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CONTRACTING ORGANIZATION: University of Wisconsin System

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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					
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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	5
4. Impact	9
5. Changes/Problems	11
6. Products	13
7. Participants & Other Collaborating Organizations	16
8. Special Reporting Requirements	19
9. Appendices	20

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	IRB approved for UW. HRPO approved for UW. IRB/HRPO apps approved at WRNMMC
Major Task 2: Specify and acquire custom sensors	1-15	Sensors working. Continuous revision of packaging.
Major Task 3: Improve BD2SD and gait analysis from wearable data.	12-30	New methods developed/implemented for estimating detailed ground clearance (assessing trip risk) and joint angles at the knee.
Major Task 4: Test 10 Subjects using four prostheses.	12-30	First subject completed. Recruitment challenges.
Major Task 4b: Test 10 subjects using two orthotic solutions for foot-drop.	12-30	Four subjects completed. Recruitment challenges.
Major Task 5: Test 15 prosthesis users with daily-use, running-specific, and activity-specific prostheses.	15-36	First subject completed. Recruitment challenges.

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%
<i>Milestone #1: HRPO approval received</i>	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
<i>Test with subjects at UW and revisit customization and specifications until all needs are met.</i>	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	80%	N/A
Subtask 2: Improve methods for identifying repeated paths (straight lines, turns, ramps, stairs).	12-27	20%	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	80%	N/A
<i>Milestone #2: Manuscripts</i> <ul style="list-style-type: none"> • <i>Metrics from wearable data during out-of-lab movement</i> • <i>Improved BD2SD methods</i> 	12-30	0%	0%

Comments:

Major development results on the data analysis methods, with case-study results. Methods include estimating whole-foot ground clearance, and for improving joint angle reconstruction at the knee and ankle.

Specific Aim 2: Tests of prosthesis features: ESR, ESR-LP, PHA, MPA			
Major Task 4: Test 10 Subjects using four prostheses	Months		
Subtask 1: Measure “real-world” movement with different prostheses. <ul style="list-style-type: none"> 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	10%	N/A
Subtask 1: Analyze movement from wearable data. <ul style="list-style-type: none"> 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	5%	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. <ul style="list-style-type: none"> 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	35% (4 subjects enrolled/ 3.5 good)	N/A
Subtask 2: Analyze movement from wearable data. <ul style="list-style-type: none"> 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	20%	N/A
<i>Milestone #3: Manuscripts on comparison of devices in everyday straight walking using field-based data.</i> <ul style="list-style-type: none"> <i>Comparison of prostheses (ESR, ESR-LP, PHA, MPA).</i> <i>Comparison of AFO vs. FES for drop foot.</i> 	24-30	0%	0%
Comments: Manuscripts on the methods are one of our high priorities.			

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	13.3%
Subtask 2: Subject Testing <ul style="list-style-type: none"> • Test 3 prostheses <ul style="list-style-type: none"> • Daily-use, running-specific, activity-specific • Four-week field-based trial with wearable data logging • Laboratory post-test 	15-33	N/A	13.3%
Subtask 3: Analyze data from wearable sensors <ul style="list-style-type: none"> • Gait kinematics and kinetics • Analysts blinded to conditions 	18-33	3%	N/A
Subtask 3: Analyze data from laboratory tests <ul style="list-style-type: none"> • Gait kinematics and kinetics 	18-33	0%	0%
Subtask 5: Comparative analysis of lab and field-based results	30-36	0%	0%
<i>Milestone #5: Co-author manuscripts on full study outcomes</i> <ul style="list-style-type: none"> • <i>Comparison of ESR vs. ESR-LP vs. PHA vs. MPA prostheses in “real life.”</i> • <i>Evaluation of acclimation rate during field trial.</i> • <i>Comparison of wearable vs. laboratory assessments</i> 	27-36	0%	0%

Comments:

Task 6:

Subtask 1: Recruitment continues to be difficult. The second subject dropped out and others have proven hard to find.

Subtask 2: Analysis of data is ongoing. It contributed to MHSRS and NACOB abstracts.

Detailed Comments:

1. Objective: Develop Improved Analysis methods.

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

- i. Result: We developed several new methods to achieve instant-by-instant estimates of both (a) what the clearance of the lowest point on the shoe is, relative to flat ground, and (b) where on the foot that point is. This information can be used to understand how a person’s propensity to trip is affected by different interventions, such as prosthetic feet or foot-drop orthoses. We presented results and methods at Dynamic Walking (June, 2022) and at North American Congress on Biomechanics (NACOB; August 2022 but using material developed during the reporting period).

To perform the foot tracking, an inertial sensor is mounted on the shoelaces inside a pouch, and worn for several days per condition. We harvest data from walking bouts during these long-term recordings, for each of the conditions. Movement of the IMU is rebuilt using pedestrian dead-reckoning techniques. We developed a new component of this technique that models and corrects reconstruction errors due to the “thump” in the vertical direction at every footfall, assuming flat ground during a given walking bout. This step enables much more precise estimates of vertical position of the foot. The reconstruction also includes IMU orientation (roll, pitch, yaw).

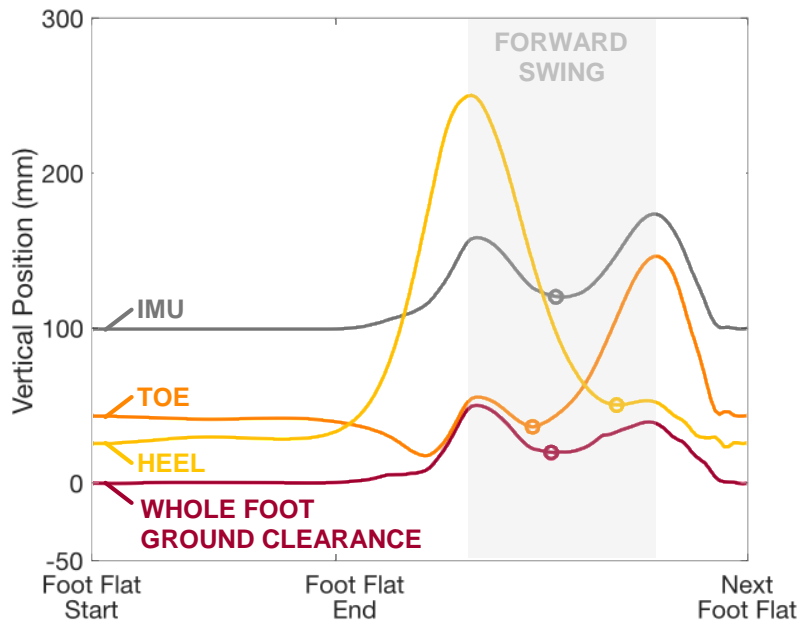
To estimate true foot clearance, we measure the spatial relationship between the IMU and the outer shape of the foot and shoe. We use a 3D scanner to scan the assembled foot and shoe with the IMU in the pouch. We insert a narrow “calibration jig” with the IMU in its pouch, which creates easily-identifiable landmarks in the 3D scan that can be located in geometric modeling software and used to localize the center of the IMU coordinate frame. Then, we transform the point cloud of the foot/shoe surface into the IMU’s coordinate frame, and compute the movements of the points on the surface in the real world by following the IMU’s movements. Finally, at each time point of the swing phase (when the foot/shoe shape is unaltered by ground contact) we compute which point on the foot is the lowest one (closest to the ground) and how high it is (whole-foot ground clearance).

The images below are taken from the presentation delivered by K. Heidi Fehr at NACOB 2022 using data from a participant with foot-drop in the UW-Madison study:

3D scan with registration of the IMU coordinate frame. The scanner (Occipital Structure scanner) is shown, with the IMU pouch and calibration jig allowing coordinate registration. Coordinate registration is shown in the center, and the resulting foot point cloud at right. The inset at shows the reconstructed full foot movement:

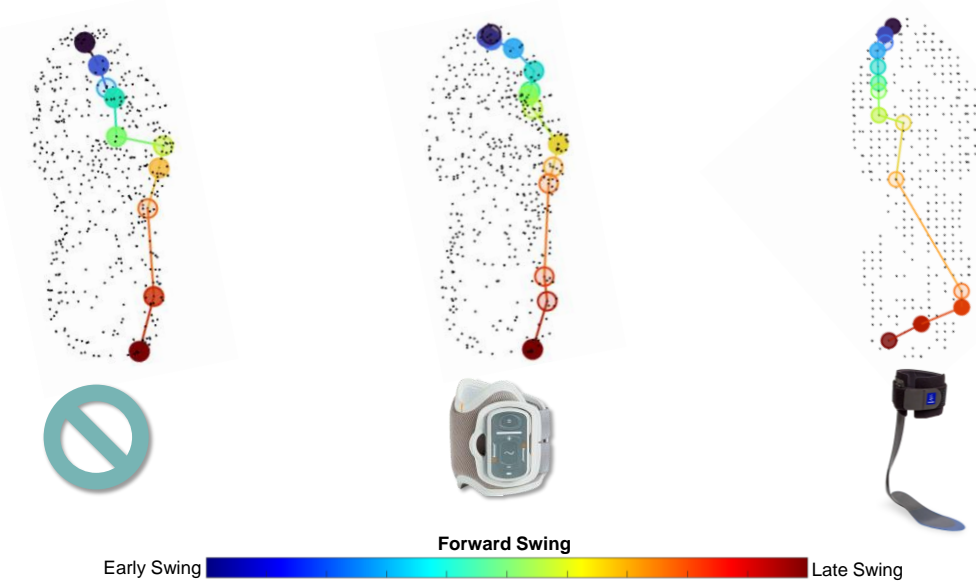


Graph of clearance estimates derived from points at the IMU, Heel, and Toe, and finally the new Whole Foot Ground Clearance.



Location of the lowest point on the shoe, from early swing (dark blue) to late swing (dark red). Three interventions for foot drop are compared: (Left) No intervention; (Center) Bioness L300 Go nerve stimulator; (Right) Thuasne SpryStep elastic carbon fiber ankle-foot orthosis.

Top View



c. *Goal: improve reconstruction of joint angles during free movement.*

- i. Foot movement is great, but another important effect of different prostheses is that they may change movement kinematics, including both the ankle (directly affected) and the knee (one joint proximal). Therefore, we look for ways to reconstruct the movement of the ankle and knee from wearable movement sensors. One of the sensors (thigh IMU) has to be placed by the participant each day. Therefore, it can move around substantially and a precalibrated coordinate registration that asserts a knee axis relative to the IMU cannot reliably quantify knee movements across days.

We have overcome this difficulty by implementing procedures for automatically determining the knee axis during the walking movement itself and using that axis to estimate knee joint movements. The specific procedures used are taken from literature, but the implementation is specific to this context of real-world use in prosthetics. The key idea is to identify the axis of knee rotation (and separately ankle rotation) as the one axis along which the angular velocity measurements of the thigh and shank are not the same. Once this is determined, the difference in angular velocity between those segments, projected along that axis, represents knee joint angular velocity; and that can be integrated over time to estimate knee angle fluctuations.

In this period, this analysis was applied to data from the first WRNMMC subject to identify different patterns of knee and ankle angle movement with the participant's daily use prosthesis and their running-specific prosthesis. The graphs below capture these differences, captured for the first time from those different prostheses and activities during free everyday living, as shown at the Dynamic Walking 2022 conference:

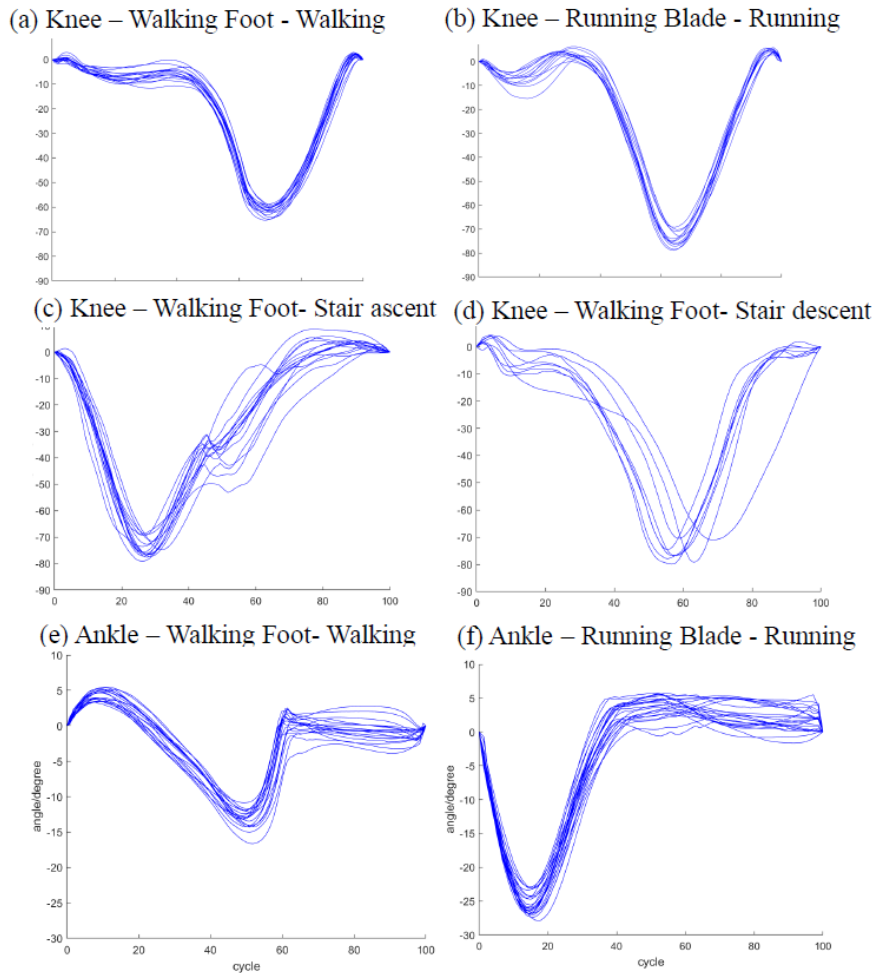


Fig 2. Joint movement reconstruction in different activities on the walking foot and the running blade, (a)(b)(d)(e)(f) plotted from heel strike to heel strike, (c) plotted from heel off to heel off

2. Objective: Mechanical tests of prostheses.

- a. Mechanical testing of prostheses is important for describing the systems used in human subjects testing. UW staff are adapting the procedures in the 2010 AOPA Report (which specifies these tests) to the mechanical testing equipment available.
 - i. Status: Prosthesis acquisition is all set up and we have the devices from our first subject under testing. The team has brought on additional undergraduate researchers (including one with amputation) to help do the testing and develop the ways of understanding the prosthesis properties.
We are working to do characterization that does not depend on a material test machine, but rather uses a human to load the prosthesis and a force plate and motion capture system to record the displacements and forces. The idea is that a human can control angle and loading direction much like a material test machine can, but more quickly and comprehensively. The goals include (a) measuring forefoot stiffness, hindfoot stiffness and angular stiffness, and some measure of damping/hysteresis in each component; and (b) developing a more comprehensive model that can predict the forces on the prosthesis from its pose (position and orientation) relative to the ground, and its recent pose history. This process remains under development.

