single medial or lateral strut, may, by the nature of their design, also impart coupled frontal and transverse plane resistive moments. Examinations of AFO properties out of the sagittal plane are less common in the literature, vary in how out of plane properties are loaded and measured, and have not been evaluated with a reliability analysis [26–33]. These frontal and transverse plane contributions may be important for certain patients [7], including those who experience pain or functional deficits during out of plane rotations such as weakness or ankle instability.

Ideally, the information on AFO mechanical properties would come from manufacturers using uniform methodology. Many manufacturers do provide qualitative information related to the stiffness characteristics of their products rating rigidity, function scales [34], or identifying a list of indications such as drop foot or mild versus moderate muscle plantarflexor weaknesses [35,36]. However, stiffness, specifically, is rarely provided in units that enable comparisons across manufacturers. For example, one manufacturer may offer stiffnesses ranging from 1 to 7 in their own units of measurement [37] while another offers a choice of different colors or names intended to represent different stiffnesses [34]. Quantitative stiffness data is generally lacking for these off-the shelf models.

Many AFOs evaluated in the literature are not off-the-shelf models, but customized to an individual, often made of thermoplastic [2,24,30,32,38], or three-dimensional printed [23,39]. Quantitative evaluations in the literature of commercial devices include how stiffness varies in the Neuroswing (Fior & Gentz, Lüneburg, Germany) [40–42] and Tammerak (Tamarack Habilitation Technologies Inc., Blaine, MN) [20,21,28,43] joints, the Carbon Ankle Seven struts (Ottobock, Duderstadt, Germany) [17,44] and varying layups of the Orthotics Composites Helix (Thusane, Levallois-Perret, France) [45]. Dynamic-response custom carbon AFOs, such as the Intrepid Dynamic Exoskeletal Orthosis, have also been evaluated in how posterior strut bending stiffness affects

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Manuscript received January 13, 2021; final manuscript received July 12, 2021; published online September 1, 2021. Assoc. Editor: Spencer P. Lake.

