AWARD NUMBER: **W81XWH-19-2-0024**

TITLE: Evaluating Mobility Interventions in the Real World

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CONTRACTING ORGANIZATION:
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REPORT DATE: AUGUST 2023

TYPE OF REPORT: Annual Report, Year 4

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

DISTRIBUTION STATEMENT: Approved for public release; distribution is unlimited.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
AUGUST 2023	Annual	15JUL2022 - 14JUL2023

4. TITLE:
Evaluating Mobility Interventions in the Real World

5a. CONTRACT NUMBER
W81XWH-19-2-0024

5b. GRANT NUMBER

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)

University of Wisconsin System
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Madison, WI 53706-1534

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

Interventions for mobility disorders include many products and rehabilitation strategies, but there is little sound information about how different treatment options affect individuals' movement in their daily lives. We propose to develop new methods to assess the clinical effectiveness of these interventions using movement data from wearable sensors during everyday life. We hypothesize that frequently-repeated locomotion, such as walking the same paths daily near the home or in the workplace, are highly repeatable as in laboratory studies, but with greater ecological validity. We propose to compare the effects of different prostheses on these repeated movements using wearable sensor data such as foot movement and limb load. In the current reporting period, efforts at the University of Wisconsin focused on developing the sensor systems and data analysis methods. Efforts at subcontractor Walter Reed NMMC focused on protocol development and regulatory procedures, to begin study activities in year 2.

15. SUBJECT TERMS

NONE LISTED

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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

Interventions for neuromusculoskeletal mobility disorders include many products and rehabilitation strategies, but there is little sound information about how different treatment options affect individuals' movement in their daily lives. In this project, we will evaluate mobility outcomes among individuals with a unilateral transtibial amputation, with particular emphasis on wearable sensors, to compare outcomes between daily-use and activity-specific prostheses in both short-term field testing (in-lab portion) and longer-term real-world locomotion testing (take-home portion). Incorporating both in- and out-of-the-lab measurements will provide a better understanding of the underlying environmental and behavioral influences on device- and activity-specific factors that collectively contribute to mobility outcomes. Such an understanding is especially important for Service Members with limb loss, who are generally high functioning, participate in a variety of activities, and often own/use multiple prosthetic devices. It is anticipated that data obtained in real-world environments will enhance ecological validity, and ultimately help drive future prescription practices for optimal functional performance, social/occupational integration, and quality of life.

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

Limb loss; mobility; prosthesis; wearable sensor;

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.

Goal	Timeline (mo.)	Status
Major Task 1: IRB and HRPO Human Subjects Approval	1-6	All approved
Major Task 2: Specify and acquire custom sensors	1-15	All complete
Major Task 3: Improve BD2SD and gait analysis from wearable data.	12-30	Preparing publications.
Major Task 4: Test 10 Subjects using four prostheses.	12-30	4 Subjects complete. 5th scheduled. Recruitment being revamped.
Major Task 4b: Test 10 subjects using two orthotic solutions for foot-drop.	12-30	Testing Complete. Analysis/Dissemination ongoing.
Major Task 5: Test 15 prosthesis users with daily-use, running-specific, and activity-specific prostheses.	15-36	4 Subjects complete. 5th enrolled.

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.

	Timeline Months	Status: Site 1 UW	Status: Site 2 WRNMMC
Specific Aim 1: Improve sensors and methods for tracking location and rebuilding gait.			
Major Task 1: Human Subjects Approval	Months		
Subtask 1: Secure IRB Approvals for Human Subjects Research – Single IRB or parallel IRB.	1-6	100%	100%
Subtask 2: Submit IRB approval and necessary documents for HRPO review.	1-6	100%	100%
Milestone #1: HRPO approval received	6	100%	100%
Major Task 2: Specify and acquire custom sensors	Months		
Subtask 1: Low-drift Inertial + GPS + environmental sensors with all-day logging: negotiate specs with Navigation Solutions, LLC	1-3	100%	N/A
Subtask 2: Pylon load sensors with Bluetooth LE streaming to data logger: negotiate specs with Orthocare Innovations	1-3	100%	N/A
Subtask 3: Customization, production, delivery (vendors)	3-12	100%	N/A
Test with subjects at UW and revisit customization and specifications until all needs are met.	12-15	100%	N/A
Major Task 3: Improve BD2SD and gait analysis from wearable data.	Months		
Subtask 1: Improve indoor location reconstruction (Kalman smoother, GPS indoor/outdoor, FootSLAM, beacons)	12-27	85%	N/A
Subtask 2: Improve methods for identifying repeated paths (straight lines, turns, ramps, stairs).	12-27	50%	N/A
Subtask 3: Improve identification of movement bouts on repeated paths. Eliminate non-equivalent bouts due to weather or behavioral outliers.	12-27	20%	N/A
Subtask 4: Improve gait metrics from wearable data.	3-27	95%	N/A
Milestone #2: Manuscripts • *Metrics from wearable data during out-of-lab movement* • *Improved BD2SD methods*	12-30	25%	0%

Comments:
Method for ground clearance is undergoing validation analysis and manuscript preparation.
Method for detecting/rejecting impact effects and improving reconstruction of level ground, ramps and stairs is in great shape, with a manuscript drafted.
Load sensors have been incorporated into additional projects based on efforts first implemented here.

Specific Aim 2: Tests of prosthesis features (ESR, ESR-LP, PHA, MPA) and orthotic solutions for foot-drop (AFO, FES)			
Major Task 4: Test 10 Subjects using four prostheses	Months		
Subtask 1: Measure "real-world" movement with different prostheses. • Recruit/enroll transtibial amputee subjects (n=10) at UW-Madison • Comparative ESR vs. ESR-LP, PHA and MPA. • 1-week real-world test for each • Collect kinematic and kinetic movement data and location using new sensor system.	12-30	40% (4 subjects tested)	N/A
Subtask 1: Analyze movement from wearable data. • Reconstruct movement • Locate repeated paths using BD2SD (existing algorithms). • Compute spatiotemporal and kinematic gait metrics. • Compute socket loads from kinetic parameters • Compare strengths and weaknesses of different prostheses.	15-30	15%	N/A
Major Task 5: Test 10 subjects using two orthotic solutions for foot-drop	Months		
Subtask 1: Measure "real-world" movement with orthotic solutions for foot-drop. • Recruit/enroll subjects with foot-drop (n=10) at UW-Madison • Comparative AFO vs. FES. • 1-week real-world test for each • Collect kinematic and kinetic movement data and location using new sensor system.	12-30	100% (12 subjects tested)	N/A
Subtask 2: Analyze movement from wearable data. • Reconstruct movement • Locate repeated paths using BD2SD (existing algorithms). • Compute spatiotemporal and kinematic gait metrics. • Compare strengths and weaknesses of different orthoses.	15-30	40%	N/A
Milestone #3: Manuscripts on comparison of devices in everyday straight walking using field-based data. • *Comparison of prostheses (ESR, ESR-LP, PHA, MPA).* • *Evaluation of acclimation rate during field trial.* • *Comparison of AFO vs. FES for drop foot.*	24-30	30%	0%

Comments:
Major Task 4: recruitment has picked up a bit; next subject starts early August, another is signed up. We will be expanding our recruitment pool.

Major Task 5: Initial analysis of Orthotics study has focused on a fatiguing long walk in hallways of academic building. This has resulted in multiple conference presentations in 2023. True "real-life" analysis yet to come.
Two manuscripts on Methods and Metrics are in preparation: one on whole-foot ground clearance (method with validation); one on foot motion reconstruction that accounts for impacts.

Specific Aim 3: Compare biomechanics of persons using multiple prostheses			
Major Task 6: Test 15 prosthesis users with daily-use, running-specific, and activity-specific prostheses	Months		
Subtask 1: Recruit and enroll subjects with transtibial amputation (n=15, all WRNMMC)	15-30	N/A	25% (4 tested, 1 enrolled)
Subtask 2: Subject Testing • Test 3 prostheses • Daily-use, running-specific, activity-specific • Four-week field-based trial with wearable data logging • Laboratory post-test	15-33	N/A	25% (4 tested, 1 enrolled)
Subtask 3: Analyze data from wearable sensors • Gait kinematics and kinetics • Analysts blinded to conditions	18-33	5%	N/A
Subtask 4: Analyze data from laboratory tests • Gait kinematics and kinetics	18-33	0%	0%
Subtask 5: Comparative analysis of lab and field-based results	30-36	0%	0%
Milestone #5: Co-author manuscripts on full study outcomes • *Comparison of daily-use vs. activity-specific prostheses.* • *Comparison of wearable vs. laboratory assessments*	27-36	0%	0%

Comments:
Task 6:
Subtask 1-2: Recruitment is a bit better. We are revising recruitment approach to access more potential subjects.
Subtask 3-5: Data are still accumulating, so analysis has not yet accelerated.

Detailed Comments:

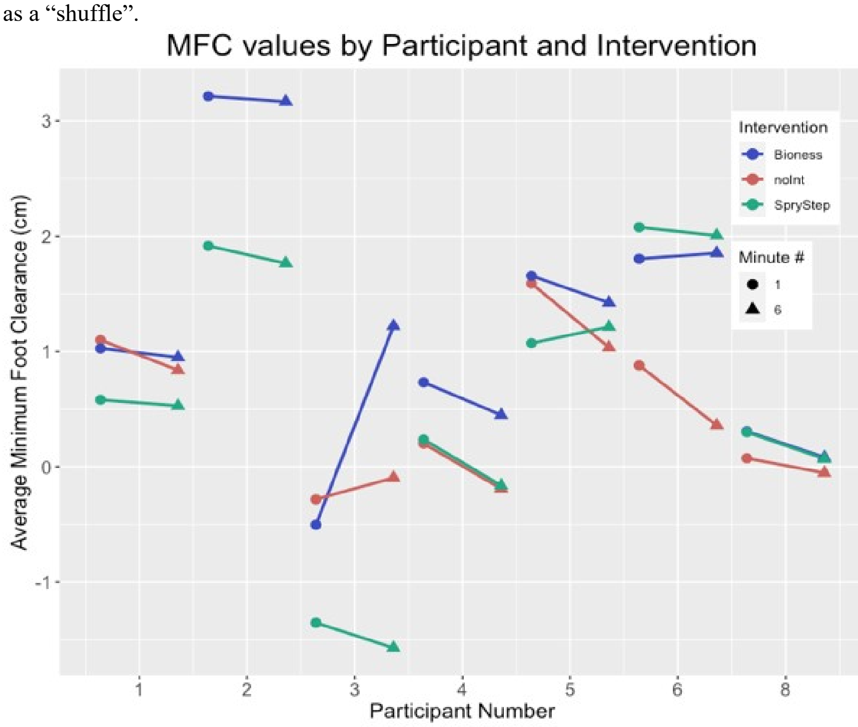
1. Objective: Develop Improved Analysis methods.

a. Goal: Develop new methods for detailed analysis of ground clearance during foot movement

i. Result: Last year we reported a novel method for whole-foot ground clearance based on reconstruction of foot motion from the IMU mounted on the foot. This year we continued fleshing out the results of that for the Orthotics study, for which we have now analyzed all the orthotics participants (a Multiple Sclerosis population with Foot Drop). We are completing a validation against motion capture using the in-lab trials that were captured by wearable system and optical motion capture. The method will be one paper, and the findings will be another. The method will also be applied to the prosthetics test data.