Image: testing of a prosthesis in a shoe by a person without amputation using a bypass orthosis.



3. Objective: Prosthetics and orthotics tests at UW-Madison

- a. Goal: test 10 persons with amputation (4 different prostheses) and 10 persons with foot-drop (no intervention, AFO and FES device) in full multiple-week take-home testing.
 - i. Status: we have tested one individual with amputation and four individuals with foot-drop. Additional subjects with foot-drop are in the pipeline; recruitment for the prosthetics study remains challenging.

4. Objective: Tests of multiple customary prostheses at WRNMMC

- a. WRNMMC is specified to run tests in which the same sensors are attached to multiple prostheses used by specific individuals, to track which is used for different activities and measure characteristics of those movements in detail.
 - i. Status: WRNMMC has tested two subjects.

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:

Two graduate students – K. Heidi Fehr and Yisen Wang – 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, and made a trip early in this project year to kick off data collections with the team at WRNMMC

Another graduate student, Jennifer Bartloff, started the orthotics study and worked with the others to collect data from several subjects.

Two undergraduate students, Katherine Konieczka and Julia Mastej, have helped with data collections, taking and processing 3D scans, and working with motion capture data.

Professional Development:

All the graduate students participated in the Dynamic Walking 2022 conference. Ms. Fehr was accepted for a presentation at North American Congress on Biomechanics (NACOB) 2022, and Mr. Wang also had a poster accepted at NACOB. The team as a whole (Ms. Fehr as lead author) also had a poster accepted at MHSRS 2022. These are opportunities to show their progress and receive feedback from other experts.

K. Heidi Fehr’s poster presentation at WE21 (Society of Women Engineers) also won 2nd place in the poster competition, providing an excellent opportunity for networking and showcasing.

Note: PI Peter Adamczyk hosted Dynamic Walking 2022 in Madison, so a certain amount of extra effort from all the students went to running that conference. This opportunity was invaluable for their professional development, including experience in how to set up a conference website and schedule, plan scientific sessions, host activities, interact with scholars of various levels from around the world, and more.

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.

Updated progress on Analysis methods and initial data were put into the various conference Abstracts shown in Summer 2022 (see previous box, and attachments).

A manuscript was published on a new way of using wearable sensor measurements to measure and potentially control DMAMA (dynamic mean ankle moment arm) in semi-active prostheses. (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 4 we plan the following steps:

UW-Madison:

- Enroll more Orthosis users
- Enroll more Prosthesis
- Formalize protocols for Mechanical testing of prostheses and finalize the analytical methods and descriptions.
- Ongoing improvement of Big Data to Small Data analysis methods and movement reconstruction methods.
- Publish a journal paper on the Method and Case Study for the whole-foot ground clearance measurements, using data from the Orthotics study.
- Publish a journal paper on the Method and Case Study using the knee and ankle joint reconstruction on data from the Prosthetics study.
- 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:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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

If there is nothing significant to report during this reporting period, state “Nothing to Report.”

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

The methods for whole-foot ground clearance using 3D foot scans provide a totally new way of looking at this idea of clearance. This new perspective has application to any population that struggles with trip-related falls, and may be suitable for clinical application in the long term.

The techniques for analysis of knee and ankle angles from wearable sensors, and the initial results we have found, are already changing how people think about the benefits of real-world data.

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.

K. Heidi Fehr’s poster presentation at WE21 (Society of Women Engineers) won 2nd place in the poster competition, enhancing visibility of the work beyond the immediate audience.

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

The Orthotics study at UW Madison was the most successful in enrolling subjects. We made several changes to inclusion criteria, such as allowing persons who occasionally use a cane or whose locomotion time per day is less than we originally demanded. These have improved the yield of our recruitment efforts.

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.

COVID delays are finally unwinding. Recruitment is still a challenge at both sites.

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.

All spending on human subjects and prosthetic/orthotic hardware was delayed. This is picking up with study enrollment.

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

Human subjects testing/enrollment were delayed, but plans have not changed and risks/benefits have not changed. Minor changes to inclusion criteria were implemented with IRB approval.

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).*

Leestma JK, Fehr KH, Adamczyk PG. Adapting Semi-Active Prostheses to Real-World Movements: Sensing and Controlling the Dynamic Mean Ankle Moment Arm with a Variable-Stiffness Foot on Ramps and Stairs. *Sensors*. 2021 Sep;21(18):6009. *Acknowledgement of federal support: yes.*

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. *Dynamic Walking 2022*. June 13-16, 2022. Madison, WI, USA. Oral presentation and Poster.

Fehr KH, Kent JA, Leestma JK, Nakum J, Major MA, **Adamczyk PG** (2021). biomimetic approach to controlling semi-active prosthetic feet. *Society of Women Engineers WE21*, October 21-23, Indianapolis, IN, USA. ****2nd place in the Graduate Student Poster Competition.**

Fehr KH, Kent JA, Leestma JK, Nakum J, Major MA, **Adamczyk PG** (2021). biomimetic prosthetic ankle control law for a variable stiffness prosthetic foot using dynamic mean ankle moment arm. *Military Health Sciences Research Symposium 2021* August 23-26, Orlando, FL, USA. *Accepted for Poster Presentation but canceled due to COVID*

Fehr KH, Kent JA, Nakum J, Major MA, **Adamczyk PG** (2021). The effect of walking speed, slopes and stairs on dynamic mean ankle moment arm. *American Society of Biomechanics 2021*, Aug 12-15, Online meeting. Refereed Poster Presentation

Wang Y, Ojeda LV, **Adamczyk PG** (2021). Wearable Sensor Suite for Long-term Wearable Real-World Tracing. *American Society of Biomechanics 2021*, Aug 12-15, Online meeting. Refereed Poster Presentation

Liu J, **Adamczyk PG** (2021). Real-time gait prediction with two sensors for semi-active prosthesis control. *American Society of Biomechanics 2021*, Aug 12-15, Online meeting. Refereed Poster Presentation

- **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
Project Role: Graduate Student
Researcher Identifier (ORCID): none
Nearest person month worked: 3
Contribution to Project: Dr. Bartloff led recruitment and testing on the Orthotics study at UW-Madison. Dr. Bartloff is a Doctor of Physical Therapy with clinical expertise in neurorehabilitation, currently studying for a PhD, with Dr. Adamczyk as a secondary advisor.

Name: Katherine Konieczka
Project Role: Undergraduate Student
Researcher Identifier (ORCID): none
Nearest person month worked: 2
Contribution to Project: Ms. Konieczka worked to prepare and manage 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: 1
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.

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.

PI has acquired one other active grant, which has not affected the availability of time to dedicate to this project.

FW-HTF-P: Collaborative Research: Exoskeleton-Assisted Worker Performance Augmentation in Construction.

Capacity: Co-PI (PI: Zhenhua Zhu)

Sponsor: NSF (Future of Work at the Human-Technology Frontier-Planning)

Dates: 2021-2022

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.*

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) Journal paper preprint: Leestma et al, *Sensors* 2021.
- b) Abstract reprint: Fehr et al. *American Society of Biomechanics* 2021
- c) Abstract reprint: Wang et al. *American Society of Biomechanics* 2021
- d) Poster reprint: Fehr et al. *Society of Women Engineers* 2021
- e) Poster reprint: Fehr et al. *Dynamic Walking* 2022
- f) Poster reprint: Wang et al. *Dynamic Walking* 2022
- g) Abstract reprint: Fehr et al. *NACOB* 2022
- h) Abstract reprint: Wang et al. *NACOB* 2022
- i) Abstract reprint: Fehr et al. *MHSRS* 2022

Article

Adapting semi-active prostheses to real-world movements: sensing and controlling dynamic mean ankle moment arm with a variable-stiffness foot on ramps and stairs

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Abstract: (1) Background: Semi-active prosthetic feet can provide adaptation in different circumstances, enabling greater function with less weight and complexity than fully-powered prostheses. However, determining how to control semi-active devices is still a challenge. The Dynamic Mean Ankle Moment Arm (DMAMA) provides a suitable biomechanical metric, as its simplicity matches that of a semi-active device. However, it is unknown how stiffness and locomotion mode affect DMAMA, which is necessary to create closed-loop controllers for semi-active devices. In this work, we develop a method to use only a prosthesis-embedded load sensor to measure DMAMA and classify locomotion mode, with the goal of achieving mode-dependent closed-loop control of DMAMA using a variable-stiffness prosthesis. We study how stiffness and ground incline affect DMAMA, and we establish the feasibility of classifying locomotion mode based exclusively on the load sensor. (2) Methods: Human subjects walked on level ground, ramps, and stairs while wearing a variable-stiffness prosthesis in low, medium, and high stiffness settings. We computed DMAMA from sagittal load sensor data and prosthesis geometric measurements. We used linear mixed-effects models to determine subject-independent and subject-dependent sensitivity of DMAMA to incline and stiffness. We also used a machine learning model to classify locomotion mode using only the load sensor. (3) Results: We found a positive linear sensitivity of DMAMA to stiffness on ramps and level ground. Additionally, we found a positive linear sensitivity of DMAMA to ground slope in the low and medium stiffness conditions, and a negative interaction effect between slope and stiffness. Considerable variability suggests that applications of DMAMA as a control input should look at the running average over several strides. To examine the efficacy of real-time DMAMA based control systems, we used a machine learning model to classify locomotion mode using only the load sensor. The classifier achieved over 95% accuracy. (4) Conclusions: Based on these findings, DMAMA has potential for use as a closed-loop control input to adapt semi-active prostheses to different locomotion modes.

Keywords: prosthesis; locomotion mode; wearables; gait biomechanics; semi-active device; prosthetic control

1. Introduction

Current passive prosthetic feet are offered in a variety of stiffness categories that are determined based on the user's body weight. This prescription method results in

prominent stiffness variability within single categories, both across manufacturers and even within single manufacturers [1]–[4]. Since these passive feet have only a single stiffness profile, the foot cannot change properties across walking speeds or locomotion modes, such as walking up or down ramps and stairs [5]. However, previous work has shown that healthy individuals actively regulate foot and ankle biomechanical properties across both speed [6]–[8] and locomotion mode [6]–[13]. Thus, current prostheses may limit a user's locomotion due to their inability to reproduce this natural adaptation.

To optimize the walking performance of persons with amputation, prosthetic foot properties need to adapt. Active control through a powered prosthetic foot may provide this capability, but the added weight, height, power requirements, and cost of such devices present barriers to adoption [14]. An alternative is semi-active prostheses, which use minimal actuation to adjust device mechanical properties but do not power the user's movement. Researchers have utilized this concept to create variable stiffness prosthetic feet that can actively modulate their stiffness during the swing phase of walking [15]–[20]. These recent prosthetic developments have the potential to improve ambulation of persons with amputation by adapting stiffness to match locomotion speeds and modes, such as level ground, slopes or stairs.

However, determining how to control stiffness adaptation is a challenge. Changes could be controlled using open-loop mapping – e.g., predetermined stiffness for every speed and locomotion mode – or using closed-loop adaptation to achieve some biomechanical outcome. For the closed-loop case, an appropriate target measure is needed that can be measured in real-time using onboard sensors. Various biomechanical measures could fill this void, such as rollover shape [5], [21], ankle impedance [22]–[24], or human foot quasi-stiffness [9], [25]. However, these measures vary throughout stance phase, making them more appropriate for fully-powered prostheses; semi-active devices that can adjust only once per stride require a control target that summarizes ankle biomechanics across the whole stance phase in a single value.

The Dynamic Mean Ankle Moment Arm (DMAMA) measure [8] was developed to be such a summary metric. DMAMA computes the ratio of sagittal ankle moment impulse to ground reaction force impulse across the whole stance phase. This measure has units of length and its value represents the mean moment arm of the ground reaction impulse in front of the ankle. DMAMA quantifies the net dynamic effects of the ground reaction force on the ankle joint, resulting in a single measure that varies across behaviors such as walking vs. running and speed changes [8]. It is related biomechanically to the interaction of ankle angle and stiffness [8]. DMAMA is conceptually and computationally simple, and is therefore well-suited as a closed-loop target to control semi-active prosthesis stiffness for biomimetic adaptation to different behaviors. However, no methods have been established to enable the calculation of DMAMA using prosthesis-embedded sensors, which is necessary for closed-loop control.

Biomimetic closed-loop control of DMAMA using a semi-active prosthesis requires both the ability to vary DMAMA (e.g. through varying prosthetic stiffness or ankle angle) across locomotion modes (level ground, ramps, and stairs), and the ability to estimate locomotion mode in real time to permit such adaptation [8]. Previous work has established the validity of locomotion mode classification for transfemoral [26], [27] and transtibial [28], [29] prostheses. However, these applications frequently require several sensors, including load cell, inertial measurement unit, and/or electromyography data [26], [30]. To better the probability of clinical adoption, ideal solutions would require limited sensors and use sensors that can be embedded in the prosthesis. Because the DMAMA calculation inherently requires a load cell sensor, an ideal locomotion mode classifier would be based only on load signals, and would not require any additional sensors. However, it is unclear if locomotion mode of individuals with a transtibial amputation can be accurately detected using only a prosthesis-embedded load cell.

This study explores the potential for DMAMA to be used as a real-time control input for semi-active prosthetic devices. We aim to understand how DMAMA can be influenced

by changes in prosthesis forefoot stiffness and by locomotion mode, specifically level ground, ramps and stairs. We further investigate whether it is feasible to use a universal control law to exploit these relationships for control, or whether subject-dependent control laws are necessary, by evaluating subject-dependent and subject-independent trends across stiffness and locomotion mode. Additionally, we explore what it would take to employ such a measure in a real-time, “outside of the lab” environment. We demonstrate a method to monitor both DMAMA and locomotion mode outside of the lab using only a prosthesis-embedded load cell sensor.

In this work, we first investigate if stiffness or locomotion mode has a significant effect on DMAMA. We then evaluate how well overall trends can explain intra-subject DMAMA fluctuations. Our first hypothesis is that there will be a positive linear sensitivity of DMAMA to forefoot stiffness across all locomotion modes (i.e., a stiffer forefoot will cause DMAMA to be farther in front of the ankle). Our second hypothesis is that there will be a positive linear sensitivity of DMAMA to ground incline across all stiffnesses (i.e., slope increasing from downhill to uphill will cause DMAMA to be farther in front of the ankle). Finally, we use linear discriminant analysis (LDA) to test the classification accuracy of locomotion mode using only prosthesis geometric measurements and the inputs from a 6-axis pylon-embedded load cell. Throughout this work, we discuss how DMAMA is affected by changes in stiffness and locomotion mode and evaluate the potential of this measure to be used in real-time control of semi-active prosthetic devices.

2. Materials and Methods

2.1. Participants

Four adult participants with transtibial amputation (a subset of a larger study) participated in this focused test of the prosthesis-embedded technology. These participants (4 male; weight 90 ± 15 kg; height 1.815 ± 0.15 m) wore a novel prosthetic foot and a suite of prosthesis-embedded and wearable sensors that recorded the signals necessary for field-based analysis of prosthetic limb mechanics. Each participant used a prosthesis for daily ambulation and walked without the help of an ambulatory aid. Prior to beginning the study, each participant signed a written consent form approved by the University of Wisconsin-Madison Health Sciences Institutional Review Board.