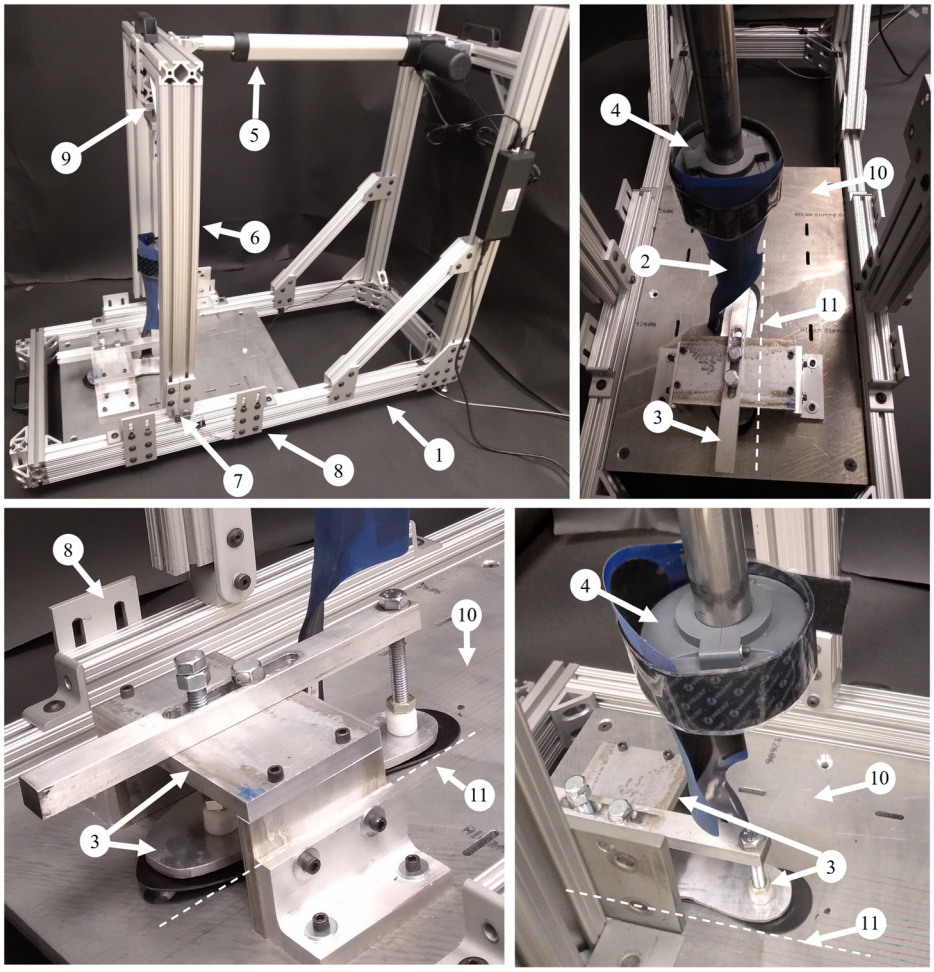

Fig. 1 Overview of the EMPIRE experimental testing fixture (1). An AFO (2) is mounted by securing the footplate with a clamping block (3) consisting of screws and a plate and strapping the tibial cuff to a surrogate shank (4). A linear actuator (5) deflects the AFO by rotating a frame (6) about a specified ankle axis (7). The position of the ankle axis can be adjusted using alignment brackets (8). Angular position is measured by an encoder at the ankle axis and loads through a load cell (9) in between the surrogate shank and the rotating frame. The base plate (10) has marked lines (representative line highlighted, (11) to aid in aligning the two medial points of the AFO.

walking, running, and inclined walking mechanics. [13–17]. While AFOs with defined hinges or joints have designed axes of rotation (e.g., Neuroswing and Tammerak), many composite AFOs do not, instead deflecting in a strut during motion. The lack of a defined AFO axis of rotation presents a challenge in defining the experimental axis and aligning/testing the devices, highlighting the need for test setups evaluated for reliability.

As the mechanical properties of most common commercially available AFOs have not been evaluated in the literature, the aim of this study was to provide clinicians with a direct comparison of multiplanar stiffness data across different manufacturers. In this study, a mechanical testing device for evaluating mechanical properties in rotating exoskeletons (EMPIRE) is described, and the reliability quantified to measure AFO stiffness about an ankle axis.

Methods

Ankle-Foot Orthoses Tested. Thirteen commercially available AFOs from four manufacturers were selected for analysis. Criteria for selected AFOs included nonarticulated, nonmodular, and constructed of carbon composite. Their use case was intended to achieve or improve symmetrical gait patterns for activities that include walking and are not intended solely for foot drop. An internal survey of VA Puget Sound orthotists identified Allard's (Helsingborg, Sweden) Blue Rocker, Blue Rocker 2½, ToeOFF, and ToeOFF 2½, Ottobock's (Duderstadt, Germany) WalkOn Reaction and WalkOn Reaction Plus, Thuasne's (Levallois-Perret, France) SpryStep, SpryStep Max and SpryStep Plus, and Trulife's (Dublin, Ireland) Matrix, Matrix Max, Matrix Max2 and Matrix Supermax as the most commonly prescribed off-the-shelf AFOs. All AFOs utilized a single strut between the tibial cuff and footplate, on either the medial (Ottobock models) or lateral (all others) side of the foot. The strut connection to the footplate was anterior to the ankle joint for all but the SpryStep and SpryStep Plus models. The model of each tested AFO was selected to fit the right foot of a hypothetical male with a size U.S. Men's 10½ shoe (275 mm), which corresponded to a size large AFO in all cases.

Fixture Design. A test fixture, the EMPIRE, was designed to evaluate rotational stiffness about a defined ankle axis. The EMPIRE was conceptually similar to the fixture previously described by Ielapi et al. [19] (Fig. 1). Engineering drawings can be found in the Supplemental Materials on the ASME Digital

Collection. The footplate was securely clamped to the base of the fixture using two screws. A contoured aluminum plate with small rubber pads was placed between the screws and the AFO to apply uniform loading and constrain deflection to the strut of the AFO. A thin rubber pad was placed underneath the footplate to minimize slippage during clamping. The tibial cuff of the AFO was strapped around a surrogate shank consisting of a 115 mm diameter, 25 mm thick disk with a rubber interface that is height-adjustable and designed to minimize the relative movement at the AFO interface (similar to the movement constraints in Ref. [21]). This differs from some prior test fixtures [18,19,24], which allow the AFO to rotate and translate along the surrogate shank axis.

The EMPIRE was designed to rotate an AFO about a simulated ankle joint, from 0 up to 25 degrees of dorsiflexion. An analog magnetic angle encoder (model RM08A, Renishaw, West Dundee, IL) measured angular deflection at the point of rotation. Loads were applied to a rotating frame using a linear actuator with a 406 mm stroke (model PA04, Progressive Automations, Arlington, WA). The actuator operated at an unloaded speed of 10 mm/sec which imparted a rotational speed of roughly 0.75 deg/sec. A six-axis load cell (Mini 58 SI-2800-120, ATI, Apex, NC) measured the resistive moments of the AFO 616 mm above the rotation axis. Ankle axis position could be adjusted vertically by adjusting the location of the rotational frame. For the tests presented here, the surrogate shank was adjusted such that loads were applied to the AFO 273 mm above the rotation axis.