The key finding is shown in a figure taken from Jenny Bartloff's abstract for the Rocky Mountain Muscle Symposium (a pre-conference summit), at which she was selected as the Promising Young Investigator. This version analyzed 7 subjects (12 have now been collected). The graph shows the minimum foot clearance in minute 1 vs minute 6 of a six-minute walk test, when the participant used an elastic ankle-foot orthosis (SpryStep) or an electrical stimulation cuff (Bioness), or no intervention (NoInt). In these preliminary results, most cases showed lower foot clearance in minute 6, demonstrating fatigue; and the electrical stimulator led to higher clearance than the ankle-foot orthosis. The analysis continues to improve and we are incorporating the rest of the data to finalize the results. Additional metrics under study include changes in distance between minute 1 and minute 6 (the distance walked index, DWI) and the cost of transport in each minute. Dr. Bartloff showed similar results at the CMSC (Clinical Multiple Sclerosis Society) meeting and has submitted an abstract to the APTA Combined Sections Meeting for 2024 in hopes of presenting the complete findings there.

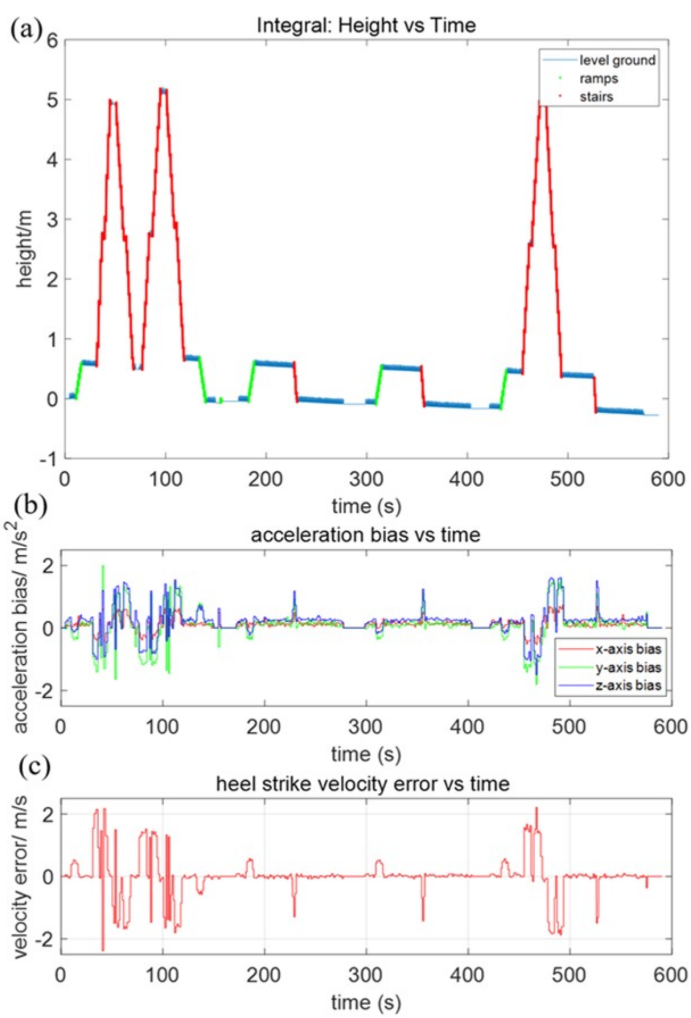
Figure 1: Trend in minimum foot clearance averages from first to last minute of 6MWT. Negative clearance suggests contact of the shoe with the ground during swing phase which is consistent in the case of subject 3, who described her gait as a "shuffle".



b. *Goal: improve reconstruction of foot motion to get accurate height measurements.*

i. The whole-foot clearance metric is very important, but it can only be gleaned from wearable sensor data if the underlying motion reconstruction is sufficiently accurate. As part of developing our clearance estimation method, we are developing a new drift correction scheme for movement reconstructed from a foot-mounted IMU sensor. The problem with past techniques is that they assume error is attributable to linear constant drift, whereas much error in the vertical direction is actually caused by impact of the foot with the ground, which is localized to the brief period of "impact" of the foot with the ground. We are developing a way of characterizing the lost information in that impact and correcting for it, based on the apparent error in velocity after heel strike. As a side benefit, the method also gives a clear separation between ramps and stairs that can be used to classify them in a trivially easy way. We have performed theoretical development and description of the new technique, and are in the midst of a comparative analysis against prior reconstruction methods.

In the figure below, part (a) is an illustration of the overall height estimate over time, from motion reconstruction of a trial in which the participant walked several laps in an academic building, including both ramps and stairs. The vertical drift is greatly reduced compared to other methods, and the colors of the plot indicate the clear classification among level ground (blue), ramps (green; up and down) and stairs (red; up and down). Part (b) is the apparent acceleration bias detected by the method, and part (c) is the heel strike velocity error. The figure is taken from Yisen Wang's abstract for the American Society of Biomechanics 2023 meeting. Mr. Wang has a manuscript drafted which will soon be edited and submitted.



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.

Training:
Three graduate students – K. Heidi Fehr, Yisen Wang and Jennifer Bartloff – had substantial one-on-one mentoring with Prof. Adamczyk on all the research methods. They also had ongoing interaction with the Prosthetics and Orthotics team at UW-Madison.

Four undergraduate students have been involved in data processing: Katherine Konieczka, Julia Mastej, Madeleine Beauvais and Matthew Wroblewski. They have helped with data collections, taking and processing 3D scans, and working with motion capture data.

Professional Development:
Dr. Bartloff (DPT) has presented the preliminary findings from the Orthotics branch at two conferences, to good reception and a great deal of helpful conversation. Dr. Bartloff was given the Promising Young Investigator recognition at the Rocky Mountain Muscle Symposium pre-conference summit on Models & Sensors to Measure Real-World Muscle Function & Movement.

Mr. Wang will present his height correction method at the American Society of Biomechanics meeting in August 2023.

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.

Analysis methods and initial data went into the various conference Abstracts shown in Summer 2023 and one submitted for early 2024 (see previous box, and attachments).

A manuscript was submitted and is in revision on a normative data set about dynamic mean ankle moment arm (DMAMA) in unimpaired persons on level ground, stairs and ramps, and with varying speed. The manuscript was a result of processing a prior data set during the COVID disruptions. The findings will be valuable in interpreting DMAMA data in the prosthetics context. (see publications).

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 Year 5 we plan the following steps:
UW-Madison:

- Test the remaining Prosthesis users
- Expand the recruitment to additional facilities
- Continue working on protocols for Mechanical testing of prostheses and finalize the analytical methods and descriptions.
- Finish and publish the manuscript on the Method and Case Study for the whole-foot ground clearance measurements, using data from the Orthotics study.
- Write and publish a manuscript on the findings of whole-foot ground clearance and fatigue from the Orthotics study.
- [repeated] Publish a journal paper on the Method and Case Study using the knee and ankle joint reconstruction on data from the Prosthetics study.
- [repeated] Hopefully publish a journal paper on the sensor system design, software and usage.

Walter Reed NMMC:

- Redouble recruitment efforts and continue collecting data.
- Process and interpret the data collected.

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).

Proven foot clearance methods are valuable for understanding movement in any case wherein people are likely to trip and fall. Both orthotics and prosthetics users have this problem, so the methods developed will and the associated findings will help understand how different devices affect this outcome.

Motion reconstruction from the foot is valuable for both movement analysis and location tracking, called pedestrian dead reckoning. The method for correcting height errors is very novel and will improve those applications.

Findings on the effects of orthoses on foot clearance will help people make informed choices about which device will help them most.

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.

Jennifer Bartloff's presentation at the Rocky Mountain Muscle Symposium pre-conference summit on Models & Sensors to Measure Real-World Muscle Function & Movement earned her the Promising Young Investigator award. This symposium is a wider group of biomechanics researchers, who have now heard about the detailed methods we have developed.

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.*

Some of our Orthotics (MS) participants gleaned valuable experience that helped select the best device for them.

We expect the results to change how prescription is practiced for both orthotics and prosthetics in the long term.

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.

The Prosthetics branch is undergoing changes to improve recruitment. We will expand to additional recruitment sites and perform off-site installation of sensors in some cases, to lower barriers to participation. IRB approval of the changes is pending.

Remember that significant changes in objectives and scope require prior approval of the agency.

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

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

Recruitment is still a challenge. See above for changes to deal with that.

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

We have a change request in with the IRB at UW-Madison to allow off-site installation of sensors on existing prostheses. This makes a minor additional risk of being identified, since installation is no longer sequestered in a lab. Some participants will be entirely remote, rather than coming to the lab.

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).*

  One manuscript is in Revision; others are in Preparation. Nothing to report here at this time.

  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.*

Conference presentations:

Wang Y, Fehr KH, **Adamczyk PG** (2022) Joint Movement Reconstruction in Long-Term Real-World Tracking. *North American Congress on Biomechanics 2022*. August 21-25, 2022. Ottawa, Ontario, Canada. Poster.

Fehr KH, Bartloff JN, Wang Y, Konieczka K, Mastej J, **Adamczyk PG** (2022). Determining whole-foot ground clearance kinematics by augmenting IMU trajectory with personalized 3D scans. *North American Congress on Biomechanics 2022*. August 21-25, 2022. Ottawa, Ontario, Canada. Oral Presentation.

Fehr KH, Wang Y, Bartloff JN, Mastej J, Konieczka K, Acasio JC, Knight A, Hendershot BD, **Adamczyk PG** (2022). Toward evaluating prosthetic feet using real-world data: preliminary results on whole foot clearance and knee angle. *Military Health System Research Symposium 2022*. September 11-15, 2022. Orlando, FL, USA. Poster.

Bartloff JN, Fehr KH, Wang Y, Konieczka K, Mastej J, Cohen E, **Adamczyk PG** (2023). Mixed-Methods Approach to Foot-Drop Device Selection in Multiple Sclerosis: An Exploratory Study. *Consortium of Multiple Sclerosis Centers 2023 Annual Meeting*. May 31-June 3, 2023. Aurora, CO, USA. Poster.