2.2. Experimental Protocol

For this study, prosthetic forefoot stiffness variation was supplied by the Variable Stiffness Foot (VSF), a custom built prosthesis previously published by Glanzer & Adamczyk [17]. The participants did not wear a foot shell or shoe on the prosthetic foot and wore their chosen athletic shoe on their unaffected foot. The height of the VSF was adjusted by a prosthetist to ensure proper bilateral alignment in the absence of a prosthetic-side shoe. Use of the VSF ensured that prosthesis alignment was consistent across trials and that stiffness profiles were consistent across participants. This prosthetic foot uses a small motor to adjust the free length of a cantilever forefoot spring, thereby altering forefoot stiffness. The study evaluated three different prosthetic forefoot stiffnesses that were scaled to participants’ body weight and comfort levels. We set the low stiffness value to the minimum stiffness permitted by each participant’s body mass, ensuring that the prosthetic keel deflection did not reach its physical limit. We set the high stiffness value to the VSF’s maximum possible stiffness of 32 N/mm, determined through mechanical testing (Model 120-P-1000, TestResources, Shakopee, MN, USA). The medium stiffness value was set at the mean of the low and high stiffnesses.

We instructed participants to walk through a circuit in a campus building that required five locomotion modes: level ground, ramp ascent ($+5^\circ$ incline) and descent (-5° incline), and stair ascent and descent (178 mm step height, 311 mm anteroposterior tread depth, 40 mm step overhang, two sequential flights of 12 and 13 stairs, up and then down). All participants walked this circuit once using each of three stiffness conditions. The participants walked the course at their preferred walking speed, as the goal of the study

was to see how participants would ambulate with various prosthesis stiffnesses in a real-world environment. The circuit resulted in 50 ± 14 level ground, 11 ± 3 up ramp, 11 ± 3 down ramp, 11 ± 1 up stairs, and 11 ± 1 down stairs strides per trial that were used for analysis. Transition steps between locomotion modes were excluded from this analysis. This experimental setup can be viewed in Figure 1.

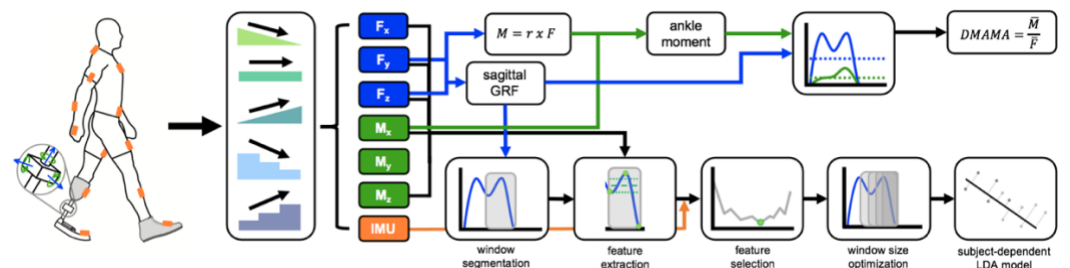


Figure 1. Collection and calculation using wearable sensors. Participants wore an IMU suit (orange) and a 6-axis load cell, which read forces (blue) and moments (green). Participants were then asked to walk across level ground, ramps, and stairs. The IMU suit and force data collected were used both to calculate DMAMA and to act as inputs to the machine learning model.

2.3. Portable Data Collection Methods

The calculation of DMAMA requires the sagittal ground reaction force (GRF) and ankle moment. In a gait laboratory, these measures are typically found from force plate and motion capture data [8]. However, this equipment is not portable, inhibiting applications in environments outside of a lab. Instead, we calculated DMAMA on the side of amputation using a six-axis load cell (iPecs, RTC Electronics, Dexter, MI, USA) embedded in the prosthetic pylon immediately below the participant's daily-use prosthetic socket. The load cell collected at a frequency of 149.9 ± 38.5 Hz (mean \pm S.D.); this variability was accounted for by using measured sample time in all calculations. The validity of the load cell for lower limb prosthetics research was previously established [31], [32]. The VSF prosthesis [17] was installed beneath the load cell. We then had a certified prosthetist perform a standard prosthetic alignment with the VSF in a medium stiffness condition.

We fit the participants with a full-body suite of inertial measurement units (IMUs); (MVN Awinda; Xsens B.V., Enschede, The Netherlands) that was used to discern changes in locomotion mode during the trials. We calibrated a kinematic skeleton model reconstructed from IMU data (XSens MVN Analyze software) using the participant's anthropometric measurements along with standing and walking calibration trials.

We used the load cell measurements as an approximation for ground reaction force and moments in the sagittal plane. Prior to beginning the study, we measured the orientation and location of the load cell relative to user's prosthetic pylon and body segments using motion capture (12-camera OptiTrack Prime13 system; NaturalPoint Inc., Corvallis, OR, USA) in the laboratory. Functional movement calibration trials were used to calibrate the model in Visual3D, allowing the determination of the biological joint centers. We determined functional joint centers for the knee and hip from the motion capture trials using the Gillette algorithm (Visual3D software; C-Motion Inc., Germantown, MD, USA). The ankle joint center for the prosthetic side was chosen as a fixed physical location on the prosthesis comparable to the biological limb, as there is no fixed prosthetic ankle rotational axis. It should be noted that this method of defining the prosthetic ankle joint axis reduces across subject variability but may result in an offset error relative to a biological DMAMA measure. The joint centers' positions relative to the center of the load cell were determined using the average across the function movement trial. This step was taken to orient the load cell forces in the pylon/shank reference frame prior to all calculations. We recorded the locations of the knee and ankle joints relative to the load cell for use in joint moment calculations.

2.4. Calculating DMAMA from Prosthesis-Embedded Load Cell Data

We measured the force and moment about the load cell origin directly from the load cell embedded in the prosthetic pylon. To correct the load cell's orientation and placement relative to the participant's shank, we found the rotation matrix ($\bar{\mathbf{R}}_{LC}^{Shank}$) that transforms the load cell's (LC) coordinate system into a shank-based coordinate system using motion capture data. We determined the orientation and position of the load cell based on the 3D coordinates of the three markers placed on it. We found the final rotation matrix for each participant by calculating the load-cell-to-shank-frame rotation matrices for 300 samples. The rotation matrices were converted to rotation vectors using the Rodrigues' rotation formula. The 300 vectors were averaged element-wise and converted into a single definitive rotation matrix. Prior to DMAMA and moment calculations, we multiplied the force and moment data reported by the load cell by the calculated rotation matrix ($\bar{\mathbf{R}}_{LC}^{Shank}$). We also determined the vectors from the knee and VSF ankle joint to the load cell center in a similar manner, calculating them for 300 samples and finding the average.

We determined joint moments about the ankle and knee, $\bar{\mathbf{M}}_{ankle}$ and $\bar{\mathbf{M}}_{knee}$, using quasi-static vector mechanics according to:

$$\bar{\mathbf{M}} = \bar{\mathbf{r}}_{LC} \times \bar{\mathbf{F}}_{sagittal} + \bar{\mathbf{M}}_{sagittal} \quad (1)$$

where $\bar{\mathbf{r}}_{LC}$ is the vector from the joint center to the center of the load cell, $\bar{\mathbf{F}}_{sagittal}$ is the load cell force vector in the sagittal plane, and $\bar{\mathbf{M}}_{sagittal}$ is the load cell moment in the sagittal plane. This equation neglects inertial terms due to low stance-phase segment accelerations. This equation was used to calculate both the ankle and knee joint sagittal plane moments using the appropriate vector $\bar{\mathbf{r}}_{LC}$ from each joint to the load cell. We then calculated the DMAMA value as the ratio of sagittal ankle moment impulse (extensor positive) to the magnitude of the sagittal ground reaction force impulse for each individual stance phase, according to:

$$DMAMA = \frac{J}{I} = \frac{\int_{HS}^{TO} \bar{\mathbf{M}}_{ankle} dt}{\left\| \int_{HS}^{TO} \bar{\mathbf{F}}_{sagittal} dt \right\|} = \frac{\bar{\mathbf{M}}_{ankle}}{\bar{\mathbf{F}}_{sagittal}} \quad (2)$$

where J is the magnitude of ankle moment impulse, I is the magnitude of the GRF impulse, $\bar{\mathbf{M}}_{ankle}$ is the ankle moment in the sagittal plane, $\bar{\mathbf{F}}_{sagittal}$ is the load cell force vector in the sagittal plane, $\bar{\mathbf{M}}_{ankle}$ is the mean ankle moment in the sagittal plane, and $\bar{\mathbf{F}}_{sagittal}$ is the magnitude of the mean load cell force vector in the sagittal plane. We normalized DMAMA to a percentage of VSF foot length. We performed these calculations with a custom MATLAB script (MATLAB 2019a; The Mathworks, Inc.; Natick, MA, USA). This processing pipeline can be viewed in Figure 1.

2.5. Machine Learning Model – Determining locomotion mode from load cell data

We investigated the use of a machine learning model to determine how well data from the pylon load cell alone could discriminate among different locomotion modes, with the goal of using locomotion mode in an eventual control algorithm. For the model, we used nine sensor inputs ($\bar{\mathbf{F}}_x$, $\bar{\mathbf{F}}_y$, $\bar{\mathbf{F}}_z$, $\bar{\mathbf{M}}_x$, $\bar{\mathbf{M}}_y$, $\bar{\mathbf{M}}_z$, $\bar{\mathbf{M}}_{ankle}$, $\bar{\mathbf{M}}_{knee}$, $\bar{\mathbf{F}}_{sagittal}$). Prior to building the model, all inputs were resampled to 100 Hz to compensate for the non-uniform data collection frequency of the load cell. We performed feature extraction once per gait cycle from a data window preceding toe-off, with toe-off detected by sagittal force falling below 8% body weight. We ended the window at toe-off because it is easily detectable using a prosthesis load cell and includes information from the stance phase prior to making a decision on how to control stiffness in swing phase. For each sensor input, we extracted a feature set consisting of mean, standard deviation, minimum value, maximum value, starting value, and ending value within the data window [26], [33], [34]. We separated feature sets by stiffness settings of the VSF (Low, Medium, High), as

stiffness would be known in the case of real-time control. We used linear discriminant analysis (LDA) to create subject- and stiffness-dependent models. We used 10-fold validation to accommodate the small data set. For the model, we performed forward feature selection using a 30 ms window of data prior to toe-off. The chosen feature set included the features that resulted in the minimum classification error during the forward feature selection process. Next, we optimized the window size of the reduced-feature model, testing 100-500 ms windows in 33 ms increments. The model was then finalized using the feature set determined from forward feature selection and window size optimization processes. This process can be viewed in Figure 1.

2.6. Statistics

Subject-independent data provide an understanding of how DMAMA is influenced by stiffness and locomotion mode across all subjects. In order to further evaluate the efficacy of DMAMA as a control strategy, we analyzed how well subject-independent trends explain intra-subject variations in DMAMA. A strong correlation between subject-independent trends and intra-subject data would suggest that a subject-independent control strategy may be feasible; however, a poor correlation may suggest that a subject-dependent controller is the needed approach.

We evaluated the effects of both stiffness and ground incline on DMAMA. We first evaluated subject-independent relationships using a linear mixed-effects model where either the stiffness or the ground incline was the fixed effect and the different participants were random effects. We separated the data by locomotion mode and ran a linear regression on the mean DMAMA values across participants and stiffness settings, allowing subject-dependent intercepts to account for the random effect. We determined the subject-independent sensitivity of DMAMA to each variable (slope of best-fit line), the statistical significance of sensitivity (p-value of being different from zero), and the amount of variance explained by the model (R^2).

Next, we evaluated subject-dependent relationships between stiffness and DMAMA and between ground incline and DMAMA. We ran a linear regression on each individual participant's data and determined the subject-dependent sensitivity of DMAMA to each variable (slope of best-fit line), the statistical significance of sensitivity (p-value of being different from zero), and reported the amount of variance explained by the model (R^2). We also evaluated the correlation strength of the subject-independent best-fit line on each participant's stride-by-stride data to determine how well the overall (subject-independent) best-fit line explained the variance in individual participants' data. To represent this, we calculated the R^2 value using:

$$R^2 = 1 - \frac{RSS}{TSS} = 1 - \frac{\sum(DMAMA_{adjusted} - DMAMA_{predicted})^2}{\sum(DMAMA_{adjusted} - DMAMA_{average})^2} \quad (3)$$

where RSS is the residual sum of squares, TSS is the total sum of squares, $DMAMA_{adjusted}$ is the DMAMA value calculated for each step and adjusted for the random effect, $DMAMA_{predicted}$ is the DMAMA value predicted by the linear mixed-effect model, and $DMAMA_{average}$ is the average adjusted DMAMA value for the individual participant.

Across all analyses, we set $\alpha=0.05$ to determine statistical significance. Statistical analyses were performed using Origin (Origin 2020. OriginLab Corporation, Northampton, MA, USA) and MATLAB (MATLAB 2019a; The Mathworks, Inc.; Natick, MA, USA).

3. Results

3.1 Sensitivity of DMAMA to Stiffness Across Ground Incline and Stairs

We first evaluated the subject-independent sensitivity of DMAMA to stiffness in each of the locomotion modes: down ramp (DR), level ground (LG), up ramp (UR), down stairs (DS) and up stairs (US); (Figure 2). There was a significant positive sensitivity of DMAMA to stiffness ($p < 0.05$) in the DR, LG, and UR conditions (sensitivity range: 2.299–3.749 percent foot length per stiffness increment), but not in the DS ($p = 0.124$) or US ($p = 0.522$) conditions (Table 1).

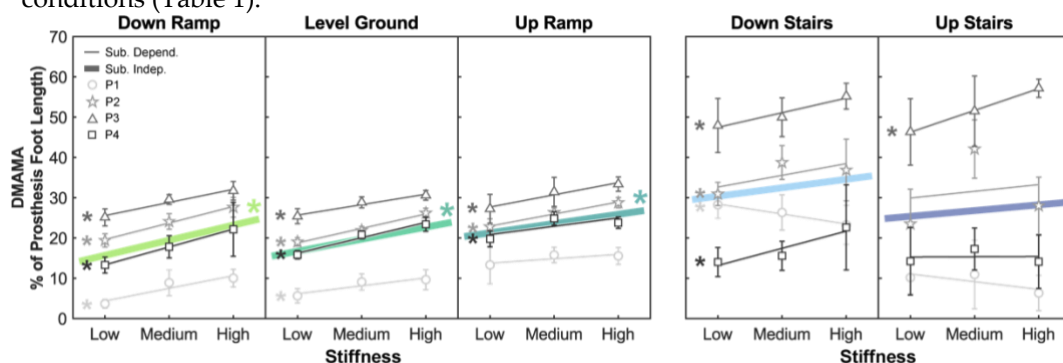


Figure 2. Linear trends showing the effect of prosthesis forefoot stiffness on DMAMA. Colored lines show the subject-independent data fit as a result of the linear mixed model. Grey markers and vertical bars show each participant's average and standard deviation values, respectively. Grey lines show subject-dependent linear fits. The asterisk (*) indicates a linear trend with a significant p-value ($p < 0.05$).