Angular position and load cell data were captured simultaneously at 100 Hz using a custom interface in LabVIEW (National Instruments, Austin, TX). Angular position was controlled using preset positions in the linear actuator. To avoid overloading the load cell, positions and loads were monitored in real-time and the actuator could be paused at any time with input from the operator.

Ankle-Axis Definition. We defined a set of generic ankle axis locations (Appendix A) as being located halfway between the positions of the medial and lateral malleoli measured from the heel [18,46]. Axis locations were computed for foot lengths corresponding to U.S. standard shoe sizes [47]. Linear regressions relating overall foot length with malleolar positions were computed from anthropometry data [48,49] and computerized tomography (CT) data previously collected from 21 healthy individuals (11 male, age: 61.5 ± 7.2 years, height: 1740 ± 96 mm, weight: 80.5 ± 13.2 kg) under 25% bodyweight loading. Sagittal plane horizontal (relative to heel) and vertical (relative to floor) positioning of the malleoli was taken as the central point in the first sagittal slice where the medial/lateral malleoli appeared and foot length was taken as the first frontal slice containing the hallux. For a size 10 $^1/_2$ shoe the average vertical position of the ankle axis was 81 mm.

Test Procedures and Alignment. The EMPIRE was first calibrated by moving through the range of motion without an AFO to account for the gravitational loading of the fixturing hardware for a set distance between the load cell and the surrogate shank mounting disk. Prior to mounting an AFO, the surrogate shank was oriented vertically. Padding on the AFO was removed to minimize movement between the AFO and the fixture. The AFO was aligned such that the two most medial prominences of the AFO footplate was parallel with the path of deflection. As the AFOs tested did not have a defined heel cup and many footplates are designed to be trimmed to fit an individual's shoe, the fore aft position was determined as the point at which the tibial cuff of the AFO contacted the mounting disk on the surrogate shank. The AFO's footplate was securely clamped using the aluminum plate and clamping screws described above. The mounting disk/surrogate shank was secured within the AFO's tibial cuff using Velcro.

To determine the repeatability of the measurements in the EMPIRE, each AFO was evaluated by two testers on two separate sessions. Prior to any testing, both testers were oriented to the fixture and instructed in the alignment and testing procedure. Each session first deflected the AFO to 3 deg of plantarflexion and then through three complete cycles moving between 3 deg of plantarflexion and 20 deg of dorsiflexion without removing the AFO from the fixture. The order in which AFOs were tested was randomized for each tester and session.

Data Analysis. Data analyses were performed using custom scripts in MATLAB (MathWorks, Natick, MA). Load cell and angular position data were filtered using a 1 Hz low-pass filter (fourth order, zero-lag, Butterworth). To account for the gravitational loads imposed by the fixture, a second-order polynomial fit was computed for the calibration (no AFO) trials between the filtered angular position and each load cell channel. These calibration curves were used to adjust the filtered load cell data from the AFO testing sessions at each angular position. Computation of the AFO resistive moment in the sagittal, frontal, and transverse planes were computed per Appendix B. The first loading cycle was treated as a preconditioning cycle and removed from further analysis. AFO sagittal, frontal, and transverse stiffness, measured in N·m/deg, were computed for the second and third cycles from a linear fit of the AFO moments relative to dorsiflexion angle during the loading phase from 0 to 18 deg of dorsiflexion. The range of motion from 3 to 0 deg of plantarflexion and from 18 to 20 deg of dorsiflexion was not fit to avoid periods when the actuator was accelerating/decelerating. To account for nonlinearities in the AFO moment versus dorsiflexion angle curve, we also report the sagittal, frontal, and transverse plane moments at 10 and 15 deg.

Statistical Analyses. Each AFO was tested twice by two separate operators (four sessions total). Descriptive statistics include the calculation of the mean and range of AFO stiffnesses. The intrasession, intersession, and interrater reliability of the AFO stiffnesses during loading were assessed with interclass correlation coefficients (ICC's) using a one and a two-way mixed model for absolute agreement (ICC (A,1) and (A,K)) for single and mean scores [50,51]. Within session reliability was calculated using the second and third cycle from all four sessions for each AFO. Between session reliability was calculated as the average stiffness from the second and third cycle of each session for both operators. Between operator reliability was calculated as the average stiffness from the second and third cycle of each session including both days. The standard error of measurement (SEM) was estimated using the square root of the mean square error [51]. The minimum detectable difference (MDD) was calculated from the SEM as $\text{MDD} = \text{SEM} \times 1.96 \times \sqrt{2}$ [51].