Bartloff JN, Fehr KH, Wang Y, Konieczka K, Mastej J, Cohen ET, **Adamczyk PG** (2023). Pairing IMU trajectory with 3D foot scans for comparison of whole-foot minimum clearance among foot drop interventions in multiple sclerosis. *Rocky Mountain Muscle Symposium pre-conference summit on Models & Sensors to Measure Real-World Muscle Function & Movement*. June 18, 2023. Canmore, Alberta, Canada. Oral Presentation. **Winner of the the Promising Young Investigator award.**

- **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 in this project year.

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: *Peter Adamczyk*
No Change

Name: *Katherine Heidi Fehr*
No Change

Name: *Yisen Wang*
No Change

Name: *Jennifer Bartloff*
No Change.

Name: *Katherine Konieczka*
Project Role: *Undergraduate Student*
Researcher Identifier (ORCID): *none*
Nearest person month worked: *3*
Contribution to Project: *Ms. Konieczka managed REDCap systems for collecting daily logs from participants at all sites; worked on 3D scans and data processing; and worked to clean and process motion capture data from lab tests.*

Name: *Julia Mastej*
Project Role: *Undergraduate Student*
Researcher Identifier (ORCID): *none*
Nearest person month worked: *2*
Contribution to Project: *Ms. Mastej worked on creating and processing 3D scans and data processing; and worked to clean and process motion capture data from lab tests.*

Name:	*Matthew Wroblewski*
Project Role:	*Graduate Student Part-time Worker*
Researcher Identifier (ORCID):	*none*
Nearest person month worked:	*1*
Contribution to Project:	*Mr. Wroblewski came onboard to do the processing the Ms. Konieczka was doing, as Ms. Konieczka graduated and moved on.*

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:
<u>Organization Name:</u>
<u>Location of Organization: (if foreign location list country)</u>
<u>Partner's contribution to the project</u> (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.*

Organization Name: Navigation Solutions, LLC
Location of Organization: Ann Arbor, MI, USA
Partner's contribution to the project: Collaboration (partner makes the motion sensor systems used in this research).

Organization Name: Orthocare Innovations, LLC
Location of Organization: Edmonds, WA, USA
Partner's contribution to the project: Collaboration (partner makes the prosthetic pylon load sensor used in this research).

Organization Name: Walter Reed National Military Medical Center
Location of Organization: Bethesda, MD, USA
Partner's contribution to the project: Collaboration (partner performs human subjects testing for part of this research).

8. SPECIAL REPORTING REQUIREMENTS

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

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

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*

Appendices attached:

a) Poster: Wang et al. *NACOB 2022*
b) Poster: Fehr et al. *MHSRS* 2022
c) Abstract: Bartloff et al. *CMSC 2023*
d) Poster: Bartloff et al. *CMSC 2023*
e) Abstract: Bartloff et al. *RMMS 2023 pre-conference summit*
f) Abstract: Bartloff et al. *APTA CSM 2024*

Not included: Fehr et al *NACOB 2022* Abstract: this was submitted last year, and it resulted in an oral presentation.

INTEGRAL RECONSTRUCTION AND STAIRS&RAMPS DETECTION USING ONE FOOT-MOUNTED IMU

Yisen Wang[1*], Katherine H. Fehr[1], Peter G. Adamczyk[1]
[1]University of Wisconsin-Madison
*email: ywang2557@wisc.edu

Introduction: Foot trajectory reconstruction using an Inertial Measurement Unit (IMU) enables biomechanics studies on human locomotion in both in-lab and out-of-lab settings. Kalman Filter based reconstruction, including Extended Kalman Filter (EKF) or Error State Kalman Filter (ESKF) are powerful methods. However, they suffer from the drift in height [1] without the correction of other sensors. One reason is due to the limited bandwidth and/or range on the IMU: heel strike impact can't be captured perfectly [2], thus causing error, especially in the vertical direction, which is not well-modeled as Gaussian noise. The inaccurate height information makes it difficult to detect ramps and stairs from only a foot-mounted IMU. In this abstract, we propose an enhancement to integral-based reconstruction that has more accurate height information and can detect ramps and stairs using only one foot-mounted IMU. Although we produce a 3D trajectory reconstruction in post-processing, here we only focus on the height information, therefore ignore the common heading drift issue. We also assume that the orientation of the IMU sensor at each moment can be obtained by any orientation filter.

Methods: We take the same sensor error model as in ESKF [3], but only keep the accelerometer bias term $b = [b_x, b_y, b_z]^T$. We introduce the heel strike velocity error Δv_{hs} to describe the discontinuity in the world z-axis velocity at the heel strike instant, k_{hs}. The velocity update from time k to time $k+1$ is computed as the following:

$$\begin{bmatrix} v_x'(k+1) \\ v_y'(k+1) \\ v_z'(k+1) \end{bmatrix} = \begin{bmatrix} v_x(k) \\ v_y(k) \\ v_z(k) \end{bmatrix} + \left(\begin{bmatrix} R_{11}(k) & R_{12}(k) & R_{13}(k) \\ R_{21}(k) & R_{22}(k) & R_{23}(k) \\ R_{31}(k) & R_{32}(k) & R_{33}(k) \end{bmatrix} \begin{bmatrix} a_{m,x} - b_x \\ a_{m,y} - b_y \\ a_{m,z} - b_z \end{bmatrix} + g \right) \Delta t \qquad (1)$$

Where $R(k)$ is the rotation matrix representing the sensor orientation at time k, a_m is the measured accelerometer signal in sensor body frame, and g is the gravity vector.

We define $\Delta v(n)$ as the accumulated velocity difference due to acceleration bias up to time n. For a single stride, we can represent the accumulated velocity difference as:

$$\Delta v(n) = \sum_{k=0}^{n} (R(k)) b \Delta t = R_v(n) b \Delta t \qquad (2)$$

Where $R_v(n) = \sum_{k=1}^{n} R(k)$ is the sum of rotation matrix from $R(1)$ to $R(n)$. We can follow the same idea to compute for position difference due to acceleration bias, because of the second order term in integrating position, we define $R_p(n) = \sum_{k=1}^{n} (R_v(k) + \frac{1}{2} R(k))$.

The heel strike velocity error Δv_{hs} will contribute to the z-axis velocity at heel strike moment as $v_z(k_{hs}) = v_z(k_{hs}) + \Delta v_{hs}$, and to z-axis position as $\Delta p_z = \Delta v_{hs}(N - k_{hs})\Delta t$, where N is the length of samples for that stride and Δt is sample period.

In the case of walking on level ground, double integrating the raw data yields residual velocity and residual height at the end of the stride. Combining the equations for velocity difference, position difference and heel strike velocity error, we obtain the system of equations (3), which can be solved to find $[b_x, b_y, b_z, \Delta v_{hs}]$, corrections that yield zero residual velocity and height.

$$\begin{bmatrix} -V_{residual,x}(N) \\ -V_{residual,y}(N) \\ -V_{residual,z}(N) \\ -H_{residual,z}(N) \end{bmatrix} = \begin{bmatrix} R_{v,11}(N) & R_{v,12}(N) & R_{v,13}(N) & 0 \\ R_{v,21}(N) & R_{v,22}(N) & R_{v,23}(N) & 0 \\ R_{v,31}(N) & R_{v,32}(N) & R_{v,33}(N) & 1 \\ R_{p,31}(N)\Delta t & R_{p,32}(N)\Delta t & R_{p,33}(N)\Delta t & (N - k_{hs}) \end{bmatrix} \begin{bmatrix} b_x \\ b_y \\ b_z \\ \Delta v_{hs} \end{bmatrix} \Delta t \qquad (3)$$

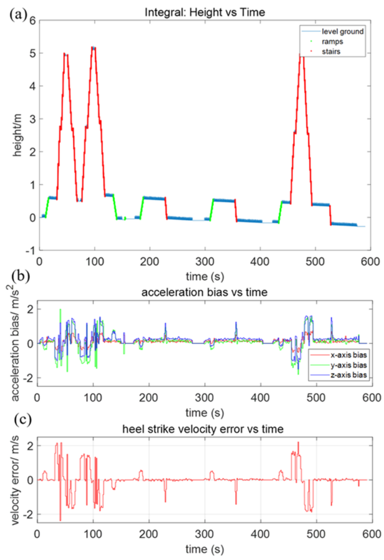


Figure 1: (a) height change on 10-minute walk, including stairs with 4.5m height; (b) acceleration bias on each step; (c) velocity error on each step.

In the case of non-level ground, there will be large deviation in the acceleration bias and heel strike velocity error from equations (3), as shown in Fig 1 (b)(c). We can apply a simple criterion to separate the ramp and stairs from level ground. For non-level ground steps, we only solve for the zero residual velocity conditions to get acceleration bias and use average heel strike velocity error from previous steps. Finally, we can use the trajectory results to separate any mix between ramp and stairs.

Results & Discussion: We tested the new method on 3 unimpaired subjects and one with unilateral amputation, using an APDM Opal sensor on top of the shoe. Subjects walked a random route, including level ground, up and down ramps, and three times up and down stairs to the upper floor, plus short stairs, then returned to the same spot. One testing result is shown in Fig 1. The stable distribution of acceleration bias demonstrates that some pattern of imperfect measurement exists in that condition. Because we do not model the sensor noise explicitly, the acceleration bias here contains effects due to both imperfect measurement of the movement and sensor noise. Table 1 summarizes the reduction in height error due to the proposed method. In general, the new method works very well on natural legs, and less well on prosthetic foot, partly because much bigger heel strike impact occurred on prosthetic leg. The main remaining height error happens on ramps and stairs.

Table 1: testing results on four subjects

Subject	Distance	Integral: Residual Height	ESKF: Residual Height
1-left	695 m	1.49 m (0.21%)	5.79 m (0.83%)
1-right	705 m	1.07 m (0.15%)	11.32 m (1.61%)
2-left	313 m	2.74 m (0.88%)	8.77 m (2.80%)
2-right	309 m	0.25 m (0.08%)	5.85 m (1.89%)
3-right	602 m	-0.27 m (0.05%)	10.64 m (1.77%)
4-prosthetic	518 m	1.54 m (0.29%)	7.79 m (1.50%)
4-unimpaired	527 m	0.38 m (0.07%)	18.85 m (3.58%)

Significance: The novel integral reconstruction provides more accurate height information, it can also detect level ground vs. ramps and stairs reliably using only one foot-mounted IMU, which is not easy only using Kalman Filter based reconstruction.

Acknowledgements: This project is funded by DOD W81XWH-19-2-0024.