Table 1. Linear mixed-effects model to explain variations of DMAMA with stiffness as the fixed effect and participants as the random effect. (Top) The linear fit for the effect of stiffness on DMAMA was generated for each locomotion mode separately. The sensitivity (percent foot length per stiffness increment), p-value, and R^2 value are shown for each linear regression. (Bottom) Goodness-of-fit when using the subject-independent sensitivity of DMAMA to stiffness to explain individuals' data; R^2 values indicate how well subject-independent trends explained intra-subject variability.

Subject-independent regression slopes (versus stiffness) and descriptive statistics for DMAMA by locomotion mode.														
DOWN RAMP			LEVEL GROUND			UP RAMP			DOWN STAIRS			UP STAIRS		
Sensitivity to Stiffness	p-value	R^2	Sensitivity to Stiffness	p-value	R^2	Sensitivity to Stiffness	p-value	R^2	Sensitivity to Stiffness	p-value	R^2	Sensitivity to Stiffness	p-value	R^2
3.749	<0.001	0.993	2.993	<0.001	0.990	2.299	0.002	0.970	2.102	0.124	0.959	1.423	0.522	0.929
Correlation strength of subject-independent model to individual data.														
Participant	R^2	R^2	R^2	R^2	R^2									
1	0.512	0.248	-0.018	-0.479	-0.136									
2	0.734	0.849	0.705	0.138	0.014									
3	0.635	0.644	0.377	0.226	0.137									
4	0.428	0.790	0.355	0.166	-0.027									

We then evaluated the subject-dependent sensitivity of DMAMA to stiffness in each of the locomotion modes (Figure 2). There was a positive sensitivity ($p < 0.05$) in all four participants in the DR condition (sensitivity range: 3.132–4.422 percent foot length per stiffness increment), all four participants in the LG condition (1.963–3.824 percent foot length per stiffness increment), three of four participants in the UR condition (2.070–3.032 percent foot length per stiffness increment), three of four participants in the DS condition (2.906–4.263 percent foot length per stiffness increment), and one of four participants in the US condition (sensitivity: 5.405 percent foot length per stiffness increment); (Table 2). There was a negative sensitivity ($p < 0.05$) of DMAMA to stiffness for one participant in the DS condition (-2.479 percent foot length per stiffness increment).

Table 2. Subject-dependent linear regression coefficients for the effect of forefoot stiffness on DMAMA in each locomotion mode, using individual participant data. The linear fit for the effect of stiffness on DMAMA is shown for each participant. The sensitivity (percent foot length per stiffness increment), p-value, and R^2 value are shown for each linear regression.

Subject-dependent regression slopes (versus stiffness) and descriptive statistics for DMAMA by locomotion mode.															
Participant	DOWN RAMP			LEVEL GROUND			UP RAMP			DOWN STAIRS			UP STAIRS		
	Sensitivity to Stiffness	p-value	R ²	Sensitivity to Stiffness	p-value	R ²	Sensitivity to Stiffness	p-value	R ²	Sensitivity to Stiffness	p-value	R ²	Sensitivity to Stiffness	p-value	R ²
1	3.132	<0.001	0.533	1.963	<0.001	0.344	1.092	0.085	0.078	-2.479	0.009	0.197	-1.915	0.147	0.067
2	4.093	<0.001	0.740	3.587	<0.001	0.873	2.994	<0.001	0.745	2.906	0.022	0.149	1.668	0.504	0.016
3	3.258	<0.001	0.650	2.596	<0.001	0.659	3.032	<0.001	0.400	3.627	0.001	0.274	5.405	<0.001	0.299
4	4.422	<0.001	0.438	3.824	<0.001	0.829	2.070	<0.001	0.361	4.263	0.005	0.224	0.064	0.967	<0.001

3.2 Sensitivity of DMAMA to Ground Incline Across Stiffnesses

Next, we evaluated the subject-independent sensitivity of DMAMA to ground incline across forefoot stiffness (Figure 3). Across all participants, there was a positive sensitivity ($p < 0.05$) of DMAMA to ground incline in the low (sensitivity: 0.540 percent foot length per degree incline) and medium (0.450 percent foot length per degree incline) stiffness conditions, but not in the high-stiffness condition (Table 3).

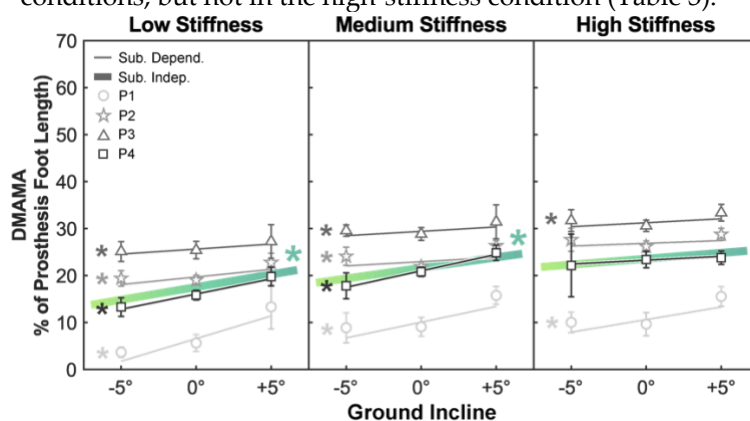


Figure 3. Linear trends showing the effect of ground incline on DMAMA. Colored lines show the subject-independent data fit as a result of the linear mixed model. Grey markers and vertical bars show each participant's average and standard deviation values, respectively. Grey lines show subject-dependent linear fits. The asterisk (*) indicates a linear trend with a significant p-value ($p < 0.05$).

Table 3. Linear mixed-effects model to explain variations of DMAMA with ground incline as the fixed effect and participants as the random effect. (Top) The linear fit for the effect of ground incline on DMAMA was generated for each stiffness setting separately. The sensitivity (percent foot length per degree incline), p-value, and R² value are shown for each linear regression. (Bottom) Goodness-of-fit when using the subject-independent sensitivity of DMAMA to ground incline to explain individuals' data; R² values indicate how well subject-independent trends explained intra-subject variability.

Subject-independent regression slopes (versus mode) and descriptive statistics for DMAMA by VSF stiffness.								
LOW			MEDIUM			HIGH		
Sensitivity to Incline	p-value	R ²	Sensitivity to Incline	p-value	R ²	Sensitivity to Incline	p-value	R ²
0.540	0.005	0.958	0.450	0.016	0.954	0.250	0.063	0.975

Correlation strength of subject-independent model to individual data.				
Participant	R ²		R ²	
	LOW	MEDIUM	LOW	MEDIUM
1	0.343	0.153	0.026	
2	-0.006	-0.380	-0.155	
3	-0.103	-0.133	-0.078	
4	0.602	0.554	0.015	

We then evaluated the subject-dependent sensitivity of DMAMA to ground incline across forefoot stiffness (Figure 3). There was a positive sensitivity ($p < 0.05$) in all four participants in the low stiffness condition (sensitivity range: 0.214–0.965 percent foot

length per degree incline), all four participants in the medium stiffness condition (0.181-0.699 percent foot length per degree incline), and two of four participants in the high stiffness condition (0.169-0.535 percent foot length per degree incline); (Table 4).

Table 4. Subject-dependent linear regression coefficients for the effect of ground incline on DMAMA in each stiffness setting, using individual participant data. The linear fit for the effect of ground incline on DMAMA is shown for each participant. The sensitivity (percent foot length per degree incline), p-value, and R² value are shown for each linear regression.

Subject-dependent regression slopes (versus stiffness) and descriptive statistics for DMAMA by locomotion mode.									
Participant	LOW			MEDIUM			HIGH		
	Sensitivity to Incline	p-value	R ²	Sensitivity to Incline	p-value	R ²	Sensitivity to Incline	p-value	R ²
1	0.965	<0.001	0.505	0.670	<0.001	0.328	0.535	<0.001	0.224
2	0.322	<0.001	0.246	0.181	0.036	0.065	0.117	0.107	0.037
3	0.214	0.035	0.066	0.187	0.029	0.068	0.169	0.023	0.071
4	0.646	<0.001	0.630	0.699	<0.001	0.641	0.165	0.258	0.024

3.3 Multivariate Regression of DMAMA to Stiffness and Incline

Considering only the ground incline conditions, the sensitivity of DMAMA to stiffness was greatest in the DR condition (sensitivity: 3.749 percent foot length per stiffness increment), moderate in the LG condition (2.993 percent foot length per stiffness increment) and least in the UR condition (2.299 percent foot length per stiffness increment). Similarly, the sensitivity of DMAMA to ground incline was greatest in the low stiffness condition (0.540 percent foot length per degree incline), moderate in the medium stiffness condition (0.450 percent foot length per degree incline), and least in the high stiffness condition (0.250 percent foot length per degree incline). We formalized this interaction by fitting a multiple linear regression with incline, stiffness, and incline-times-stiffness interaction terms to the DMAMA data for the three ground incline conditions and three stiffnesses (Figure 4). This multivariate regression revealed positive coefficients for sensitivity to stiffness (coefficient: 3.01, CI: ± 0.744 percent foot length per unit stiffness) and incline (coefficient: 0.413, CI: ± 0.149 percent foot length per degree incline) and a negative sensitivity to their interaction (coefficient: -0.145, CI: ± 0.182).

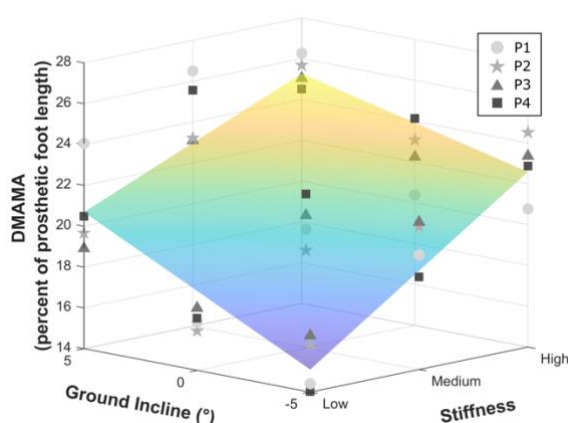


Figure 4. Multivariate regression on the combined effects of stiffness and ground incline on DMAMA.

3.4 Accuracy of Gait Mode Classification from Prosthesis-Embedded Load Cell

We then evaluated the accuracy of the subject-dependent LDA classifier. After the initial input of 54 features extracted from a 300 ms window, forward feature selection led to the elimination of 32 features, leading to a model that used 22 features. We then optimized the window size, leading to the selection of a 300 ms window. This final subject-

and stiffness-dependent LDA model accurately classified 90.9% of down ramp steps, 98.2% of level ground steps, 87.6% of up ramp steps, 96.8% of down stairs steps, and 96.6% of up ramp steps (Figure 5). This led to an overall model accuracy of 95.72%. It should be noted that this model used imbalanced classes for training and testing, with the majority class being level ground.

True Class	DR	90.9%	5.5%	0.9%	1.8%	1.0%	90.9%	9.1%
	LG	0.4%	98.2%	1.2%	0.0%	0.2%	98.2%	1.8%
	UR	0.0%	12.4%	87.6%	0.0%	0.0%	87.6%	12.4%
	DS	2.7%	0.5%	0.0%	96.8%	0.0%	96.8%	3.2%
	US	3.3%	0.0%	0.1%	0.0%	96.6%	96.6%	3.4%
		DR	LG	UR	DS	US		
Predicted Class								

Figure 5. Confusion matrix results from a linear discriminant analysis locomotion mode classifier. The true class is shown on the left axis, indicating the correct locomotion mode. The predicted class is shown on the bottom axis, indicating the locomotion mode predicted by our classifier. The table to the right of the confusion matrix shows the percentages of strides that were correctly (left) and incorrectly (right) classified by our model.

3.5 Calculation of Joint Moments Using a Prosthesis-Embedded Load Cell

Because DMAMA is a summary measure computed from traditional joint mechanics data, these joint mechanics are also available within the analysis. We provide these data as an illustrative supplement in the Appendix, including graphs of both knee and ankle moment for a representative participant as time series plots (Figure A1), peak ankle moment (Figure A2), peak knee moment (Figure A3), and walking speed (Figure A4).

4. Discussion

4.1 Methods for “Outside of the Lab” DMAMA Calculation from a Load Cell Sensor

Biomimetic closed-loop control of semi-active prostheses demands a biomechanical control target that can be measured and manipulated in environments “outside of the lab”. DMAMA is a suitable metric to drive semi-active control due to simplicity and can be measured in real-world scenarios. In this work, we established a method to calculate DMAMA from only a pylon-embedded load cell sensor and prosthesis geometric measurements, eliminating the need for force plates and motion capture systems. Prior work established that wearable technology (specifically, pressure-measuring insoles measuring intact limbs) could evaluate trends in DMAMA with similar sensitivity to laboratory-based measurements. The present work extends this to approximate the ideal case of a direct force and moment measurement fully embedded in the device that uses the data. Both these cases relied on approximations of the location of the ankle joint relative to the sensor, introducing potential offset errors in DMAMA. In contrast, future implementation of a load cell directly embedded in an ankle-foot prosthesis would result in specified, rather than measured, geometric relationships between the load cell and the ankle, and would therefore eliminate the approximation steps required in this work and reduce variability and uncertainty in the measurements.

4.2 Relationship Between DMAMA and Stiffness

The results suggest a significant positive sensitivity of DMAMA to forefoot stiffness in down ramp, level ground, and up ramp conditions, but no clear effect on stairs due to high variability. Additionally, the linear fit showed a strong correlation between stiffness and DMAMA in the down ramp, level ground, and up ramp conditions. Within the ramp conditions, the significant sensitivity of DMAMA to stiffness varied across ground incline, with DMAMA being less sensitive to stiffness as incline increased. This leads us to partially accept our first hypothesis (increase of DMAMA with stiffness): DMAMA does increase with forefoot stiffness in walking-like conditions, but perhaps not on stairs. The high variability of DMAMA on stairs may reflect qualitatively different stair-ambulation strategies across individuals, which have made it difficult to study this behavior in other real-world studies as well [13].

We next looked to understand how well subject-independent sensitivity trends could explain individual participants' DMAMA values. In down ramp, level ground, and up ramp conditions, the subject-independent sensitivity provided a moderate to strong fit for individual participant data, while it provided a weak fit in the down stairs and up stairs conditions. No locomotion mode showed that a generalized sensitivity provided a strong fit for all participants. Even during the ramp and level ground conditions, where all individual participants had a significant positive sensitivity, participants had differing levels of sensitivity. Thus, we conclude that increasing forefoot stiffness can increase DMAMA in all participants, but the quantitative sensitivity is subject-dependent.

4.3 Relationship Between DMAMA and Ground Incline

The results also suggest a significant positive sensitivity of DMAMA to ground incline in the low and medium stiffness settings, but not in the high stiffness setting. Additionally, the linear fit showed a strong correlation between ground incline and DMAMA in the low stiffness condition and moderate correlations in the medium and high stiffness conditions. As expected, because of similar interaction trends seen in the stiffness analysis, the sensitivity to incline decreases as stiffness increases. This leads us to partially accept our second hypothesis: DMAMA does increase with ground incline, but with reducing sensitivity at higher stiffness settings.