Results

Intrasession, intersession, and interrater reliability of AFO stiffness were good to excellent [50] with all ICC's ≥ 0.95, ≥ 0.86, and ≥ 0.95 for sagittal, frontal and transverse planes, respectively (Table 1). The MDD was 0.53, 0.36, and 0.06 N·m/deg, in the sagittal, frontal, and transverse planes, respectively.

Linear fits of AFO stiffness accounted for greater than 99% of the variance in the sagittal plane moment across all AFOs and sessions. In the frontal and transverse planes, linear fits of the AFO stiffness accounted for an average of 99% and 95% of the variance in moments (minimum (92% and 53%, respectively). A representative AFO moment versus dorsiflexion angle is shown in Fig. 2. Measured AFO stiffnesses in the sagittal plane ranged from 0.58 (Matrix) to 3.66 N·m/deg (Blue Rocker) (Fig. 3, Table 2) with an average measured plantarflexion moment of 7.4–52.2 N·m at 15 degrees of dorsiflexion (Table 3). While all deflection occurred in dorsiflexion, the AFOs generated frontal plane moments (at 15 degrees of dorsiflexion), ranging from 12.3 N·m of eversion (Sprystep Max) to 9.9 N·m of inversion (WalkOn Reaction) and transverse plane moments of 4.1 N·m of internal

Table 1 Reliability for AFO stiffness in the sagittal, frontal, and transverse planes

		Sagittal stiffness	Frontal stiffness	Transverse stiffness
Within session	ICC (A,1) [95% CI]	1.00 [1.00–1.00]	1.00 [1.00–1.00]	1.00 [1.00–1.00]
	ICC (A,k) [95% CI]	1.00 [1.00–1.00]	1.00 [1.00–1.00]	1.00 [1.00–1.00]
	SEM (N·m/deg)	0.01	0.01	0.00
	MDD (N·m/deg)	0.03	0.03	0.01
Between session	ICC (A,1) [95% CI]	0.95 [0.89–0.98]	0.88 [0.75–0.95]	0.95 [0.87–0.98]
	ICC (A,k) [95% CI]	0.98 [0.94–0.99]	0.94 [0.86–0.97]	0.97 [0.93–0.99]
	SEM (N·m/deg)	0.18	0.11	0.02
	MDD (N·m/deg)	0.50	0.31	0.06
Between operator	ICC (A,1) [95% CI]	0.95 [0.90–0.98]	0.86 [0.71–0.93]	0.96 [0.90–0.98]
	ICC (A,k) [95% CI]	0.98 [0.95–0.99]	0.92 [0.83–0.97]	0.98 [0.95–0.99]
	SEM (N·m/deg)	0.19	0.13	0.02
	MDD (N·m/deg)	0.53	0.36	0.06

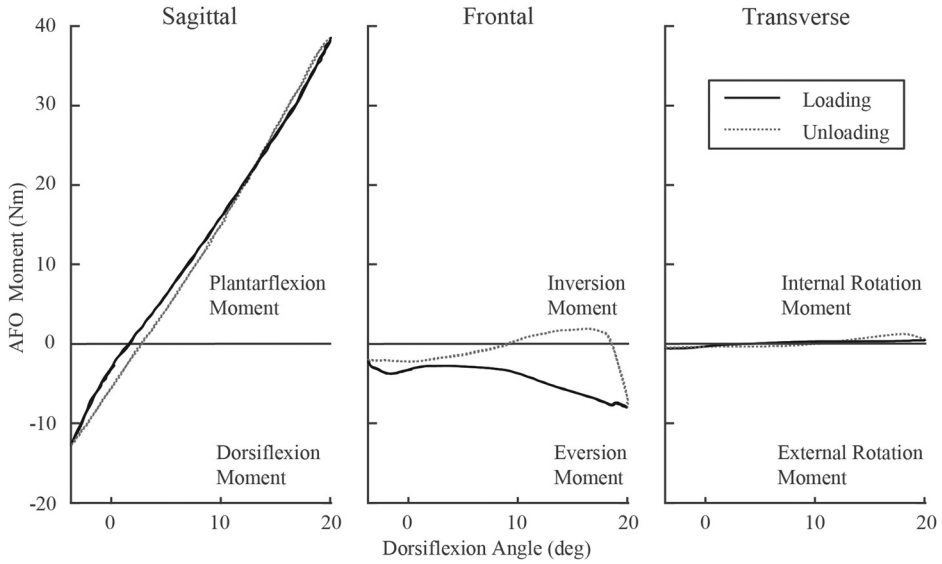

Fig. 2 Representative moments versus dorsiflexion angle curves for one session (two cycles shown). Defection in the sagittal plane elicited reaction moments in all three planes. AFO stiffness was taken as the linear fit in each plane between 0 and 18 degrees of dorsiflexion during loading. AFO shown in figure: Allard ToeOff.

rotation (Sprystep Plus) to 1.4 N·m of external rotation (WalkOn Reaction).