References: [1] Hsu, et al. 2017 *IEEE Sensors* [2] Ju, et al. 2015 *Measurement Sci & Tech* [3] Solà 2017 *arXiv.*

Toward evaluating prosthetic feet using real-world data: preliminary results on whole-foot clearance and knee angle

Katherine Heidi Fehr[1], Yisen Wang[1], Jennifer Nicole Bartloff[1], Julia Mastej[1], Katherine Konieczka[1], Julian C. Acasio[2,3], Ashley Knight[3,4,5], Brad D. Hendershot[3,4,5], Peter G. Adamczyk[1]

[1]University of Wisconsin-Madison, [2]Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Bethesda, MD , [3]Walter Reed National Military Medical Center, Bethesda, MD, [4]DoD-VA Extremity Trauma and Amputation Center of Excellence, Bethesda, MD, [5]Uniformed Services University of the Health Sciences, Bethesda, MD

Background

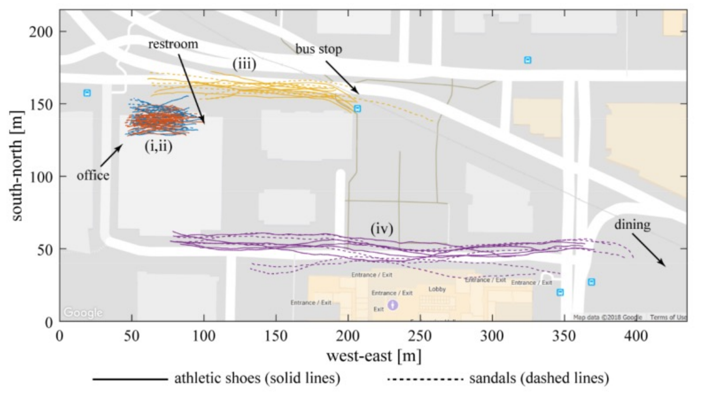


Fig 1. Frequently-repeated straight walking trajectories

Real-World Tracking for Science[1]

- Controlled Comparisons: repeatable locations, activities

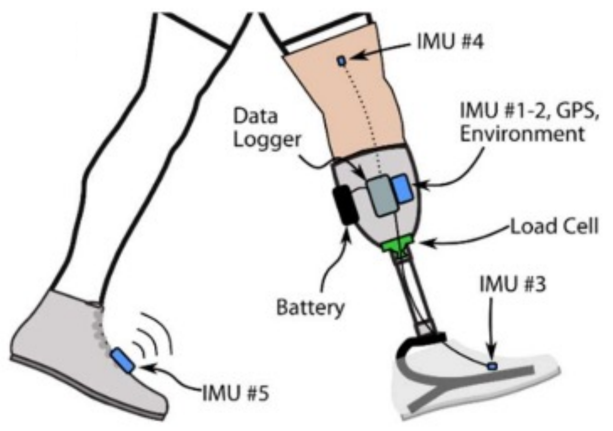
Valuable gait data about real-world performance

- IMU-based joint movement reconstruction
- Whole-foot ground clearance

System Overview

1 Sensor Suite

- **5 IMUs**
  - 3 low-cost IMUs
  - 1 high-accuracy IMU
  - 1 Bluetooth Low Energy IMU
- **RTK GPS**
- **Environmental sensors**
- **Europa+ smart Pyramid**[2]
  - 3-axis BLE load cell
- **RasPi Zero W**
  - data logging, power management, error detection
- **Android Phone APP**
  - monitor & configure system
- ***Used in: Prostheses Studies***

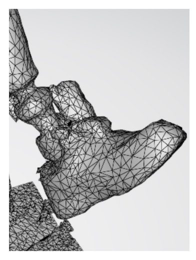


2 Compact Sensor Suite

- 3 IMUs (APDM Opals)
- GPS Phone APP
- *Used in: Orthoses Study*

Support material

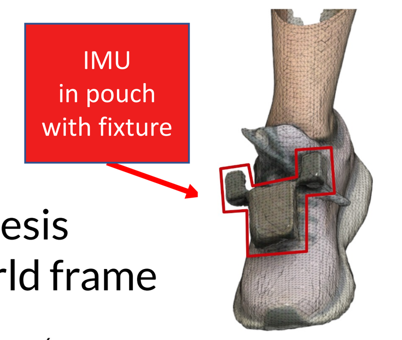
REDCap surveys
Record activities

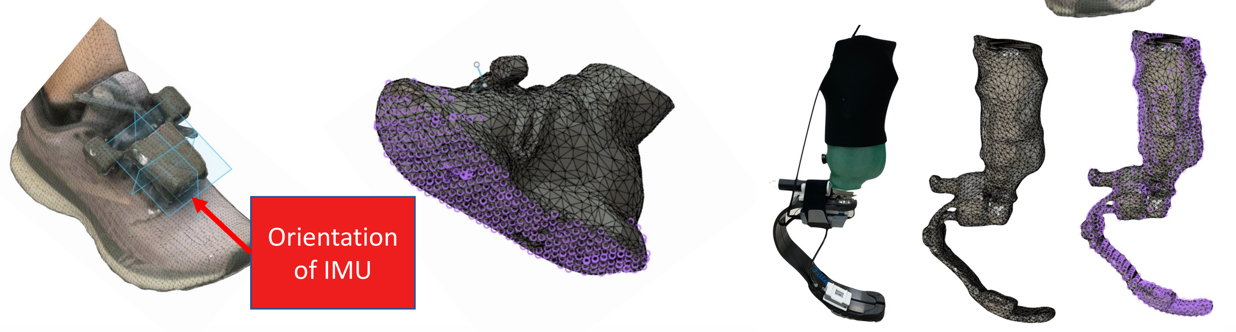


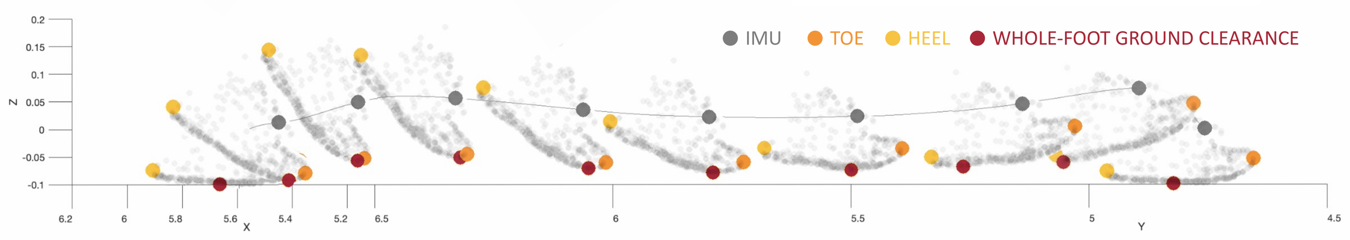
3D scans
Estimate Clearance

Method: Whole-Foot Ground Clearance

1. 3D scan foot/prosthesis with IMU in pouch with fixture
2. In CAD software, use fixture position to determine foot geometry relative to IMU
   - orientation of the IMU
   - toe
   - heel
   - points projected onto the shoe/prosthesis
3. Reconstruct whole-foot/prosthesis in world frame



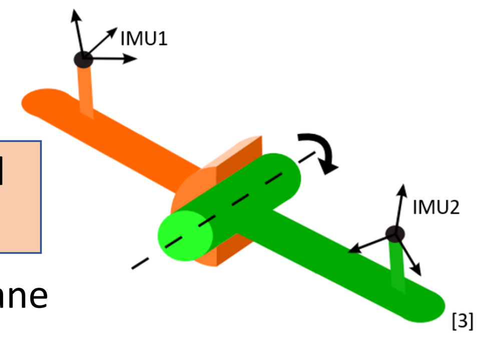




Method: Joint Movement Reconstruction

- Calculate joint axis based on hinge joint constraints[3]

g_i angular rate, j_i joint axis unit vector, both in local IMU frame i=1,2



Angular velocity of two rigid bodies connected by a hinge have the same off-axis component

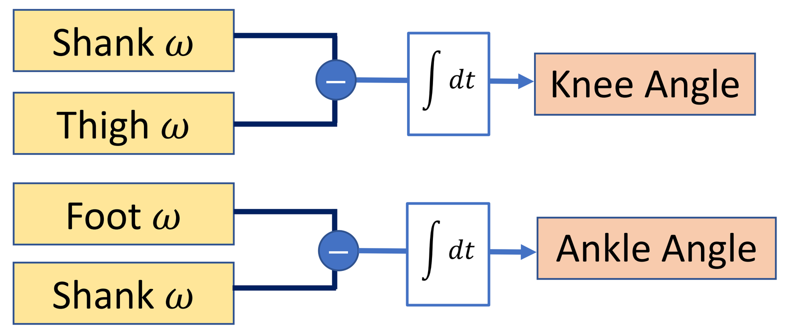
same magnitude of projection onto joint axis plane

$$\|g_1(t)\times j_1\|_2 - \|g_2(t)\times j_2\|_2 = 0$$

Off-axis component of gyroscope data 1 — Off-axis component of gyroscope data 2

- Find joint axis: minimize hinge constraint error

$$argmin_{j_1 j_2} \sum e_i^2, \; where \; e_i = \|g_1(t_i)\times j_1\|_2 - \|g_2(t_i)\times j_2\|_2$$

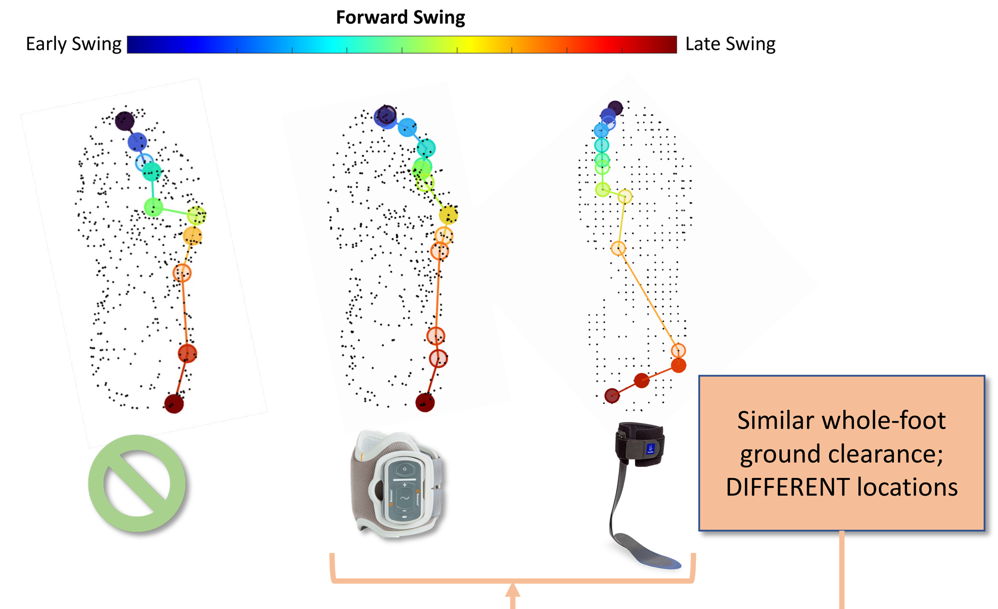


Results and Discussion: Comparing Orthoses – Ground Clearance

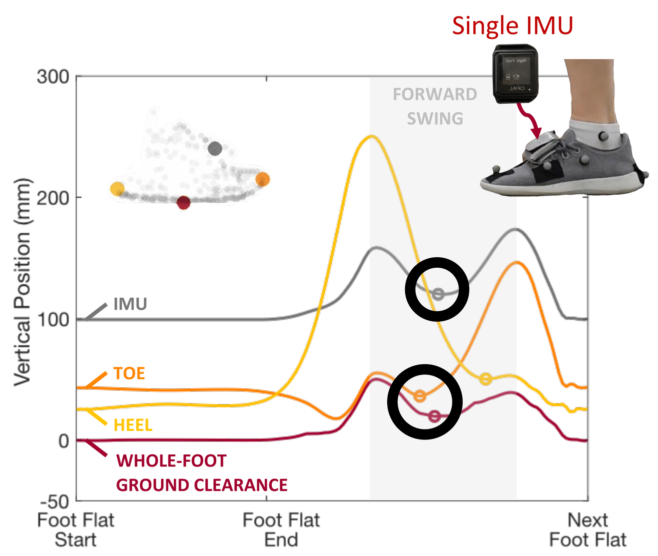
Case study: Which orthosis will increase ground clearance for participants with Drop Foot? (test case: Multiple Sclerosis)