We again looked to understand how well subject-independent sensitivity of DMAMA to ground incline could explain individual participants' DMAMA values. All participants exhibited a positive sensitivity of DMAMA to ground incline. The goodness-of-fit of the subject-independent sensitivity to individual participants was highly variable across participants and ground inclines. Across all stiffness conditions, the subject-independent sensitivity provided some explanations of trends seen in participants 1 and 4, though the goodness-of-fit was highly variable. However, the subject-independent sensitivity provided a poor explanation of trends seen in participants 2 and 3. Therefore, as above we conclude that increasing ground incline can increase DMAMA in all participants, but the quantitative sensitivity is subject-dependent.

4.4 Interaction Between Stiffness and Ground Incline

Some of the effects above could be explained by the interaction of our two independent variables, stiffness and ground incline. Our multiple regression revealed a negative best-fit coefficient for the interaction between stiffness and ground incline, though the coefficient did not reach the threshold for statistical significance. Nevertheless, an interaction with negative sign could explain the trends observed above: that sensitivity of DMAMA to either independent variable is reduced at higher values of the other. This interaction can be thought of as a kind of saturation, as opposed to compounding (interaction with positive sign). This effect makes sense mechanistically: both a stiffer forefoot and an uphill slope move the center of pressure toward the toe and lead to earlier heel lift-off and toe-only support, such that a high value of either leaves little room for additional forward movement due to the other. It is possible that avoiding such situations

is itself a valuable goal in prosthetic ankle control; if so, a controller that reduced stiffness on uphill slopes and increased stiffness on downhill slopes would serve to keep DMAMA lower in support of this goal.

4.5 Interpretation of DMAMA Changes with Stiffness and Ground Incline

The positive sensitivity of DMAMA to stiffness could be explained if participants maintain similar leg kinematics regardless of forefoot stiffness. If leg kinematics remain constant, stiffening of the forefoot will cause a more rapid forward shift of the COP during foot roll-over, therefore increasing the DMAMA value. The observed variation in DMAMA with stiffness suggests that persons with amputation may not change their kinematics to maintain the same DMAMA value when stiffness changes. This demonstrates that DMAMA can be varied in persons with amputation by manipulating stiffness. Direct evaluation of how well kinematics are retained is a component of the broader study from which these pilot data were collected and will be explored in future work.

4.6 Feasibility of DMAMA to Drive a Closed-Loop Biomimetic Controller

The moderate stride-by-stride fluctuations in DMAMA (standard deviation bars in Figures 2-3) imply that a controller should not adjust the prosthesis' stiffness in response to rapid changes in DMAMA measurements, as both the DMAMA value and the predicted effect of a stiffness change have too much residual variability. However, the generalized sensitivity to stiffness and incline was effective in explaining trends in participants' mean DMAMA values, meaning that participants' average behavior was well-characterized by the sensitivity. Thus, a control system could make meaningful adjustments by evaluating a moving average DMAMA value over several steps, rather than by just evaluating the previous step, when making a stiffness change. This slower-adapting control strategy would drive the controller with a data point more representative of steady-state behavior rather than individual step behavior. It would also be more stable and robust in the face of isolated fluctuations, and therefore would likely be preferable to subjects who demand predictability from their prostheses. It could be overridden or reset in cases where a qualitative behavioral change would benefit from a rapid open-loop adjustment, such as switching to stairs, turning around on a slope, or running.

4.7 Subject-Independent vs. Subject-Dependent DMAMA Targets

The limited ability of subject-independent trends to fit individual participants' data inhibits but does not necessarily preclude the ability to use a subject-independent control architecture using DMAMA. Subject-independent trends with stiffness and incline were correct in sign for all four participants, suggesting that a generalized controller would satisfy them all qualitatively, even if slightly mismatched from their preferred changes. On the other hand, both the offset in DMAMA (intercept of the linear fit, or the subject's mean value) and the behavior in up-stairs vs. down-stairs conditions were highly subject-dependent. Thus, some level of subject-dependent tunability in a DMAMA-based controller would likely be beneficial – for example, adjusting the range and sensitivity of the target DMAMA setting to variations in slope.

4.8 Locomotion Mode Classification

To determine if real-time detection of locomotion mode was possible with limited instrumentation, we evaluated the ability of an LDA classification algorithm to detect locomotion mode based only on measures from a pylon-embedded load cell and shank segment geometric measurements. Our results show that an LDA model was able to accurately classify locomotion mode for 95.72% of steps. The LDA model feature selection process revealed which sensors and signal features were the most useful in determining locomotion mode. This selection process eliminated all features that were derived from

the sagittal force, but kept features derived from the remaining 8 sensor inputs. The selection process kept all feature types (such as mean or starting value), indicating that all feature types provided some value in determining locomotion mode. The model's selection of 2 features that were derived from sensor input that required some calculation before passing into the model ($\vec{M}_{ankle}, \vec{M}_{knee}$) reveal that subject-dependent prosthesis geometric measurements and biomechanically meaningful preprocessing contribute to accurate locomotion classification.

The LDA model disproportionately misclassified up ramp (UR) trials in comparison to other classes, where up ramp misclassifications were primarily classified as level ground (LG) steps. We expect that this error is primarily attributed to the class imbalance in the data set, where we collected 50 ± 14 level ground and 11 ± 3 up ramp steps per participant. This class imbalance also explains why a comparable percentage of level ground steps are not misclassified as up ramp steps. Previous work has shown that the feature space between level ground and up ramp steps is similar, which may provide an explanation for the increased difficulty discerning these steps using our model [27], [35]. Other studies of lower limb prostheses have demonstrated the feasibility of combining level ground and up ramp classes, both for locomotion mode classification and defining impedance parameters for a prosthesis [36], [37]. Our finding of reduced sensitivity of DMAMA to stiffness agrees with this idea, as misclassifying up ramp steps as level ground steps would cause relatively little error in adjusting the prosthesis' stiffness. This suggests that future applications of this model could combine level ground and up ramp classes, eliminating the concern for this misclassification.

This analysis was intended to investigate the feasibility of locomotion mode classification from a single sensor (i.e. pylon-embedded load cell) using a simple machine learning model. However, we believe that more advanced machine learning algorithms may be able to improve subject-dependent model accuracy or provide subject-independent classifiers [33]. Our results support the feasibility of using only a load cell sensor to classify locomotion mode in individuals with transtibial amputation, permitting the use of such a classifier in a closed-loop device controller that adjusts based on mode.

4.9 Addressing Hypotheses

The results of this study supported both key hypotheses: that there would be 1) positive linear sensitivity of DMAMA to forefoot stiffness across all locomotion modes and 2) positive linear sensitivity of DMAMA to ground incline across all stiffnesses. These results suggest that both stiffness and locomotion mode influence DMAMA, and therefore both variables need to be considered when targeting DMAMA changes. Stiffness can be considered in real time using the known stiffness value from the foot's existing control system. Additionally, locomotion mode can be determined using only a pylon-embedded load cell and prosthesis geometric measurements as inputs into a machine learning model. These results suggest that DMAMA could feasibly be used as a control parameter for a variable stiffness foot, and potentially for other semi-active prosthetic devices.

4.10 Future Directions

The core practical application of these findings is to use variations in stiffness to enable some level of adjustment of a prosthesis to the user's behavior and the terrain. The sensitivity of DMAMA to stiffness was modest in this experiment, suggesting that this effect might be limited in its application. However, current prostheses allow no adaptability at all; if emerging technology can offer any benefit, it will be an improvement on the current experience of prosthesis users. Furthermore, the VSF was originally conceived to also adjust parameters like energy storage and return from the prosthesis and stability in qualitatively different behaviors like standing vs. walking [17]; if continuous adjustments across locomotion mode or incline is another addition on top of these substantial benefits, it will be worth including in the device's final controller.

One additional use case for a controlled VSF could be a DMAMA-matching controller that seeks to match this metric on the prosthetic side to values measured in real-time from the intact limb. Such measurements could be made using force-sensitive insoles [8], or even body-mounted wearables such as the recent developed technology of tendon tensiometry [13]. Alternatively, pre-mapped rules to determine DMAMA targets on different terrain could be used. The same control targets could also be used for powered prostheses, and in that case could rely on sensors internal to the prosthesis to determine the DMAMA estimate and directly control the ankle moment. Furthermore, the ability to estimate DMAMA from other sensors (not just pylon-embedded load cells) could enable extensions of DMAMA-based control to exoskeleton applications, to improve compatibility of these systems with normal gait on different terrain.

4.11 Limitations

This study used a subset of data from a larger study to explore this concept of DMAMA as a possible real-time control variable. The study is limited by the small number of participants who used all the sensors required to compute DMAMA and track and label the different terrains. The small sample limits our ability to make conclusive claims about the biomechanical results of DMAMA. A study in a larger sample, perhaps also including tests that implement the controllers suggested by this analysis, could further explore subject-independent vs. subject-dependent control laws and classifiers and could establish an “existence proof” of the closed-loop control motivated through this study.

Each participant wore the same VSF for this study, preventing our ability to match the length of the VSF prosthesis to their prescribed prosthesis or intact foot. A practical implementation of a VSF in clinical use would need to accommodate multiple sizes of prostheses for users of different height, but this was not possible with only one prototype.

Another potential limitation is the treatment of footwear in this study; participants wore their chosen athletic shoe on their biological foot, and no shoe at all on the prosthesis. The use of preferred (rather than standardized) shoes could have affected the gait biomechanics across individuals in this study. Using a prosthesis with no shoe is uncommon in daily use, but is common with certain high-performance prostheses [38] and running prostheses [39]–[41]. In future uses of advanced prostheses such as the VSF, it could become more common as users seek to maximize the function of their prosthesis without letting a shoe affect its properties [42].

Lastly, this study allowed participants to walk at their preferred speeds across all conditions so that the tests would be ecologically valid relative to the eventual use of these results in uncontrolled real-world scenarios. Testing in these conditions provided us with information about how stiffness and ground incline changes will alter DMAMA in unconstrained environments; however, these results may be limited when evaluating how DMAMA is affected in speed-constrained studies or in conditions of varying speed. Additional studies of natural gait across locomotion mode or with combinations of speed and mode could build on prior findings of how DMAMA varies with speed on level ground [8].

5. Conclusions

In conclusion, we found that DMAMA had significant positive sensitivity to both stiffness and ground incline, and negative sensitivity to their interaction. Sensor data from a pylon-embedded load cell and limited subject-dependent prosthesis geometric measurements provided sufficient information to compute DMAMA without external instrumentation, and also to classify locomotion mode through a machine learning model. DMAMA may be a suitable practical control parameter for a semi-active variable stiffness foot, enabling real-time alteration of prosthetic forefoot properties for improved biomechanics in comparison to passive prostheses.

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Institutional Review Board Statement: The study was approved by the University of Wisconsin-Madison Health Sciences Institutional Review Board.

Informed Consent Statement: All study participants provided informed consent prior to participation in the study.

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Conflicts of Interest: The authors declare no conflict of interest.

Abbreviations:

DMAMA	Dynamic Mean Ankle Moment Arm
DOF	Degrees of freedom
DR	Down ramp
DS	Down stairs
$DMAMA_{adjusted}$	DMAMA value adjusted for random effect
$DMAMA_{average}$	Average adjusted DMAMA value
$DMAMA_{predicted}$	DMAMA value predicted by linear mixed-effect model
$\vec{F}_{sagittal}$	Force in sagittal plane
$\bar{F}_{sagittal}$	Magnitude of mean force in sagittal plane
\vec{F}_x	Force in x-direction
\vec{F}_y	Force in y-direction
\vec{F}_z	Force in z-direction
GRF	Ground reaction force
IMU	Inertial measurement unit
I	Magnitude of ground reaction force impulse
J	Magnitude of ankle moment impulse
LC	Load cell
LDA	Linear discriminant analysis
LG	Level ground
\vec{M}_{ankle}	Ankle moment
\vec{M}_{knee}	Knee moment
$\vec{M}_{sagittal}$	Moment in sagittal plane
$\bar{M}_{sagittal}$	Mean ankle moment in sagittal plane

\vec{M}_x	Moment in x-direction	677
\vec{M}_y	Moment in y-direction	678
\vec{M}_z	Moment in z-direction	679
\vec{r}_{LC}	Vector from joint center to center of load cell	680
\vec{R}_{LC}^{Shank}	Rotation matrix from load cell coordinate system to shank coordinate system	681
RSS	Residual sum of squares	682
TSS	Total sum of squares	683
UR	Up ramp	684
US	Up stairs	685
VSF	Variable Stiffness Foot	686

Appendix

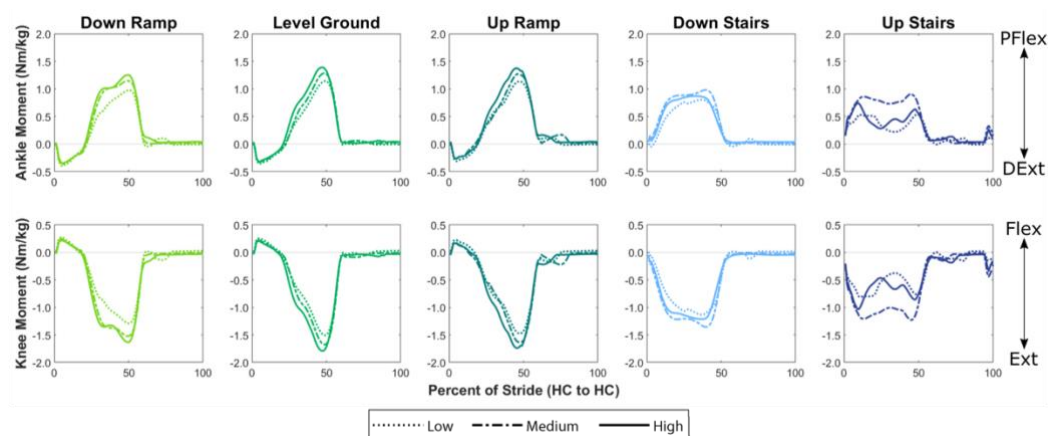


Figure A1. Ankle and knee moment throughout the gait cycle across stiffness for each locomotion mode. These graphs show the average moment profiles across all trials for a representative subject.