Discussion

This study evaluated the rotational stiffness about an ankle axis of commercially available AFOs across models and manufacturers. With only a few exceptions, the stiffnesses measured in this work are largely in line with the progressive order expected from manufacturer provided information and a prior comparison of AFOs [22]. There were, however, two instances where our findings did not align with the manufacturer-provided information. We found that the Thuasne SpryStep Max and SpryStep Plus had similar stiffness values (within 1% of each other), which was unexpected as the SpryStep Max is indicated to be stiffer than the Plus [35]. Similarly, we found comparable stiffness values (within 5% of each other) between the Ottobock WalkOn Reaction and WalkOn Reaction Plus, despite the manufacturer indicating that the WalkOn Reaction Plus is stiffer. We also note that the newer Blue Rocker $2^1/_2$ is 16% less stiff than the original Blue Rocker.

There are several likely explanations for any inconsistencies with prior reports. Perhaps the foremost factor is that the methods by which manufacturers evaluate AFOs are not broadly known.

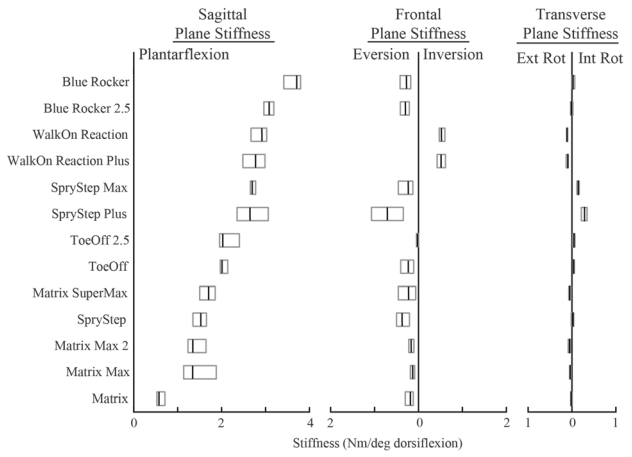

Fig. 3 Measured AFO stiffness (mean [range]) across a total of four sessions (two per operator). Sagittal plane stiffness across AFOs varied from 0.58 to 3.66 N·m/deg of dorsiflexion. Most AFOs produced an eversion moment in the frontal plane, while the two AFOs with medial struts produced an inversion moment.

Table 2 Calculated AFO stiffness across four sessions

	Sagittal stiffness (N·m/deg)		Frontal stiffness[a] (N·m/deg)		Transverse stiffness[a] (N·m/deg)	
AFO	Mean (SD)	[Range]	Mean (SD)	[Range]	Mean (SD)	[Range]
Blue Rocker	3.66 (0.15)	[3.42 to 3.80]	−0.27 (0.09)	[−0.42 to −0.18]	0.03 (0.02)	[0.01 to 0.06]
Blue Rocker 2.5	3.08 (0.10)	[2.96 to 3.19]	−0.29 (0.07)	[−0.41 to −0.21]	−0.01 (0.02)	[−0.03 to 0.02]
WalkOn Reaction	2.88 (0.14)	[2.67 to 3.03]	0.53 (0.05)	[0.47 to 0.60]	−0.11 (0.01)	[−0.12 to −0.10]
WalkOn Reaction Plus	2.75 (0.19)	[2.48 to 2.99]	0.52 (0.08)	[0.42 to 0.61]	−0.10 (0.02)	[−0.13 to −0.09]
SpryStep Max	2.70 (0.05)	[2.66 to 2.78]	−0.24 (0.14)	[−0.46 to −0.13]	0.14 (0.02)	[0.11 to 0.16]
SpryStep Plus	2.68 (0.30)	[2.35 to 3.06]	−0.71 (0.27)	[−1.07 to −0.35]	0.26 (0.05)	[0.21 to 0.34]
ToeOff 2.5	2.02 (0.06)	[1.97 to 2.14]	−0.23 (0.12)	[−0.40 to −0.11]	0.04 (0.01)	[0.03 to 0.05]
ToeOff 2.5	1.99 (0.06)	[1.93 to 2.09]	−0.01 (0.01)	[−0.03 to 0.00]	0.03 (0.01)	[0.02 to 0.04]
Matrix SuperMax	1.69 (0.14)	[1.50 to 1.85]	−0.22 (0.15)	[−0.46 to −0.06]	−0.05 (0.02)	[−0.07 to −0.03]
SpryStep	1.51 (0.12)	[1.35 to 1.65]	−0.37 (0.11)	[−0.50 to −0.21]	0.02 (0.02)	[−0.02 to 0.04]
Matrix Max 2	1.35 (0.18)	[1.24 to 1.64]	−0.17 (0.06)	[−0.22 to −0.11]	−0.06 (0.02)	[−0.09 to −0.04]
Matrix Max	1.34 (0.33)	[1.14 to 1.88]	−0.13 (0.04)	[−0.18 to −0.09]	−0.04 (0.01)	[−0.06 to −0.02]
Matrix	0.58 (0.08)	[0.53 to 0.71]	−0.19 (0.07)	[−0.30 to −0.12]	−0.01 (0.01)	[−0.02 to −0.01]