Example data: n=1

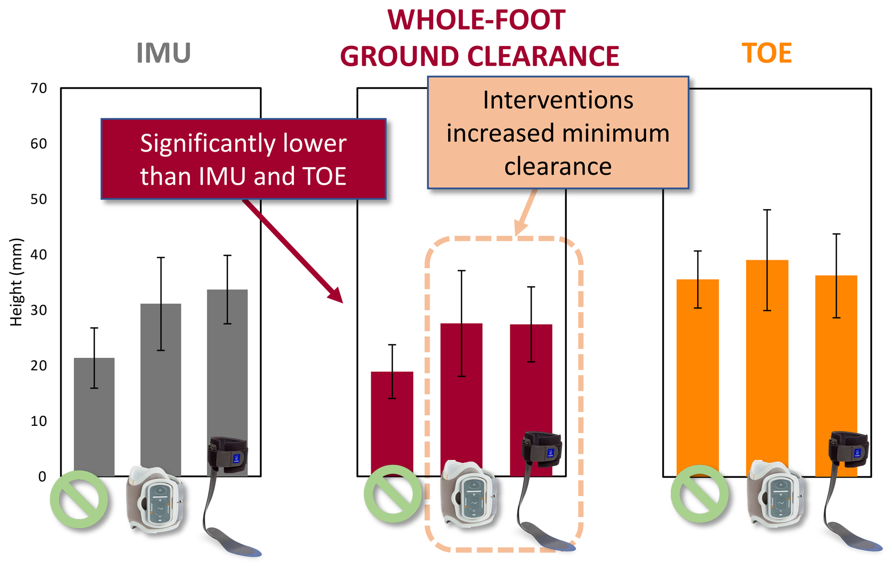
View our animations here!



Location of whole-foot ground clearance
(Representative strides)



Vertical position of key points
(Representative stride)



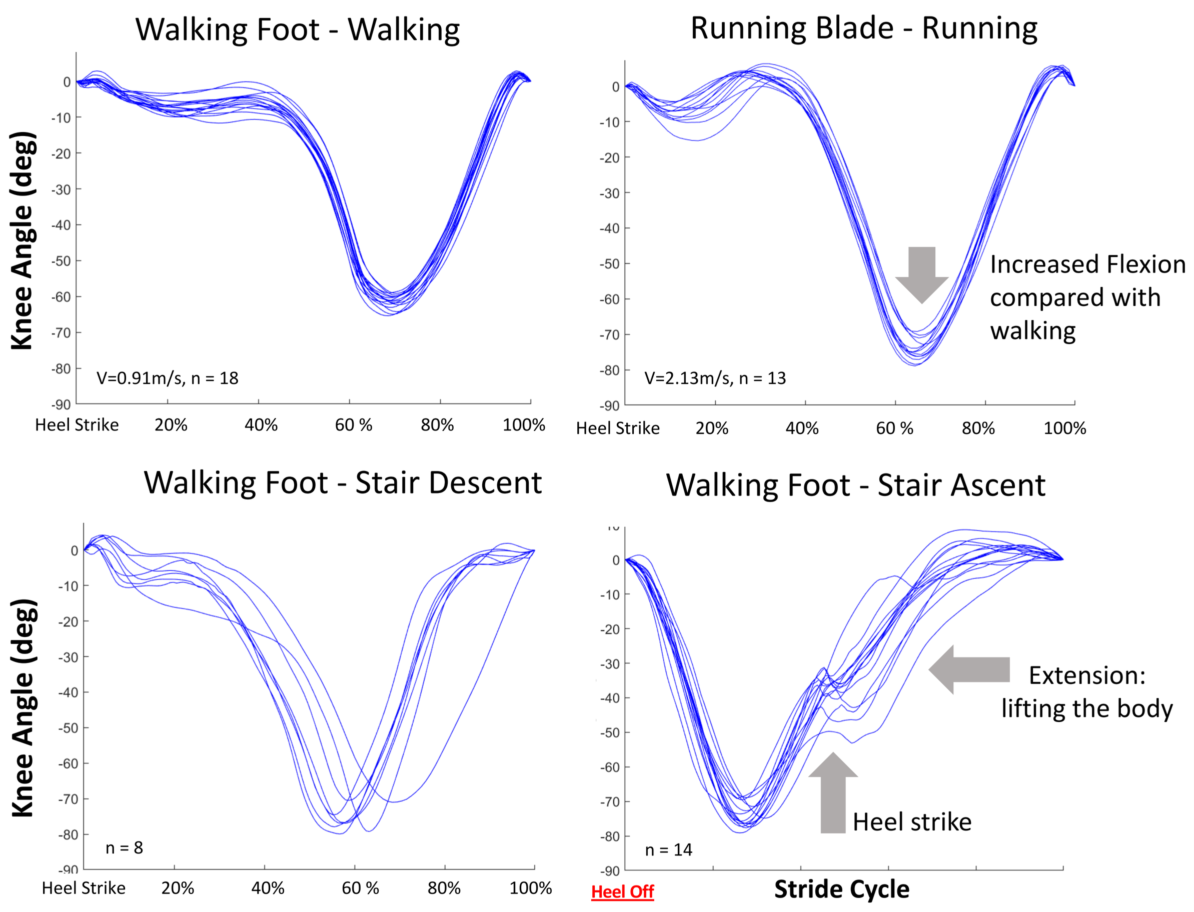
Minimum ground clearance
(600 strides/intervention)

Discussion:

- Increased clearance may lead to less falls
- Method augments information from a single sensor
- Method useful for studying pathologies that result in “non-sagittal” gait.

Results and Discussion: Knee Kinematics Vary with Prosthesis and Activity

Example data: n=1



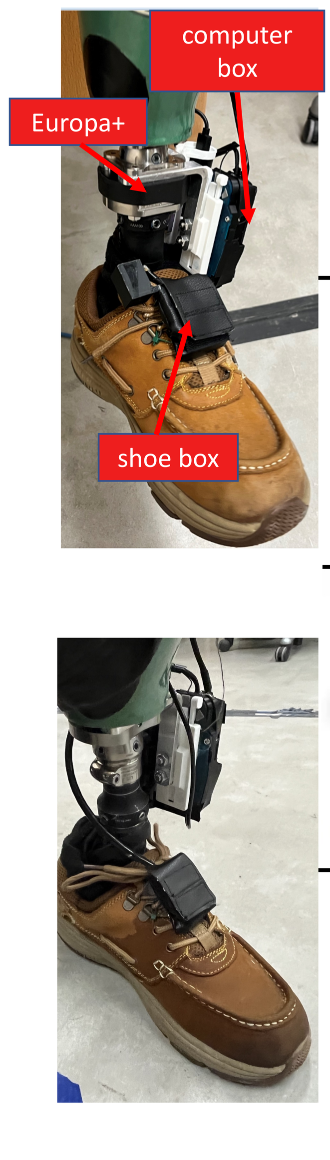
Discussion:

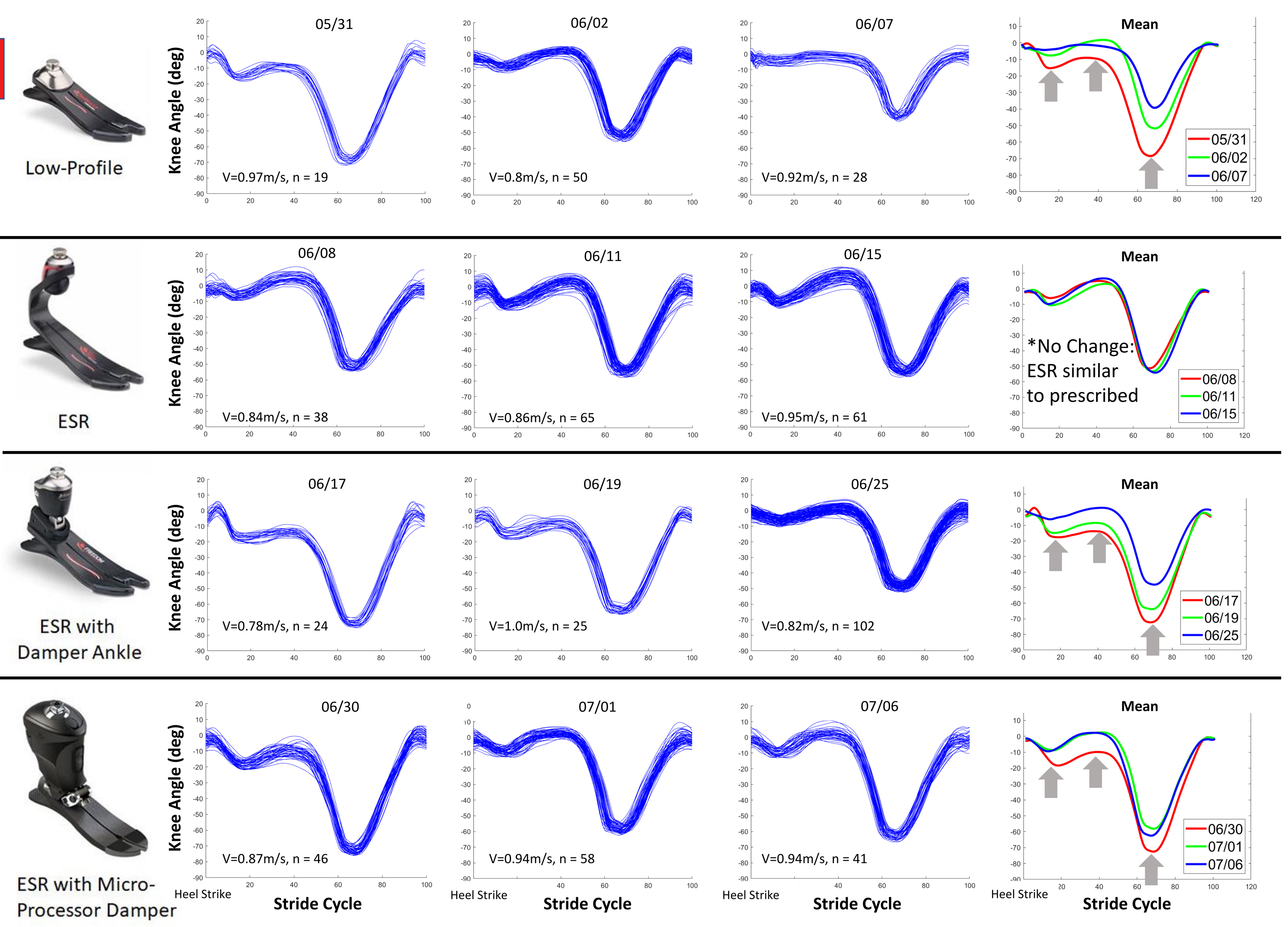
Knee functions differently

- Straighter in Walking
- More flexed in Running
- Stairs include lowering and raising with the knee