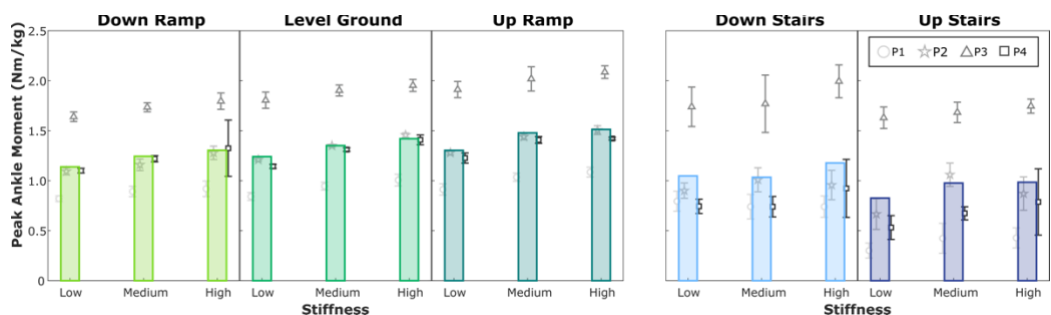
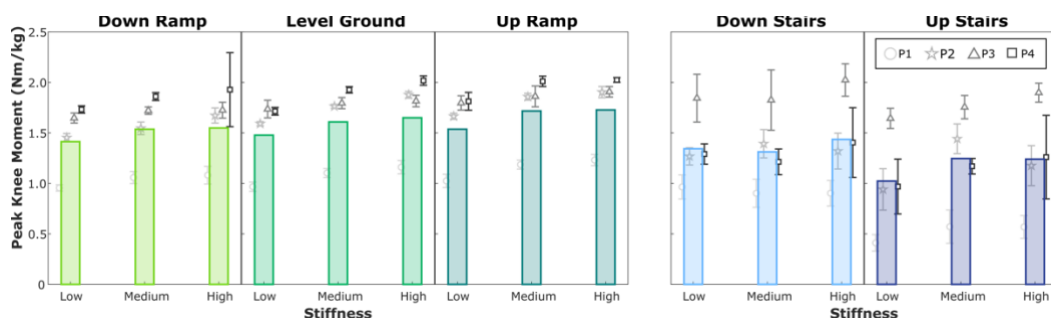


Figure A2. Peak ankle plantarflexion moment across stiffness for each locomotion mode. Colored bars show the subject-independent average. Grey markers and vertical bars show each participant's average and standard deviation values, respectively.



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Figure A3. Peak knee extension moment across stiffness for each locomotion mode. Colored bars show the subject-independent average. Grey markers and vertical bars show each participant's average and standard deviation values, respectively.

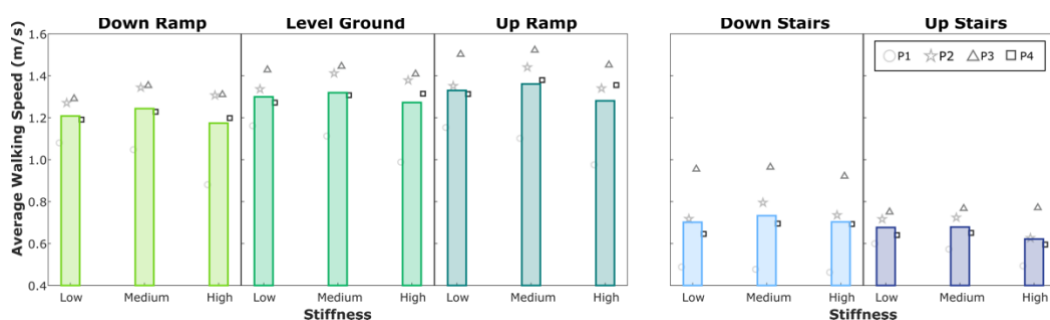


Figure A4. Average walking speed across stiffness for each locomotion mode. Walking speed was not controlled for in this study. Colored bars show the subject-independent average walking speed for each condition. Grey markers show each participant's average walking speed.

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THE EFFECT OF WALKING SPEED, SLOPES, AND STAIRS ON DYNAMIC MEAN ANKLE MOMENT ARM

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Introduction

Understanding the control mechanism of the human foot-ankle complex can inform the design of novel foot prostheses. To improve the adaptation of these designs to different activities such as ramp and stair descent, it is important to observe the way ankle control changes in a non-impaired human limb. In this study, we observe the changes in dynamic mean ankle moment arm (DMAMA) [1] when performing different activities. DMAMA describes the way the ankle controls the location of force interaction with the ground (moment arm). This summative measure accounts for temporal, spatial, and directional variations in the applied force in a single value. This makes DMAMA a useful target measure for semi-active prostheses that adjust only once per stride.

Methods

Eight unimpaired adults (age: 30±6 years; mass: 65±13 kg; foot length: 28±2 cm; mean ± SD) provided written informed consent to participate in this study. Participants performed at least 8 trials of each of the 7 activities. Walking speeds were self-selected. Kinematics were collected using a 12-camera motion capture system and ground reaction forces using multiple force plates: 6 embedded in a level walkway, 2 in a 5° incline ramp, and a force plate stairway with 3 steps, the last step forming a part of the top platform.

We used Visual3D (C-Motion, Inc.) to filter the force and kinematic data, determine foot contact with force plates, and calculate ankle moment and ground reaction force/moment. We used a custom MATLAB script to determine heel contact (HC) and toe-off (TO) and calculate DMAMA during stance phase according to Equation 1 where M is the ankle moment and F is the sagittal ground reaction force [1]. DMAMA values were subsequently normalized to participant foot length.

$$DMAMA = \frac{\int_{HC}^{TO} M dt}{\left\| \int_{HC}^{TO} F dt \right\|} = \frac{\bar{M}}{\bar{F}} \quad (1)$$

To assess the difference in DMAMA across different activities, we fit a linear mixed model (LMM) to the means of each subject's DMAMA for each category: speed, slope, and stairs. We included DMAMA as the dependent variable, the activities as the fixed effects and the participant as a random effect. We define sensitivity in table 1 as the regression coefficient from this LMM and each change in activity corresponds to an increment of one (e.g., for speed: slow (-1), normal (0), fast (1)). Critical α was set to $p < 0.05$.

Results and Discussion

As walking speed increased, DMAMA decreased as shown in figure 1 and table 1. This result matches previous work by Adamczyk [1], who also found that DMAMA tended to move towards the heel (decrease) as walking speed increased. Higher DMAMA at slower walking speeds may be due to an increased plantar flexor moment attempting to slow the body's progression [2]. We observed an even sharper decrease in DMAMA when participants ascended stairs versus descended them.

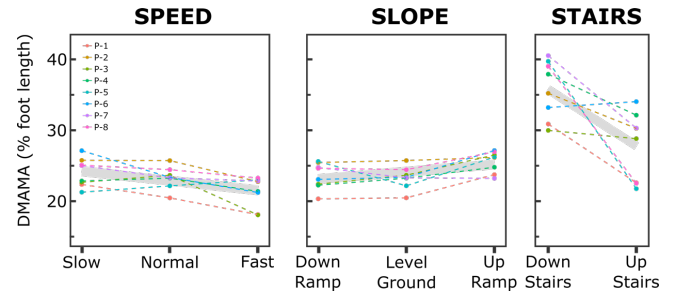


Figure 1: Trends in DMAMA across activities. The thick grey lines show the subject-independent data fit as a result of the linear mixed model. Colored markers connected by dashed lines represent each participant's average in the different categories.

Table 1. Subject-independent regression – LMM			
Fixed Effect	Sensitivity (DMAMA per increment)	p-value	R ²
Walking Speed	-1.34	0.002	0.49
Slope	+1.01	0.010	0.60
Stairs	-8.00	0.003	0.46

Table 2. Mean DMAMA (% foot length) by Activity			
Activity	Mean ± SD	Activity	Mean ± SD
LG Walking:		Down Ramp (-5°)	23.6 ± 2.60
Slow	23.9 ± 2.85	Up Ramp (5°)	25.5 ± 2.20
Normal	23.3 ± 2.28	Up Stairs	27.8 ± 5.48
Fast	21.1 ± 2.54	Down Stairs	35.9 ± 4.99

As the ground incline changed from negative to positive, we observed a significant shift forward in DMAMA. This is consistent with prior work by Leestma et al. [3] who showed a similar increase in DMAMA with increasing ground slope in participants with amputation using an experimental foot-ankle prosthesis. While the sensitivities in table 1 may appear small, DMAMA moving 1-8% foot length per increment, it is important to note that typical DMAMA values fall within a relatively narrow numerical range [1].

Significance

The results of this study can be used to design more biomimetic assistive devices such as prostheses, exoskeletons and orthoses. Using approaches such as varying prosthetic keel stiffness to tune DMAMA, semi-active prostheses can alter the biomechanics of a person's gait [3]. Target DMAMA values, such as the ones presented in this work, could be used to inform the control algorithms of novel prostheses, allowing them to adapt to different activities. DMAMA could also be used as a performance metric in fully robotic devices to evaluate and adjust their continuous ankle torque controllers. Having the ability to adapt to different speeds and terrains may improve the experience of prostheses users, e.g., by reducing maladaptive socket torques.

Acknowledgments

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WEARABLE SENSOR SUITE FOR LONG-TERM REAL-WORLD TRACKING

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Introduction

Biomechanics analysis may need abundant data from real world tracking, where more information can be extracted to enable scientific comparison of mobility interventions compared to pure lab testing. However, long-term tracking suffers from the trade-off of accuracy vs convenience as well as heading drift due to absence of GPS in indoor environments. As an attempt to resolve these problems, we are developing a sensor suite with a redundant high-accuracy IMU to mitigate long-term drift, three other low-cost IMUs and two Bluetooth devices for collecting motion and force data, as an extension to our previous method [1] with only a foot-mounted IMU. Here we describe the use of transfer alignment techniques to align and reconstruct knee and shank IMU motions which by themselves alone are impossible to build accurately.

Methods

Hardware: Our system incorporates 7 sensors with a total weight around 350 grams and similar diameter to the natural leg when attached on a prosthetic pylon. Various sources of data are collected to facilitate reliable reconstruction during long periods using sensor fusion techniques:

- 1) Five IMUs form the basis of sensor system. A low-cost cabled IMU is mounted on the instrumented foot and a Bluetooth Low Energy IMU on the other foot. The cabled IMU functions as the input of an Error State Kalman Filter for Pedestrian Dead Reckoning algorithm. Two more low-cost IMUs are attached to the shank and above the knee to reconstruct lower leg and upper leg motion. A high-accuracy low-drift IMU is installed together with the shank IMU, to maintain accurate heading during long-duration indoor motion.
- 2) Europa smart pyramid is an instrumented prosthetic pylon that monitors flexion and abduction bending moments and axial force via Bluetooth connection.
- 3) Environment sensors provide humidity, temperature and barometer data to distinguish indoor vs outdoor data and changes in height.
- 4) An RTK-GPS module provides centimeter-accuracy position measurements during outdoor movement to locate the system in the global frame.

Software: The sensor system runs on a Raspberry Pi Zero W and utilizes Robot Operating System to manage and monitor all sensors. A central node coordinates the data logging, error detection, timestamp synchronization and power management for sensor nodes.

Movement Reconstruction: The trajectory of each foot-mounted IMU is reconstructed using an Error State Kalman Filter [2], which leverages the Zero Velocity Update (ZUPT) [3] assumption at every foot fall to reduce error in absence of GPS data.

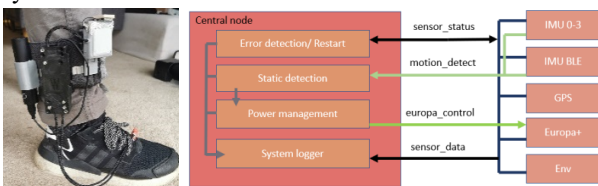


Figure 1: (a) sensor suite on leg (b) software architecture

The more challenging part is the reconstruction for the shank and thigh IMUs, where the ZUPT is not valid, making it difficult to bound the velocity and heading error. However, we have the knowledge that these IMUs move with foot-mounted IMU, with error around 0.1m in horizontal plane due to leg motion. Thus, we use position results from the foot-mounted IMU as observations for the shank and thigh Kalman filters at every footfall to perform transfer alignment [4]. This process gradually aligns the shank and thigh IMUs with a global coordinate frame.

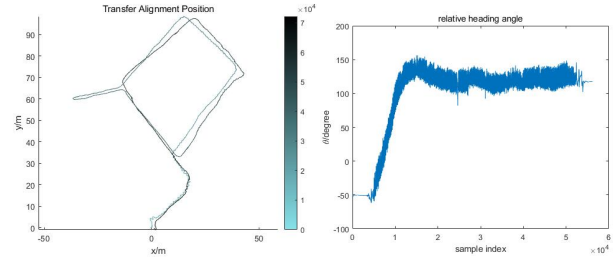


Figure 2: (a) transfer alignment results (b) relative heading angle

Results and Discussion

Fig. 2 demonstrates convergence and bounded error of the shank’s final heading with respect to foot-mounted IMU and position during testing on an intact subject. The wiggling part at the beginning is an effect of orientation error before the transfer alignment converges. Once the initialization stage finishes, the result is smooth and has bounded relative heading error.

It is worth mentioning that the sensor system housing is attached on pants, which is not as strong as attachment to a rigid object like a prosthesis or ankle-foot orthosis. At every footfall, the shank IMU endures significant shaking due to impact with the ground. However, even under this condition, the results still demonstrate a reliable reconstruction of heading and position.

In the special case of a prosthetic foot, there is a further rigid body relationship between the foot and shank IMUs during swing phase because the ankle joint angle is fixed. By applying orientation correction as an addition to position correction, the speed and accuracy of transfer alignment will be improved.

Reconstruction in indoor environments suffers most from heading error because of inevitable gyro drift. In both AFO and prosthesis cases, the previously aligned high-accuracy shank IMU can function as a low-drift reference during indoor periods to correct heading error in the foot-mounted IMU.

The preliminary results shown here demonstrate the effectiveness of transfer alignment in bringing multiple inertial sensors into long-term heading alignment for multi-body reconstruction. These techniques will be applied to compare different types of prosthetic feet and orthoses in a controlled test.

Acknowledgments

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A biomimetic approach to controlling semi-active prosthetic feet



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Motivation

Types of Prosthetic Feet

Adaptation to real world

Complexity, Weight, Height, Cost

Passive

Fixed stiffness, can be modeled as a spring-damper system.

Vari-Flex® by Ossur

Semi-Active

Change mechanical properties once per stride when foot is not bearing weight.

Variable Stiffness Foot [1]

Active

Fully robotic, adapts during entire gait cycle.

Empower® by Ottobock

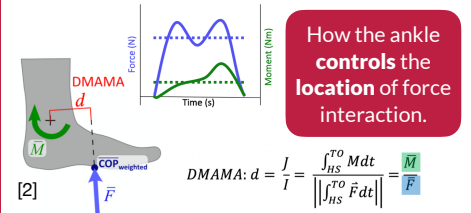
Semi-active prostheses offer an attractive balance between simplicity and real-world adaptation. They are also accessible to more people as their cost, weight, and height is lower. Research is needed to develop a suitable control strategy for semi-active prostheses that modulate stiffness.

How can we control a semi-active prosthetic's once-per-stride adjustment in a way that mimics unimpaired biomechanics?

DMAMA

(Dynamic Mean Ankle Moment Arm [2])

This study explores the application of DMAMA as a control target measure since it results in a single value per stride—ideal for the control of a foot that adapts once per stride.



DMAMA is driven by the angular impulse about the ankle which can be influenced by the amount of time the foot is in contact with the ground (walking speed) and the magnitude of forces during that time. This can give you an idea if the walk was bouncy or smooth.

Study A

How does DMAMA change with prosthetic forefoot stiffness when walking on level ground and ramps? [3]

Variable Stiffness Foot [1]

Xsens IMU's

iPecs 6-axis Load Cell (LC)

Methods:

- 4 participants with below-the-knee amputation were outfitted with various wearable sensors (see diagram on left).
- Participants walked over **level ground, a -5° decline, and a +5° incline** with the variable stiffness foot set to low, medium, and high stiffnesses.