[a]Negative stiffness values in the frontal and transverse plane represent eversion and external rotation.

Table 3 Calculated AFO moments at 10 and 15 deg of dorsiflexion

	Sagittal moment (N·m)		Frontal moment (N·m)[a]		Transverse moment (N·m)[b]	
	10 deg	15 deg	10 deg	15 deg	10 deg	15 deg
Blue Rocker	32.1	52.2	−9.4	−11.2	0.4	0.4
Blue Rocker 2.5	25.8	42.6	−3.7	−5.7	0.1	0.2
WalkOn Reaction	25.6	40.9	6.6	9.9	−0.9	−1.4
WalkOn Reaction Plus	25.5	39.7	7.0	9.8	−0.8	−1.4
SpryStep Max	21.6	35.5	−9.1	−12.3	0.3	0.8
SpryStep Plus	23.5	36.6	−3.9	−7.9	2.4	4.1
ToeOff	16.8	27.5	−3.4	−5.4	0.2	0.3
ToeOff 2.5	18.4	29.6	−1.4	−0.1	0.1	0.5
Matrix SuperMax	10.5	19.8	−6.5	−8.1	−0.3	−0.8
SpryStep	12.4	19.4	−2.3	−4.2	0.2	0.3
Matrix Max 2	9.1	16.4	−4.1	−5.4	−0.2	−0.6
Matrix Max	9.7	16.8	−3.3	−4.4	−0.4	−0.7
Matrix	4.2	7.4	−2.5	−3.9	−0.3	−0.4

[a]Negative stiffness values in the frontal and transverse plane represents eversion
[b]Negative stiffness values in the frontal and transverse plane represents external rotation.

As noted in the introduction, testing methods may characterize either linear or rotational stiffness. Our testing occurred on new devices. To what extent the stiffness of the tested AFOs may change with repeated cycling is unclear but prior examinations of residual stiffness in carbon composites suggest that the stiffness may decrease by as much as 5% to 30% [52]. The size of an AFO has previously been shown to impact the rotational stiffness [53] and some models are indicated to have different mechanical properties targeted to the size of a patient [54]. Another factor was that we confined our investigation to a single speed of rotation (0.75 deg/sec). Previous investigations have found either no impact of loading speed on AFO stiffness [25,30,53] or small, but significant differences that are generally less than the minimal detectible difference of the fixture [55]. It is also currently unclear how much individual AFOs may vary between batches and specimens, as the mechanical properties of carbon composites are dependent not only on the geometry and material but also on the process control in many manufacturing steps including layup of the individual carbon fiber sheets [6].

In addition, this study constrained deflection of the AFO purely to the sagittal plane. Frontal and transverse plane stiffness were calculated from the out-of-plane moments developed while moving through the range of sagittal motion similar to the methods described by Klassen et al. [33] and Singerman et al. [28]. Other methods described in the literature involve deflecting the AFO in multiple planes simultaneously [26,27], or deflecting an AFO through a range of motion in the frontal plane independently [30–32]. These different approaches are clearly related but not readily comparable, as independently testing the frontal plane measures a resistance to frontal plane motion, while our methods indicate a preferred direction of coupled loading by the AFO.

Across the AFOs tested, we found that AFOs with a lateral strut tended to exert an eversion moment during dorsiflexion, while the two AFOs with a medial strut tended to exert an inversion moment. This was expected and broadly agrees with the work by Cappa et al. [27], who found that internally wound spiral AFOs (most similar to the lateral strut AFOs tested here) were stiffer in inversion than eversion. Motion of the ankle joint is not purely sagittal, coupling dorsiflexion with eversion [46]. Our study suggests that AFOs with lateral struts may deflect with this coupled motion while medial struts may resist it, but further work is needed to evaluate the impact of strut orientation on patient frontal plane motion during gait.