Results and Discussion: Adaptation to Four Feet across 4+ Weeks

Example data: n=1: ~90,000 walking strides





Discussion:

Adaptation over several days

- Relearn to extend knee in Stance?
- Knee flexion in Swing reduces over time

Minimal change with ESR foot

- ESR foot is similar to their clinically prescribed foot

Low-profile foot is different

- Adapts toward minimal flexion, stance and swing

Wearable sensor technologies offer a unique opportunity to evaluate prosthetic devices outside the laboratory by quantifying not only activity levels but also important movement outcomes such as foot clearance, limb kinematics, or limb loading. Such an understanding can, in turn, enable better-informed care decisions and overall improve outcomes following limb loss/impairment.

UW BADGER Lab
Biomechatronics, Assistive Devices, Gait Engineering & Rehabilitation

References:
[1] Wang et al 2019 Sensors, [2] Europa+, Orthocare Innovations, LLC, [3] Thomas 2012, IEEE Conference on Control Applications, [4] Thomas et al 2014 Sensors

Acknowledgments:
This work was supported by DOD grant W81XWH-19-2-0024 and Walter Reed National Military Medical Center

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Then scroll all the way down to the bottom of this page and click "Conclude Submission".

Mixed-Methods Approach to Foot-Drop Device Selection in Multiple Sclerosis: An Exploratory Study

Jennifer N Bartloff, DPT, NCS, MS[1], K. Heidi Fehr, .[1], Yisen Wang, .[1], Katherine Konieczka, .[2], Julia Mastej, .[2], Evan Cohen, PT, MA, PhD, NCS[3] and Peter Adamczyk, PhD[1], (1)Mechanical Engineering, University of Wisconsin, Madison, WI, (2)Biomedical Engineering, University of Wisconsin, Madison, WI, (3)Physical Therapy, Arcadia University, Glenside, PA

Abstract Text:
Background: Persons with Multiple Sclerosis (PwMS) commonly exhibit footdrop (FD) (weak control of ankle dorsiflexors), fatigability (rapid performance degradation), and elevated cost of transport (COT, metabolic energy required to move a unit distance) in gait. The fatigued state can worsen FD, compounding the risk of falls. The combination suggests 3 potential outcome metrics of gait intervention effectiveness: minimum foot clearance (mFC) (minimum height between the ground and any part of the foot during swing phase); (change in speed during an extended walk), and COT.

Objectives: To compare mFC, fatigability, and COT during gait at baseline to gait with two devices that address FD: ankle foot orthoses (AFO) and functional electrical stimulation (FES). We hypothesized that mFC would increase, some with AFO and more with FES; and that COT and fatigability would decrease with AFO but not with FES. We also hypothesized that preference would correlate with these changes.

Methods: A sample of persons with FD caused by MS (age 33-63 years; current n=4; target enrollment =10).

Participants were first tested with no intervention device (NoInt). They were then given an AFO (Sprystep Carbon) and FES (Bioness L300 Go) each for a 10-day at-home habituation period followed by a lab visit. At each visit, participants performed a 6-minute walk test (6MWT) while wearing 3 inertial measurement units (IMU). mFC was estimated from IMU data combined with a 3D foot scan. Metabolic rate was estimated from oxygen consumption. Net metabolic rate (É , W/kg) was the difference between a 3 minute standing baseline test and the mean rate over the last 3 minutes of the 6MWT. COT was the quotient of divided by 6MWT speed (m/s). Fatigability was quantified by the Distance Walked Index (DWI), the percent change in distance walked in the 6th vs. 1st minute. At the study's end, participants indicated their device preference vs. none.

Results: The mean DWI percent was -11% (range +2.5 to -24.9%), -7.1 (range 0.03 to -12.4), and -7.2 (range +3.2 to -34.0), for AFO, FES, and NoInt respectively. Mean COT values (J/kg/m) were 2.8 (range 1.5-4.5) and 2.8 (range 1.7-4.5), and 2.8 (range 1.7 to 5.4) for AFO, FES, and NoInt. mFC (cm) was 2.64 (range 0.08-7.68) and 2.76 (range 0.26-5.57) and 1.79 (range 0.02-4.81) for AFO, FES, and NoInt.

2/4 participants preferred the device yielding their highest COT. A different 2/4 preferred the device yielding their best DWI. 2 preferred the device with the lower average mFC.

Conclusions: FES appears to have a better impact on DWI compared to AFO with similar energy consumption (COT) between conditions. Preference did not correlate with any of the outcome metrics, suggesting that minimizing COT and improving DWI and mFC may not be the only contributors to user preference.

User preference may not match objective COT, fatigability, nor minimum foot clearance. This study may inform clinical selection of FD devices resulting in the safest and most efficient gait.

Title:
Mixed-Methods Approach to Foot-Drop Device Selection in Multiple Sclerosis: An Exploratory Study

Submitter's E-mail Address:
bartloff@wisc.edu

Have you simultaneously submitted this abstract to another organization for consideration?:
No

Comments to organizers:

I hope to be considered for CMSC submission if not accepted in the Whitaker Research Track.This study is currently collecting data on 3 subjects and anticipate reaching our target enrollment by end of March with a data analysis on the larger set to be presented at CMSC, if accepted.

Keywords:
Equipment in MS and Management of activities of daily living in MS

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FINAL STEPS

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Conclude Submission

Mixed-methods Approach to Foot-Drop Device Selection in Multiple Sclerosis: An Exploratory Study

Jennifer Nicole Bartloff[1], Katherine Heidi Fehr[1], Yisen Wang[1], Katherine Konieczka[1], Julia Mastej[1], Evan T. Cohen[2], Peter G. Adamczyk[1]
[1]University of Wisconsin-Madison, [2]Arcadia University, Glenside, Pennsylvania

Background

How do Foot Drop Devices Affect Fatiguability and Minimum Foot Clearance?

The Problem:
Common issues impacting gait in MS are foot drop, fatiguability, and elevated physiological cost of transport (COT)

Objective:
To understand how distinct types of foot drop intervention impact whole foot clearance, fatiguability, and cost of transport

Bioness L300 Go
Functional Electrical Stimulation (FES) device

Thuasne SpryStep
Carbon Fiber Ankle Foot Orthosis (AFO)

Hypotheses:
1. Minimum Foot Clearance (mFC) would increase, some with AFO and more with FES
2. COT and fatiguability would decrease with AFO but not with FES
3. Participant preference would correlate with these changes

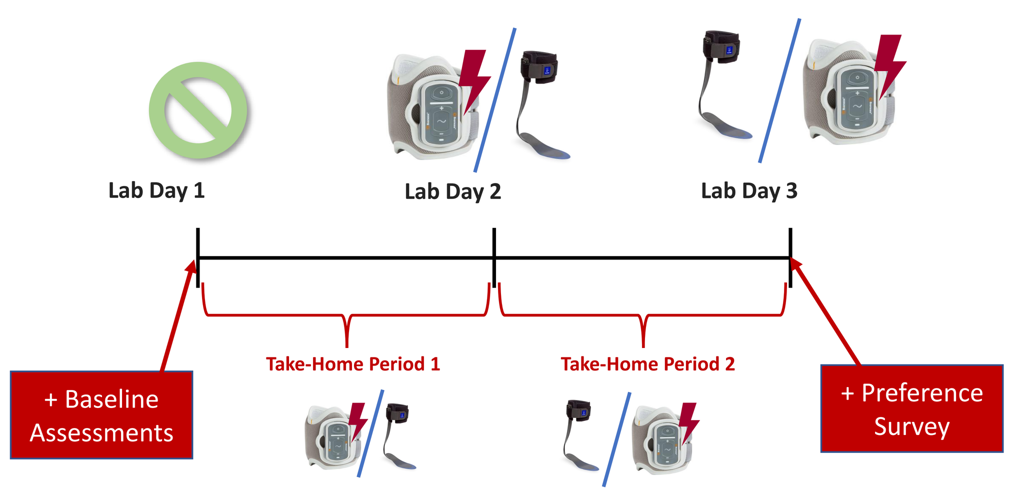
Participant Characteristics

7 participants (ave. age 45.57 yrs, 5 female)
Inclusion criteria:
- Diagnosis of MS with uni- or bi-lateral foot drop
- Report average walking time per day of at least 45 minutes-with or without a unilateral walking assistive device
- No recent experience with foot-drop interventions similar to those used in our study

Baseline Assessments (median, range):
- Self-EDSS[1] (4, 2-6)
- MFIS[2] (26.5, 7-59)
- MSWS[3] (41, 28-60)

Method: Study Design

Crossover Design:



3 visits >=10 days apart

At each lab visit:
- 6-minute walk test (6MWT)
- 3D scans of feet

Method: Fatiguability

Fatiguability was quantified by the **Distance Walked Index (DWI)**
- % change in distance walked in the last vs. first minute of the 6MWT[4]

Method: Minimum Foot Clearance

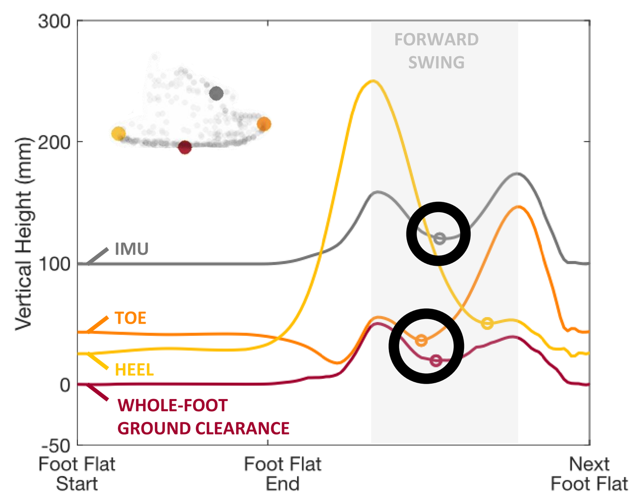
Minimum Foot Clearance (mFC)
- Measured in centimeters
- Lowest height of the foot during forward swing