Moveable Fulcrum to Adjust Stiffness

Still from Xsens reconstruction

Study B

How does DMAMA change in non-disabled participants when walking on level ground and ramps?

Methods:

- 10 unimpaired participants performed walking trials in a motion capture laboratory using surface-embedded force plates and a 12-camera motion capture system.
- Participants walked over **level ground, a -5° decline and a +5° incline**.

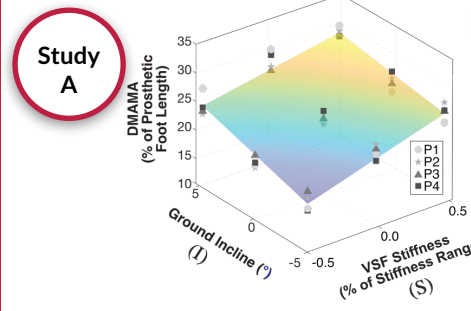
Floor-embedded force plates

Ramp-embedded force plates

Stair-embedded force plates

Still from 3D motion capture reconstruction (Visual3D)

Key Results

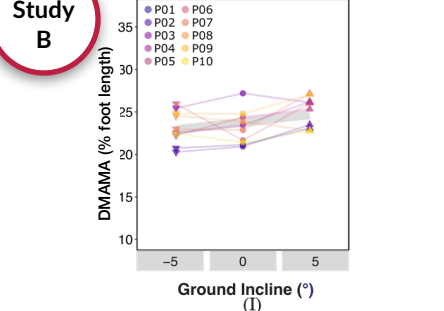


Planar fit:

$$DMAMA = 5.56S + 0.43I - 0.3SI + \text{Offset}$$

As stiffness and ground incline increased, DMAMA shifted forward indicating a more fore-footed walk.

a d, low stiffness & -5° decline
b d, high stiffness & +5° incline



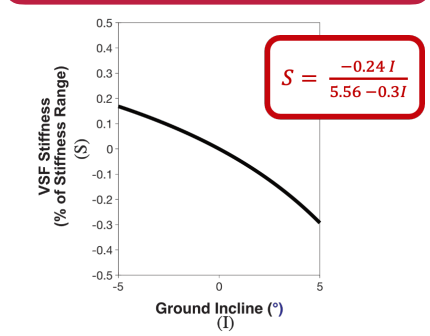
Linear fit:

$$DMAMA = 0.19I + \text{Offset}$$

As ground incline increased, DMAMA shifted forward but to a lesser extent than in Study A.

a d, -5° decline
b d, +5° incline

Biomimetic Prosthetic Ankle Control Law



Combining the results from studies A and B, a control law was generated to describe the extent to which prosthetic keel stiffness should be adjusted when climbing ramps to mimic an unimpaired ankle.

Conclusions & Future Work

The proposed control law can be used to enable greater terrain adaptability in a generation of more accessible prostheses.

The proposed control law suggests that in order to be biomimetic, prosthetic keel stiffness should be decreased when ascending a ramp and increased when descending a ramp. Future work includes similar analysis to determine the optimal control for prosthetic stiffness when climbing stairs or walking at different speeds. Having the ability to adapt to different speeds and terrains may improve the experience of prostheses users, e.g., by reducing maladaptive socket torques. DMAMA can also be used as a performance metric in fully robotic devices to evaluate and adjust their continuous ankle torque controllers.

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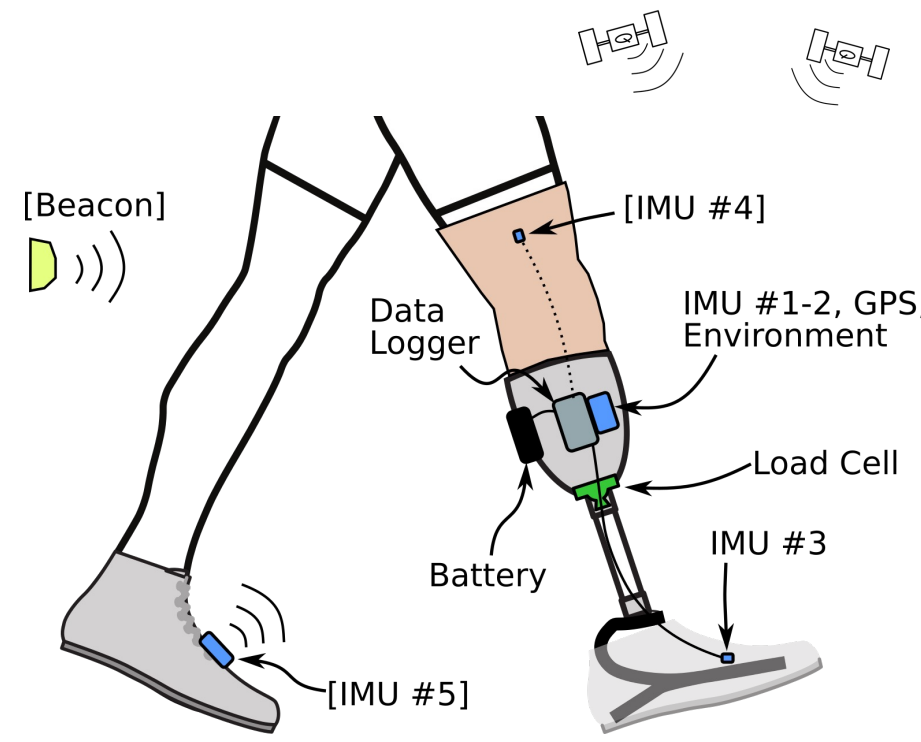
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Real-World Whole Foot Ground Clearance

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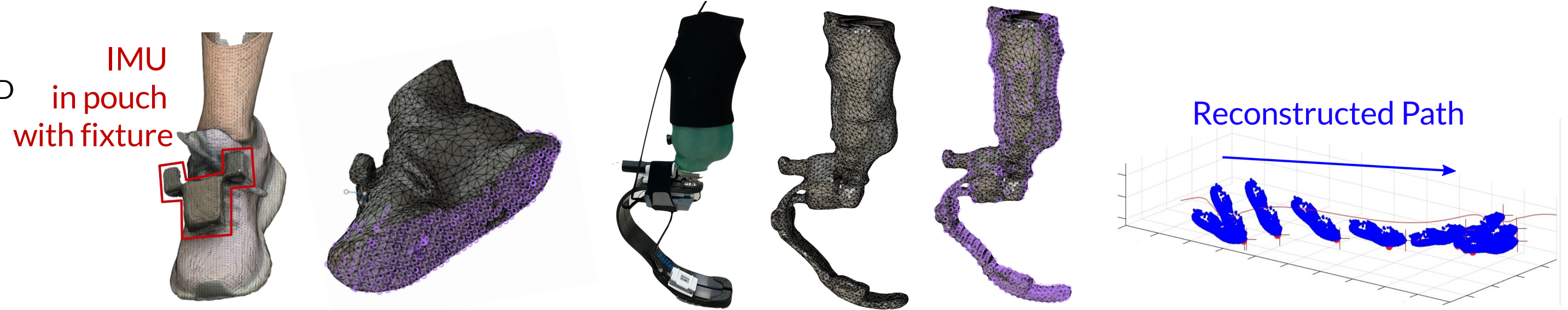
Goal
Develop methods to improve richness of data collected via wearable sensors

- Current studies:
- Comparison of orthotics (~10 days/device)
 - Comparison of prostheses (~7 days/foot)
 - Analysis of the use of activity-specific prosthetics (30 days)

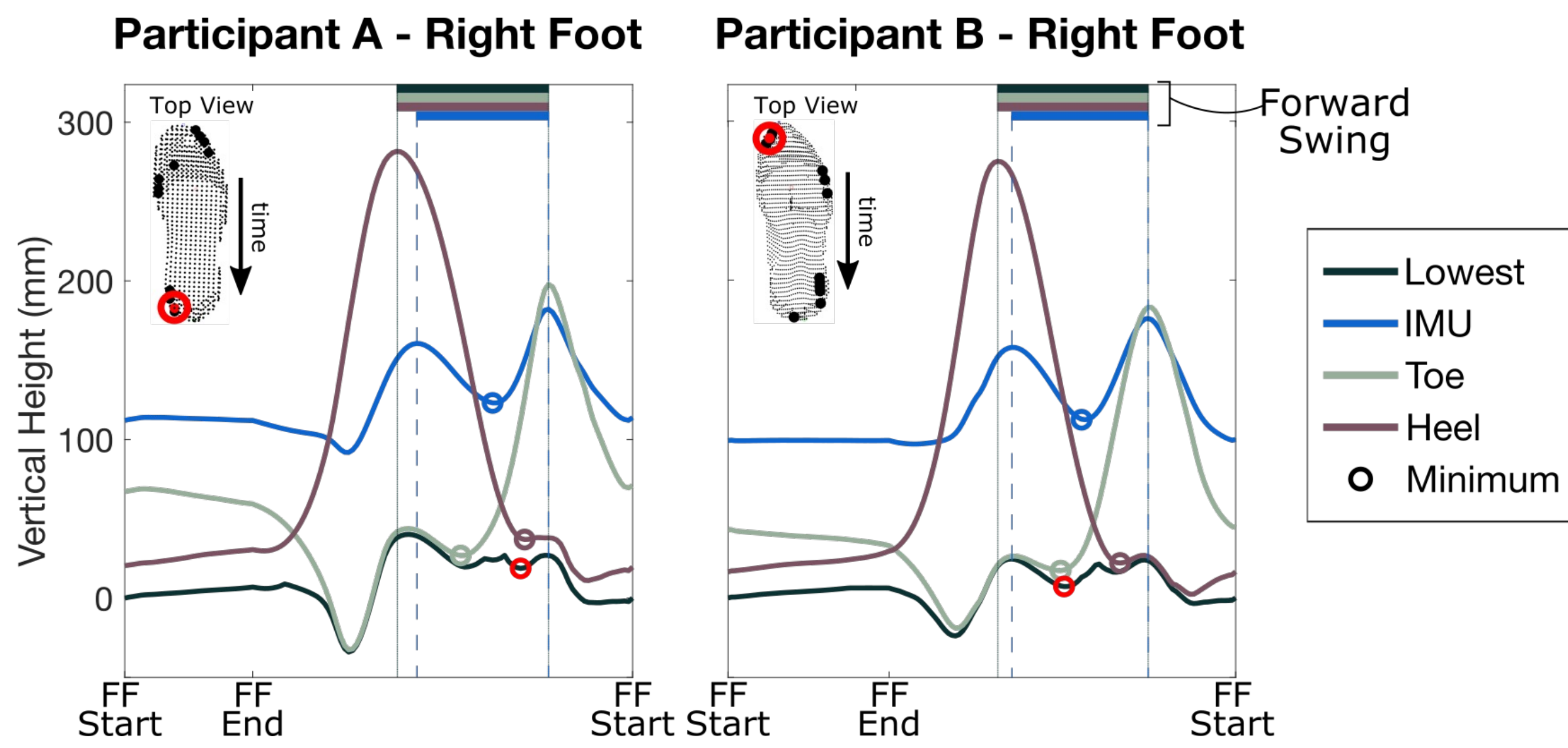


Improving foot clearance measurement by augmenting the IMU trajectory with 3D scans

- Method**
1. 3D scan foot/prosthesis with IMU in position
 2. Using a locating fixture determine important landmarks in CAD software
 - pose of the IMU
 - toe
 - heel
 - cloud of points along bottom of shoe
 3. Relate the CAD coordinate system to the IMU coordinate system and ultimately to the world coordinate system.



Preliminary Exploration: Comparison of 2 unimpaired participant's ground clearance

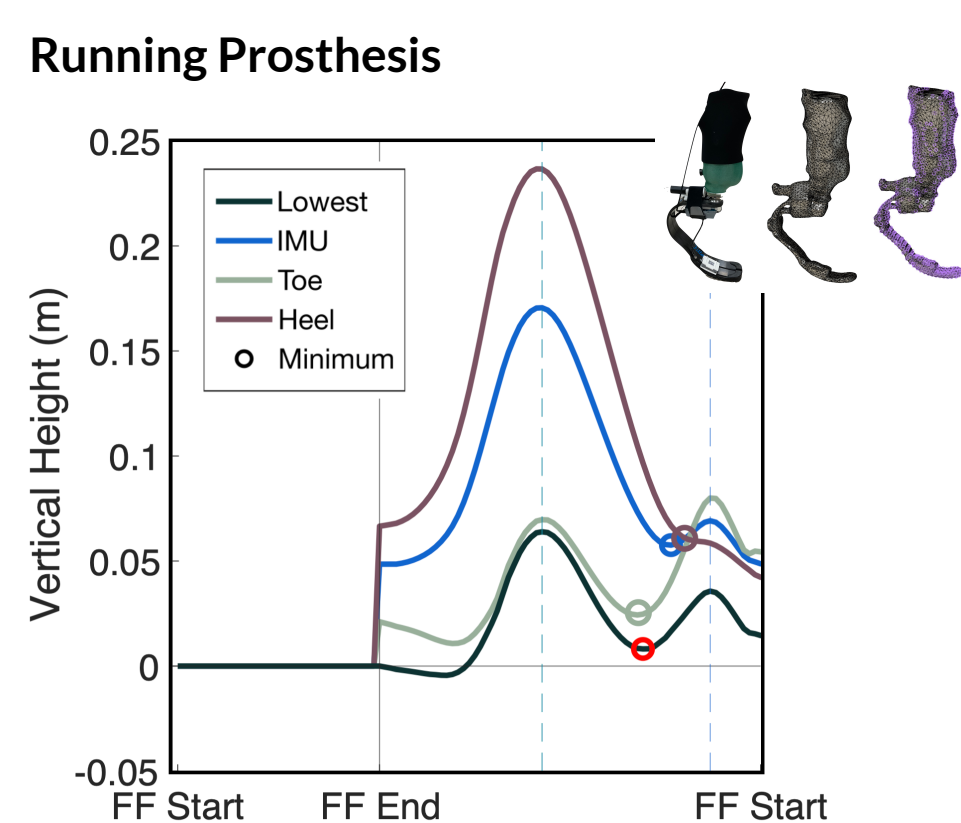


ID precise locations that may lead to trips, scuffs, or falls!
Important in patients with gait impairments.
Measure to compare prosthetic & orthotic effectiveness

Participant	Lowest	Toe	Heel	Virtual IMU
A	18.2±4.9	32.4*±6.7	36.3*±6.2	14.26±4.2
B	4.1±4.5	13.4*±3.0	20.8*±3.0	10.2*±3.3
Average	11.1±8.6	22.9*±11.2	28.6*±9.27	12.2±4.2

*denotes significantly greater average clearance than Lowest, p<0.0167

Coming soon...



Effects on stride length, variability, socket load, ground clearance...