The design of the commercial AFOs tested in this study required some alignment assumptions for standardization of testing. Features common in AFOs tested in the literature including hinges and heel cups defining the position of the foot were absent. Instead, all included AFOs had a single strut and trimmable foot plates, which allow an off-the-shelf AFO to be easily customized to an individual. Considering these features, we defined a sagittal orientation by aligning the two most medial prominences of the AFOs footplate parallel with the path of deflection and the fore/aft

position by lightly contacting the tibial cuff to the surrogate shank. However, foot plate geometry varied by manufacturer, which may impact the alignment between models. Moreover, the bottom of many of the foot plates were contoured causing the AFO to rotate during clamping. We were able to mitigate the challenges imparted by AFO designs with our alignment protocol, resulting in robust intersession and intertester reliability comparable to previous reports in the sagittal plane (ICC's $\geq$ 0.95 here versus 1.00 [18], 0.99 [19,24], and 0.97 [3]). To our knowledge, this is the first study to examine the repeatability of out of plane stiffnesses, finding good reliability [50], in the frontal and transverse planes (ICC's $\geq$ 0.83). This is a critical metric to report when evaluating a test fixture for future use in both clinical and research areas.

There are several limitations to this study. While we were able to test thirteen commercial AFOs, our investigation was by no means comprehensive. Our tests were limited to a single size, specimen, testing speed, and ankle axis location for each model, as described above, and only performed on new AFOs. An important feature to note about the design of the EMPIRE is that we intentionally defined a generic ankle axis location based upon the position of the malleoli in the anthropometric literature. However, there exists considerable variability in ankle axis position between individuals. While a significant impact of ankle axis position on AFO stiffness has been demonstrated in hinged AFOs, [20,21] it remains unclear how the choice of ankle axis location may impact AFO stiffness in the AFOs tested here. Similarly, it is currently unclear how the stiffness of each AFO may change over time with use. We did not evaluate how the footplate may contribute to the overall stiffness of the device [18,45,56], although this contribution would be largely impacted by the choice of shoe and how much the footplate was trimmed or altered during fitting (e.g., the application of wedges or supplemental foot orthotics). The contribution of the footplate may partially explain the inconsistencies in stiffness between our results and prior reports. Finally, while we evaluated repeatability of our fixture, we did not directly compare our findings with any other test fixtures. As such, this study did not seek to establish the validity of the test fixture, but to provide a comparison across commercially available AFOs from a range of manufacturers. A previous cross fixture comparison [24] found some systemic differences in stiffness, and the numerous methodological decisions presented in this study highlight how important it is to rigorously evaluate test methods across the literature in the absence of standardized procedures. Future work will compare outcomes from a range of evaluation methods previously presented in the literature. Finally, this work does not identify clinically meaningful differences in stiffness, as individual responses to AFO's are highly heterogeneous. Thus, our results only provide a tool to augment clinical decision-making, realizing that the clinician must interpret these results within the context of the individual.

Conclusions

We directly compared AFO stiffnesses across 13 commercially available carbon composite AFOs using the EMPIRE, a reliable, custom mechanical testing device. In this study, we evaluated the multiplanar stiffness of thirteen nonarticulated, nonmodular, carbon composite AFOs ranging from 0.58 to 3.66 N·m/deg. This research provides a tool through which clinicians can apply their expertise in identifying appropriate AFOs for their patients.

Acknowledgment

We would like to thank G. Eli Kaufman, CPO, for his clinical recommendations and Matt Kindig for his support in the design and engineering of the test fixture. The WalkOn Reaction and WalkOn Reaction Plus AFOs were graciously lent to us by Ottobock. The view(s) expressed herein are those of the author(s) and do not reflect the official policy or position of the U.S. Army Medical Department, the U.S. Army Office of the Surgeon General, the Department of the Army, Department of Defense, Department of Veterans Affairs, or the U.S. Government.

Funding Data

This study was funded by the Extremity Trauma and Amputation Center of Excellence (EACE) Rehabilitation Technology Development Fellowship by an appointment to the Department of Defense (DOD) Research Participation Program administered by the Oak Ridge Institute for Science and Education (ORISE) through an interagency agreement between the U.S. Department of Energy (DOE) and the DOD. ORISE is managed by Oak Ridge Associated Universities (ORAU) under DOE Contract No. DE-SC0014664; Funder ID: 10.13039/100006229. All opinions expressed in this paper are the author's and do not necessarily reflect the policies and views of DOD, DOE, or ORAU/ORISE. CT data used to define the ankle axis location was originally funded under National Institute of Health (NIH) Grant No. R21 AR069283; Funder ID: 10.13039/100000002.