Minimum Foot Clearance Index
- % change in mFC average in the last vs. first minute of the 6MWT

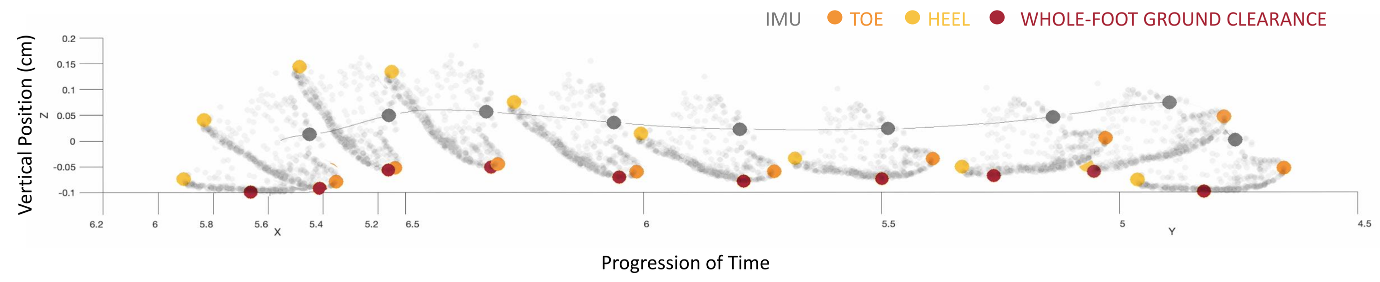
Novel method of pairing 3D scans of foot/shoe with IMU trajectory data *(use QR code for greater detail)*

APDM Opal IMU's

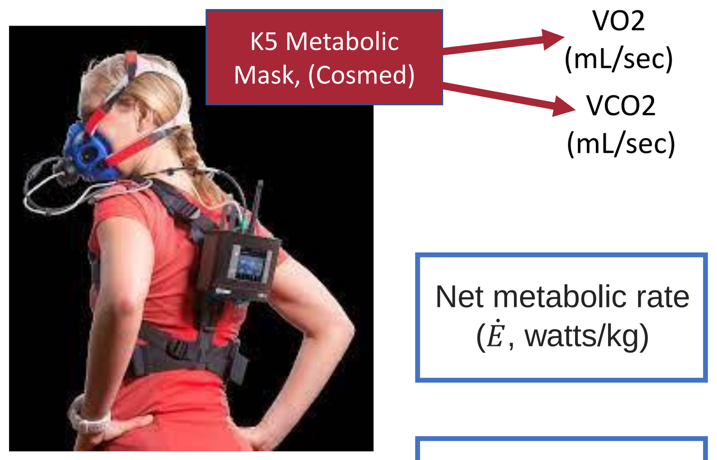
Vertical Position of Key Points
(Representative stride)



Time-Based Representation of Key Points During Stride



Method: Cost of Transport



Metabolic rate (watts/kg) = 16.48VO2 + 4.48VCO2

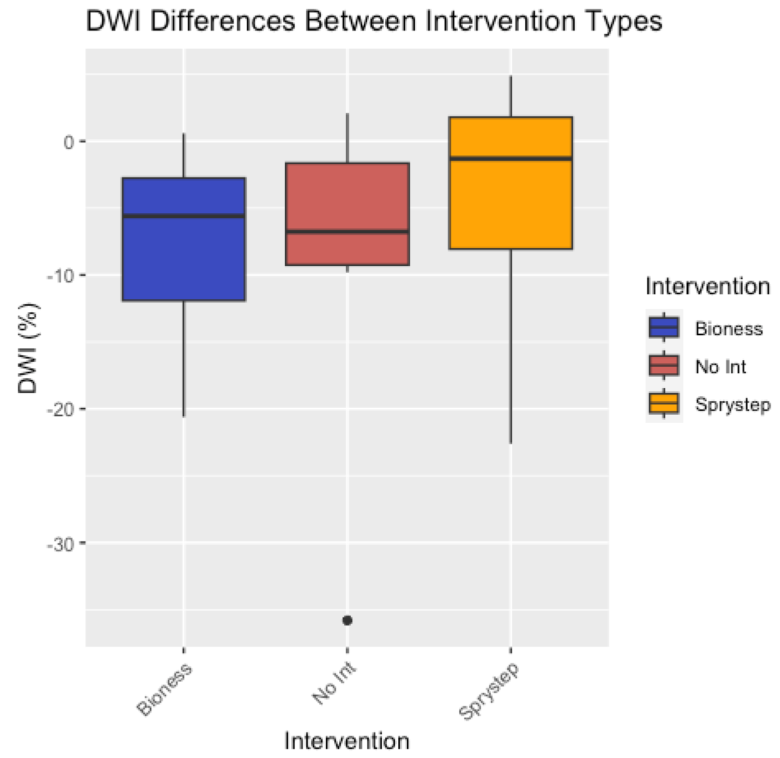
Net metabolic rate ($\dot{E}$, watts/kg) = Mean metabolic rate over the last 3 minutes of the 6MWT - Mean metabolic rate from 3 minute standing baseline test

Cost of Transport (COT, /kg/m) = $\dot{E}$ / 6MWT speed

Results and Discussion: Fatiguability

How did different foot drop interventions impact fatiguability?

DWI Differences Between Intervention Types



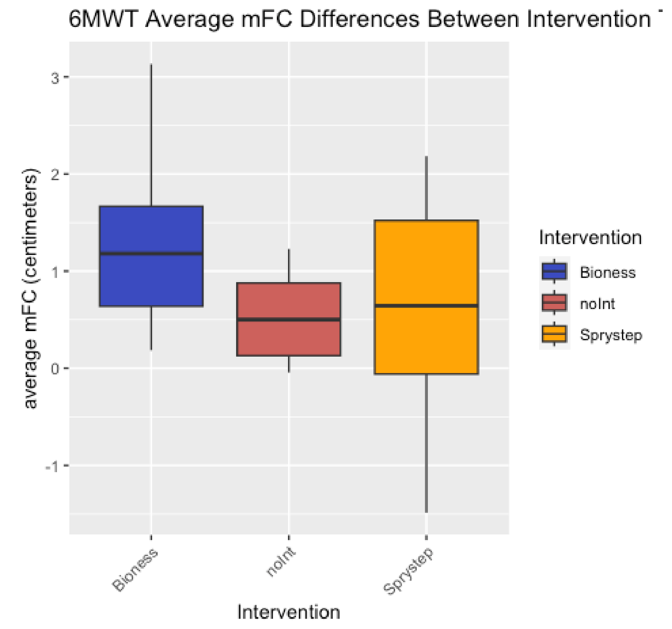
- Two-way ANOVAs revealed no significant effects of intervention or subject on DWI (p = 0.57, p = 0.12, respectively)
- Lack of effect with high variability

Discussion:
- At relatively low Self-EDSS scores, fatiguability may not be captured in 6MWT. This appeared to be the case for some participants, where DWI was positive

Results and Discussion: Comparing Orthoses – Ground Clearance

Which orthosis caused the greatest increase in minimum foot clearance?

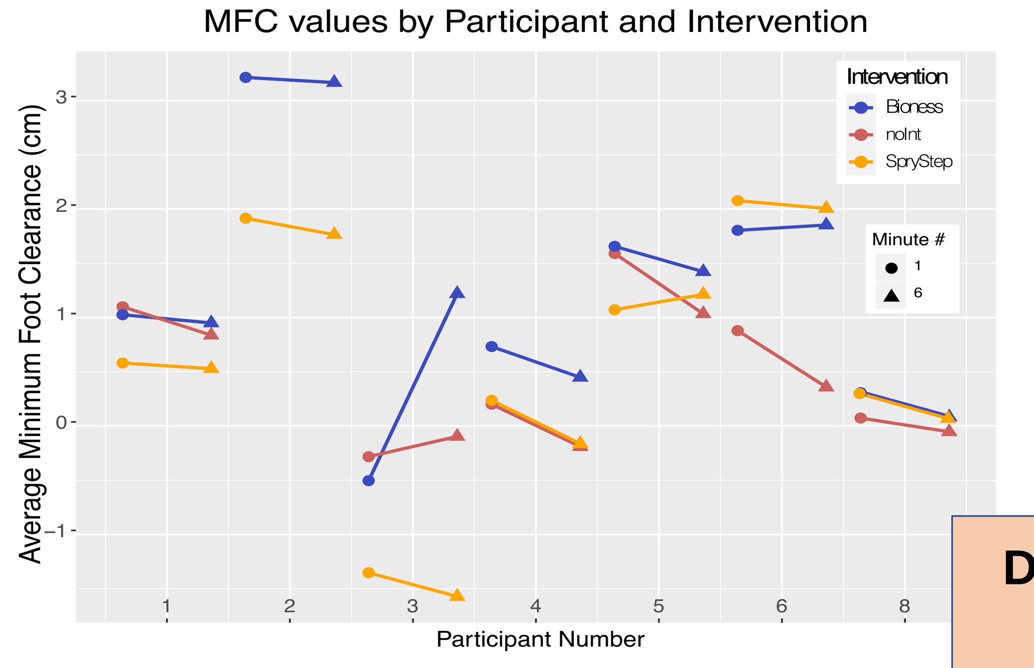
6MWT Average mFC Differences Between Intervention



Two-way ANOVA: marginally significant effect of intervention on average mFC (p = 0.05008), and significant effect of subject (p = 0.00238) on average mFC

What is the trend in minimum foot clearance from the first to last minute?

MFC values by Participant and Intervention



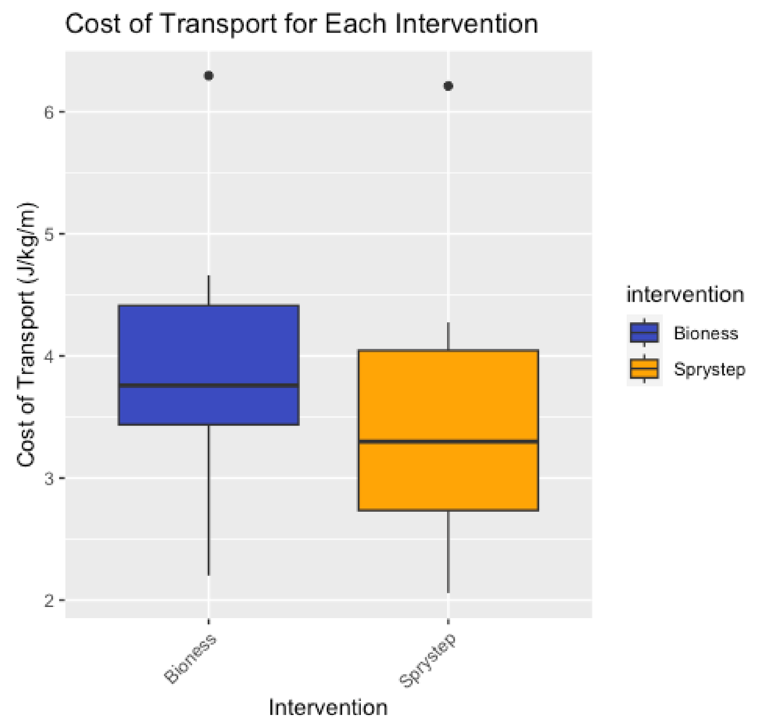
Two-way ANOVAs revealed: for mFC Index, there was a significant effect of intervention (p = 0.0372), but no effect of subject

Discussion
- Negative clearance suggests contact of the shoe with the ground during swing phase
- mFC Index may reveal effects of fatigue

Results and Discussion: Cost of Transport

How did different foot drop interventions Impact Cost of Transport?