Nomenclature

AFO = ankle-foot orthosis
CT = computerized tomography
$D_{X,Y,Z-LC}$ = distance between the load cell origin and point of force application
$D_{X,Y,Z-AFO}$ = distance between the center of the AFO axis and point of force application
EMPIRE = test fixture for evaluating mechanical properties in rotating exoskeletons
F_X, F_Y, F_Z = forces measured in the load cell
H_{LC-AFO} = vertical distance between the load cell origin and the ankle axis
ICC = interclass correlation coefficient
MDD = minimum detectable difference
SEM = standard error of measurement
$T_{\text{Sagittal}}, T_{\text{Frontal}}, T_{\text{Transverse}}$ = torques at the AFO rotation axis
T_X, T_Y, T_Z = torques measured in the load cell

Appendix A

	Foot length		Ankle axis			
			Height		Depth	
US men's shoe size	mm	(in)	mm	(in)	mm	(in)
7	246	(9 2/3)	69	(2 11/16)	57	(2 1/4)
7.5	250	(9 5/6)	70	(2 3/4)	58	(2 5/16)
8	254	(10)	72	(2 13/16)	59	(2 5/16)
8.5	258	(10 1/6)	74	(2 15/16)	61	(2 3/8)
9	262	(10 1/3)	76	(3)	62	(2 7/16)
9.5	267	(10 1/2)	78	(3 1/16)	64	(2 1/2)
10	271	(10 2/3)	79	(3 1/8)	65	(2 9/16)
10.5	275	(10 5/6)	81	(3 3/16)	66	(2 5/8)
11	279	(11)	83	(3 1/4)	68	(2 11/16)
11.5	284	(11 1/6)	85	(3 3/8)	69	(2 3/4)
12	288	(11 1/3)	87	(3 7/16)	71	(2 3/4)
12.5	292	(11 1/2)	89	(3 1/2)	72	(2 13/16)
13	296	(11 2/3)	90	(3 9/16)	73	(2 7/8)

Ankle height is measured from the bottom of the heel, ankle depth is measured from the most posterior end of the heel. Calculations were based on regressions of centile data from White et al. [48], Parham et al. [49], and measurements taken from CT data ($N = 21$).

Appendix B

The measured torques at the load cell can be written as a combination of the measured forces multiplied by the load cell moment arm offsets

$$T_X = F_Z * D_{Y,\mathrm{LC}} - F_Y * D_{Z,\mathrm{LC}}$$
$$T_Y = F_X * D_{Z,\mathrm{LC}} - F_Z * D_{X,\mathrm{LC}}$$
$$T_Z = F_Y * D_{X,\mathrm{LC}} - F_X * D_{,\mathrm{LC}}$$

Similarly, the torques at the AFO can be written as a combination of the measured forces multiplied by the AFO moment arm offset

$$T_{\mathrm{Sagittal}} = F_X * D_{Z,\mathrm{AFO}} - F_Z * D_{X,\mathrm{AFO}}$$
$$T_{\mathrm{Frontal}} = F_Z * D_{Y,\mathrm{AFO}} - F_Y * D_{Z,\mathrm{AFO}}$$
$$T_{\mathrm{Transverse}} = F_Y * D_{X,\mathrm{AFO}} - F_X * D_{Y,\mathrm{AFO}}$$

We defined the AFO origin as being located on the axis of rotation in line with the shank axis (load cell Z). Thus, the moment arms between the load cell and the point of force application relate to the moment arms between the AFO origin through the following, where the height of the load cell is defined by the fixture design and the vertical (z) distance between the load cell and the point of force application is adjustable and measured:

$$D_{X,\mathrm{LC}} = D_{X,\mathrm{AFO}}$$
$$D_{Y,\mathrm{LC}} = D_{Y,\mathrm{AFO}}$$
$$D_{Z,\mathrm{LC}} = \mathrm{Height}_{LC} - D_{Z,\mathrm{AFO}}$$

The following equations were then used to convert between the loads measured by the load cell and the moments generated by the ankle:

$$T_{\mathrm{Sagittal}} = F_X * (\mathrm{Height}_{LC} - 2 * D_{Z,LC}) + T_Y$$
$$T_{\mathrm{Frontal}} = F_Y * (\mathrm{Height}_{LC} - 2 * D_{Z,LC}) + T_X$$
$$T_{\mathrm{Transverse}} = T_Z$$

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