Cost of Transport for Each Intervention



Paired t-test revealed no significant difference in COT between interventions (0.2843)

Summary Statistics (mean, std. dev., range):
Bioness: (3.97, 1.4, 2.2-6.3)
No Int: (3.82, 2.04, 1.43-7.46)
SpryStep (3.79, 1.4, 2.06-6.21)

Discussion
- Bioness utilizes metabolic energy through muscle contraction
- Sprystep adds energy to push-off phase of gait

Results and Discussion: Device Preference

Summary of device performance and subject preference

Subject	Most Favorable DWI	Lowest COT	Highest mFC	Most Favorable mFC Index	Preference
1	SpryStep	SpryStep	Bioness	SpryStep	Bioness
2	SpryStep	SpryStep	Bioness	Bioness	SpryStep
3	SpryStep	Bioness	Bioness	Bioness	SpryStep
4	Bioness	SpryStep	Bioness	Bioness	Bioness
5	Bioness	SpryStep	Bioness	SpryStep	SpryStep
6	Bioness	Bioness	SpryStep	Bioness	SpryStep
8	SpryStep	SpryStep	Bioness	Bioness	Bioness

Summary

- SpryStep more favorable for COT than Bioness
- Bioness more favorable for DWI and mFC than SpryStep
- Minimizing COT and improving DWI and mFC may not be the only contributors to user preference.
- User preference may not match objective COT, fatigability, nor minimum foot clearance

Future Work
- More participants!
- Real-world gait kinematics from take-home trials
- Quantification of ground reaction forces and kinematics in fatigued and non-fatigued states

UW BADGER Lab
Biomechatronics, Assistive Devices, Gait Engineering & Rehabilitation

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Acknowledgments:
This work was supported by DOD grant W81XWH-19-2-0024
We express gratitude to Brad Hendershot. Julian Acasio, and Ashley Knight for their formative input throughout this project

PAIRING IMU TRAJECTORY WITH 3D FOOT SCANS FOR COMPARISON OF WHOLE-FOOT MINIMUM CLEARANCE AMONG FOOT DROP INTERVENTIONS IN MULTIPLE SCLEROSIS

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INTRODUCTION

Persons with Multiple Sclerosis (PwMS) commonly exhibit footdrop (FD) (weak control of ankle dorsiflexors) and fatigability (rapid performance degradation) during gait. The fatigued state can worsen FD, compounding the risk of falls. This combination suggests two potential outcome metrics of gait dysfunction and intervention effectiveness: minimum foot clearance (mFC) (minimum height between the ground and any part of the foot during swing phase) and fatigability (change in speed during an extended walk). The purpose of this study was to compare mFC and fatigability during gait at baseline to gait with two devices that address FD: ankle foot orthoses (AFO) and functional electrical stimulation (FES). Our methods enabled a more comprehensive view of mFC by pairing inertial measurement unit (IMU) data with 3D scans to determine the lowest point on the shoe, rather than assuming the toe.

METHODS

Foot-mounted IMU's paired with 3D scans of participants' feet were utilized to reconstruct gait for analysis of mFC of participants with FD caused by MS (age 33-63 years; current n=7; target enrollment=10). We securely placed one Opal (APDM) IMU sensor in a small pouch on each participant's walking shoes. We 3D-scanned participants' feet/shoes with a Structure Sensor (Occipital Inc.) connected to an iPad (Apple) using the companion Occipital "Scanner" app. To properly locate the position and orientation of the IMU we placed a 3D printed fixture inside the pouch during the scan.

Participants were instructed to walk "as far and as fast" as they could for the 6 minute walk test (6MWT) in a hallway with no intervention for FD (NoInt). They were then given an AFO (Sprystep Carbon Fiber) and FES (Bioness L300) for 2 consecutive 10-day take-home habituation periods, each followed by additional testing including 6MWT with these devices. Fatigability was quantified by the Distance Walked Index (DWI), the percent change in distance walked in the 6th vs. 1st minute of the 6MWT. MFC Index was calculated as the percent change in the average MFC for the 6th minute vs 1st minute. At the study's end, participants indicated their device preference: none, AFO, or FES. Descriptive statistics were used to report the findings.

RESULTS AND DISCUSSION

The mean DWI percent was -4.5% (range +4.9 to -22.6%), -7.4 (range 0.6 to -17.3), and -9.5 (range +2.1 to -35.8), for AFO, FES, and NoInt respectively. Average mFC (cm) was 0.6 (range -1.5 – 2.2), 1.3 (range 0.2 - 3.1) and 0.5 (range 0 – 1.2) for AFO,

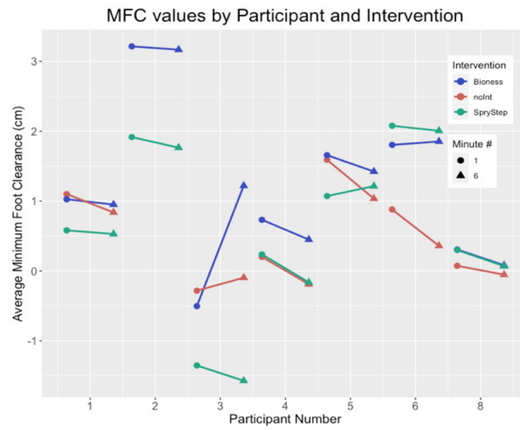

Figure 1: Trend in minimum foot clearance averages from first to last minute of 6MWT. Negative clearance suggests contact of the shoe with the ground during swing phase which is consistent in the case of subject 3, who described her gait as a "shuffle".

FES, and NoInt, respectively. 3 of 7 participants preferred the device with the smallest within-participant DWI. All participants preferred a device to NoInt. Two-way ANOVAs revealed: No significant effects of intervention or subject on DWI. For MFC, there was a significant effect of subject ($p = 0.00238$) and a marginally significant effect of intervention ($p = 0.05008$). For MFC Index, there was a significant effect of intervention ($p = 0.0372$), but no significant effect of subject.

Three participants preferred the device with the lower 6MWT average mFC. FES appears to have a better impact on DWI compared to AFO. Average mFC was greater in both intervention conditions vs. NoInt. Preference did not correlate with any of the outcome metrics, suggesting that improving DWI and mFC may not be the only contributors to user preference.

Results from this study may inform clinical selection of FD devices resulting in the safest gait. Further data analysis from this study will involve real-world gait kinematics from take-home trials of FD devices, correlation with cost of transport during 6MWT trials, and quantification of ground reaction forces in fatigued and non-fatigued states using force plates. Our group is continuing to refine our model and analysis of MFC.

ACKNOWLEDGEMENTS

Funding provided by DOD W81XWH-19-2-0024.

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Mixed-methods Approach to Foot-Drop Device Selection in Multiple Sclerosis: An Exploratory Study

Authors: Jennifer N. Bartloff, K. Heidi Fehr, Yisen Wang, Katherine Konieczka, Julia Mastej, Evan T. Cohen, Peter Adamczyk

Purpose Persons with Multiple Sclerosis (PwMS) commonly exhibit foot-drop (FD) (weak control of ankle dorsiflexors) and fatigability (rapid performance degradation) in gait. The fatigued state can worsen FD, compounding the risk of falls. The combination suggests 3 potential outcome metrics of gait dysfunction and intervention effectiveness: minimum foot clearance (mFC) (minimum foot height during swing phase); fatigability (change in speed during an extended walk), and cost of transport (COT, metabolic energy required to move a unit distance). The purpose of this study was to compare mFC, fatigability, and COT during gait at baseline to gait with two devices that address FD: ankle foot orthoses (AFO) and functional electrical stimulation (FES). We hypothesized that mFC would increase, COT and fatigability would decrease, some with AFO and more with FES. We also hypothesized that preference would correlate with these changes.

Subjects A sample of persons with FD caused by MS (age 33-63 years; current n=4; target enrollment =10).

Methods
Subjects first underwent testing with no intervention device (NoInt). They were then given an AFO (Sprystep Carbon Fiber) and FES (Bioness L300 Go) for 2 consecutive 10-day take-home habituation periods before returning for testing. At each visit, subjects performed a 6-minute walk test (6MWT) while wearing 3 inertial measurement units (IMU). mFC was estimated from IMU data combined with a 3D foot scan. Metabolic rate was estimated from oxygen consumption. Net metabolic rate ($\dot{E}$, W/kg) was the difference between a 3-minute baseline test and the mean rate over the last 3 minutes of the 6MWT. COT was the quotient of $\dot{E}$ divided by 6MWT speed (m/s). Fatigability was quantified by the Distance Walked Index (DWI), the percent change in distance walked in the 6th vs. 1st minute. At the study's end, subjects indicated their device preference: none, AFO, or FES. Descriptive statistics were used to describe the findings.

Results
The mean DWI percent was -11.71 (range +2.52 to -24.88), -6.14 (range 0 to -12.43) for AFO and FES, respectively. Mean COT values (J/kg/m) were 4.12 (range 3.28-5.95) and 4.47 (range 2.97-9.16) for AFO and FES, respectively. mFC (cm) was 0.91 (range 0.77-1.03), 1.31 (range 0.84-1.81), and 1.46 (range 0.77-2.11) for NoInt, AFO, and FES, respectively.
3 of 4 subjects preferred the device with the highest within-subject COT. A different sample of 3 of 4 subjects preferred the device with the largest within-subject DWI. 2 subjects preferred the device with the lowest 6MWT average mFC.

Conclusions: FES appears to have a better impact on DWI compared to AFO. Minimizing COT and improving DWI and mFC do not appear to drive user preference.

The data from this study will be used to determine necessary sample size for future experiments of biomechanical and metabolic impacts of FD interventions.
Clinical Relevance User preference may not match objective measures of energy usage or fatigability, nor average minimum foot clearance. Results from this study will inform clinical selection of FD devices resulting in the safest and most energy-efficient gait.

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