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Background

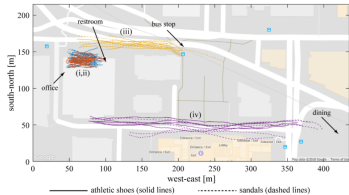


Fig 1. Frequently-repeated straight walking trajectories

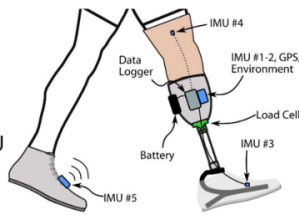
Real-World Tracking for Science^[1]

- Controlled Comparisons in repeatable locations and activities
- IMU based joint movement reconstruction**
- Interesting data for evaluating real-world performance
- No calibration movement needed

System overview

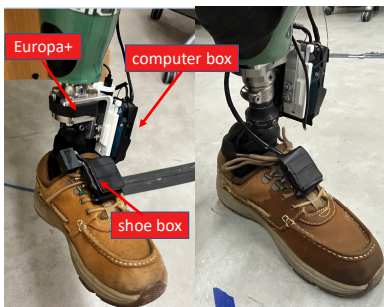
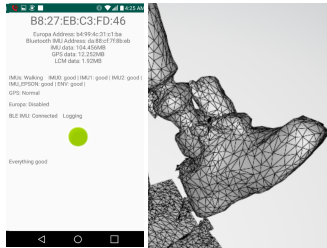
Sensor suite

- 5 IMUs**
 - 3 low-cost IMU
 - 1 high-accuracy IMU
 - 1 Bluetooth Low Energy IMU
- RTK GPS**
- Environmental sensors**
 - elevation, indoor vs outdoor
- Europa+ smart Pyramid^[2]**
 - 3-axis BLE load cell
- RasPi Zero W**
 - data logging, power management, error detection



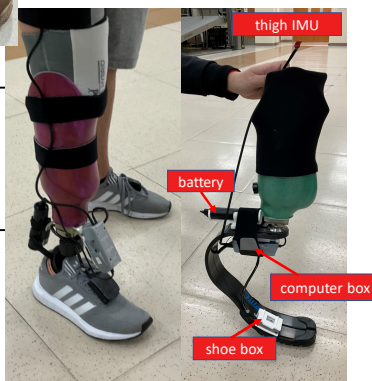
Support material

- REDCap survey**
- 3D scan**
 - precise position of IMU
- Android Phone APP**
 - monitor & configuration
- Mounting system**
 - For all types of foot!



- Full sensor configuration(left)
- Evaluate each foot for 1 week:
 - standard foot (left),
 - high profile foot (right)
 - with passive hydraulic ankle
 - ankle with microcontroller

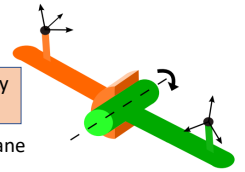
- No Europa
- Switch sensor suite between
 - walking foot for daily activities
 - running blade for sports



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 body connected by hinge joint have the same off-axis component



same magnitude of projection onto joint axis plane

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

- Find joint axis by solving least square optimization

$$\text{argmin}_{j_1, j_2} \sum e_i^2, \text{ where } e_i = \|g_1(t) \times j_1\|_2 - \|g_2(t) \times j_2\|_2$$

- Integrate the difference between gyroscope data from shank/thigh or shank/foot IMU to get knee/ankle joint movement
 - accurate, slowly drifting
 - No calibration movement needed

Question to be answered:

Apply the accelerometer-based driftless method in [4]?

Use hinge joint assumption to correct the heading of other IMU?

Results and Discussion

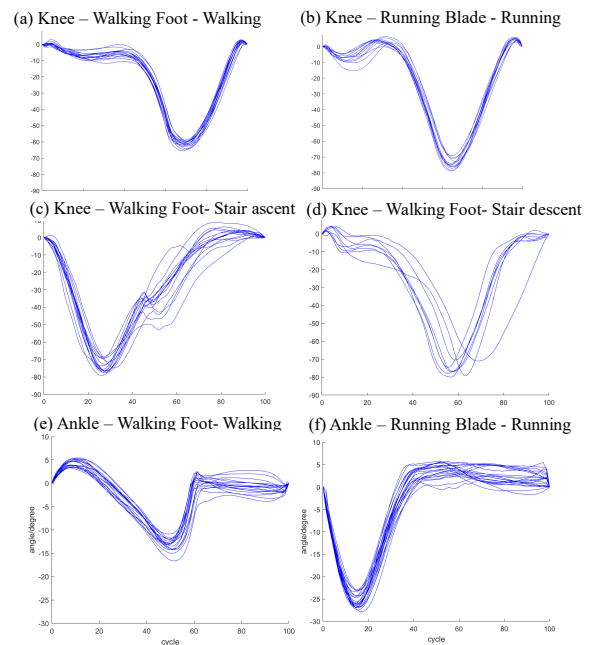


Fig 2. Joint movement reconstruction in different activities on the walking foot and the running blade, (a)(b)(d)(e)(f) plotted from heel strike to heel strike, (c) plotted from heel off to heel off

The joint reconstruction results are extracted from the subject in Washington DC during a 3-week trial.

Increased flexion on the running blade

No plantar extension on the running blade after heel strike

Stair ascent/descent: can you figure out how and why they move their leg from the figures?

Future work

- Improve reconstruction using the 3D scan model
- Combine hinge joint correction with the transfer alignment techniques for correct heading
- Explore driftless method

References:

- Wang et al 2019 Sensors
- Europa+, Orthocare Innovations, LLC
- Thomas 2012, IEEE Conference on Control Applications
- Thomas et al 2014 Sensors

Acknowledgments:

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DETERMINING WHOLE-FOOT GROUND CLEARANCE KINEMATICS BY AUGMENTING IMU TRAJECTORY WITH PERSONALIZED 3D SCANS

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Introduction

Estimation of minimum foot clearance using wearable IMU’s typically assumes that the toe or a point on the midfoot is the lowest vertical point relative to the walking surface during swing phase [1]. This assumption could lead to inaccurate foot clearance estimates in individuals with gait impairments who demonstrate atypical swing phase kinematics such as excessive inversion or lack of controlled dorsiflexion [2]. Further, this assumption does not hold during stair negotiation for healthy individuals [3]. Our pilot study aims to accurately characterize whole-foot minimum clearance during gait through observing the true lowest point on the shoe via use of 3d scanning to reconstruct and analyze entire shoe movement along a trajectory described by a shoe-mounted IMU.

Methods

Experimental Protocol

Two adult, female, unimpaired participants consented to participate in this pilot study. We securely placed one Opal (APDM) IMU sensor in a small pouch on each participant’s running shoes. We 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 walked in a straight line down a hallway at a self-selected speed. Eight strides per participant were analyzed.

Processing of the 3D Scans

We used CAD software (Autodesk) to place points describing the IMU’s center and axes, the toe, the heel, and a grid of points that covered the bottom surface of the participant’s shoe. These salient points were located based on the fixture’s rectangular “ears” that were visible to establish datum planes and edges.

Trajectory Reconstruction

The trajectory was reconstructed using a Kalman Smoother from the foot IMU’s acceleration and gyroscope data. To reduce drift due to sensor bias, we applied Zero Velocity Update (ZUPT) at every footfall and Zero Attitude Rate Update (ZARU) for long stationary periods. This procedure yielded the IMU’s position and orientation relative to global reference frame at each instant.

Minimum Clearance Calculation

Having the global pose of the IMU from the reconstruction and the pose of the salient points on the shoe with respect to the IMU

in the 3D scan’s reference frame, we calculated the location of the foot’s points in the global frame throughout of the trials. “Lowest” clearance was defined as the lowest height of the lowest point on the shoe during the forward swing, defined between the maxima of heel and toe height during swing phase. For comparison, we calculated virtual IMU clearance as the minimum height above a line connecting successive footfalls during forward swing, here defined between the two maxima [4].

Results and Discussion

Clearance values are shown in Table 1. In addition to providing a more sensitive metric of whole foot clearance during forward swing, this method provides information on the magnitude and at-risk location of minimum foot clearance. Further, our analysis revealed strikingly different patterns between participants in the anatomical location of the lowest points during forward swing, shown in Figure 1.

Table 1: Vertical clearance in millimeters (Mean±St.Dev.)

Participant	Lowest	Toe	Heel	Virtual IMU
A	18.2±4.9	32.4*±6.7	36.3*±6.2	14.26±4.2
B	4.1±4.5	13.4*±3.0	20.8*±3.0	10.2*±3.3
Average	11.1±8.6	22.9*±11.2	28.6*±9.27	12.2±4.2

*denotes significantly greater average clearance than Lowest, $p < 0.0167$

Significance

This novel approach results in a more comprehensive understanding of minimum foot clearance than current methods and enables precise identification of anatomical locations most likely to lead to scuffing, tripping, and falls during gait. Such information collected from real-world mobility via IMU’s, could offer a new objective comparison of prosthetic & orthotic effectiveness and can better inform selection and design of such devices based on individual foot clearance patterns.

Acknowledgments

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

References

- [1] Delft et al., 2021. *Int. J of Env. Research and Public Health.*,
 [2] Lee & Hogan, 2015. *IEEE Transactions on Neural Sys. And Rehab. Eng.* [3] Telonio et al., 2013. *J Biomech.* [4] Wang & Adamczyk, 2019. *Sensors.*

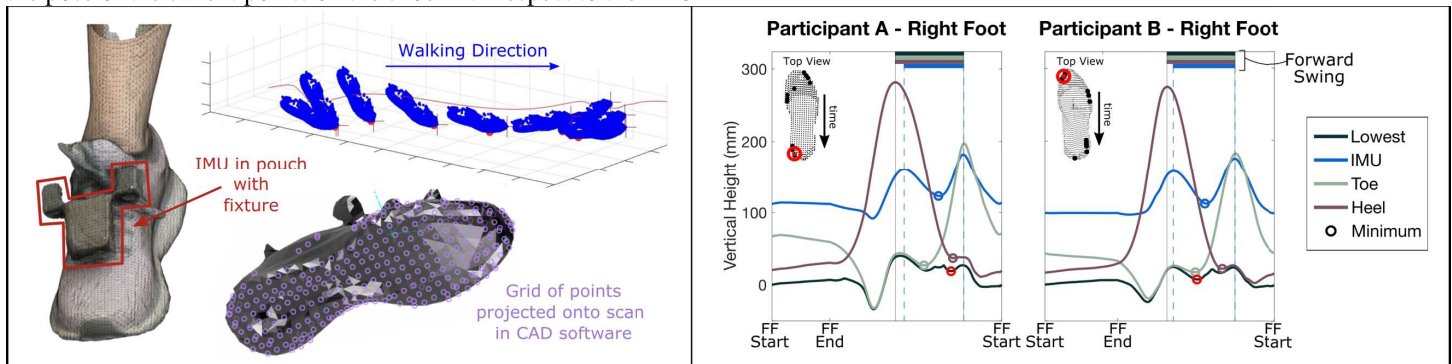


Figure 1: Left—images of the scan of a participant’s foot and an example reconstruction of a single stride. Right—representative trajectories for each participant between consecutive foot falls (FF).

JOINT MOVEMENT RECONSTRUCTION IN LONG-TERM REAL-WORLD TRACKING

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Introduction

Evaluating mobility intervention such as prostheses during everyday, real-world movement can help elucidate how different prosthetic feet perform in different activities. However, compared with in-lab settings, one of the challenges is the trade-off between data richness and convenience. We want as many sensors as we can, yet it can't be too bulky to affect people's normal life. In this abstract, we demonstrate the design of a sensor suite aimed for long-term real-world tracking, explain how we achieve a reasonable balance between convenience and richness, and show some preliminary joint reconstruction results from our first subject in a 20-day trial.

Methods

a. Hardware

Our sensor suite comprises a Raspberry Pi Zero W, 5 Inertial Measurement Units (IMUs), an RTK-GPS module, a Europa+ load cell and environmental sensors. One foot IMU is on the prosthetic side for trajectory reconstruction. Two IMUs are placed on shank and thigh for reconstructing the whole leg movement. One high-accuracy IMU on the shank provides a low-drift reference to reduce heading drift. One Bluetooth IMU is placed on the other foot. The total sensor suite without battery weighs 118g and has a similar diameter to natural leg. The system can work around 9.5 hours with one charge.

Since participants may have several prosthetic feet for different activities, we designed a rapid-change connector on the Computer box and a sliding connector on the Shoe box, and only installed a connector base on each prosthetic foot. Subjects can change the sensor suite from one foot to another in one minute.

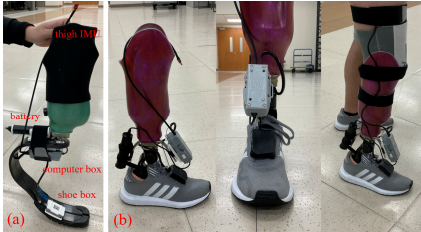


Figure 1: (a) Running blade and (b) walking foot with sensor suite.

The sensor system uses C++ programs managed by Robot Operating System (ROS) to control and monitor all sensors, including error detection and power management. We developed an Android phone app for basic status checking by Bluetooth.

b. Reconstruction

The foot IMU reconstruction uses a Kalman Smoother which computes position and orientation from raw acceleration and gyroscope data of foot IMU. We applied Zero Velocity Update (ZUPT) and Zero Attitude Rate Update (ZARU) to reduce the drift due to sensor noise [1]. GPS data is used to align the reconstruction frame with the world frame. Transfer alignment techniques are used for shank and thigh IMU reconstruction [2].

We reconstructed knee joint movement to study how movement changes among different activities and prostheses [3]. Based on the kinematic constraints from a hinge joint assumption, we formulate a least-square optimization problem using angular velocity data, then solve the direction of the hinge joint axis expressed in each IMU's own frame. The joint angle is computed by projecting the angular velocity onto the joint axis and

integrating the difference between the two segments. We segmented strides based on the heel strike (walking, running, stair descent) or toe off (stair ascent) [4].

Results and Discussion

Our first subject wore the sensor suite throughout a 20-day trial with two prostheses: an Ossur Proflex foot for daily activities include boxing, and a Fillauer Obsidian running blade for intense activities. Each day the subject filled an electronic survey for recording special activities and changes of prosthesis. Activities captured included walking, running, tennis, boxing, and more.

The knee joint movement shown in Fig 2 is computed from the shank and thigh IMUs. Fig 2a is extracted from walking on the daily foot; 2b from running on the running blade. The graphs reveal differences in peak flexion and extension during stance-phase and peak flexion during swing. We also extracted the knee movement in stair ascent (Fig 2c) and descent (2d). Stair ascent demonstrated rapid, deep knee flexion to create enough foot clearance to reach the next step safely at heel strike, followed by knee extension to lift the body. Stair descent demonstrated an extended flexion period while lowering onto the other foot, then rapid extension to reach down to the next stair.

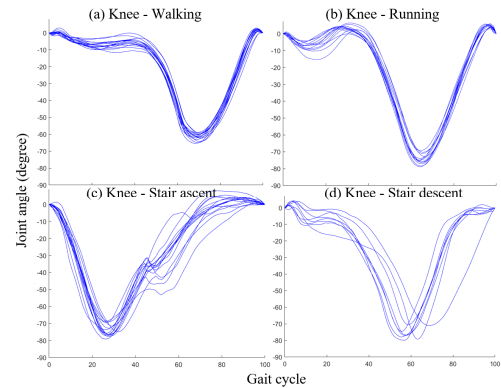


Figure 2: Knee angle in (a) walking (b) running (c) stair ascent (d) stair descent. (a)(b)(d) plotted from heel strike to heel strike, (c) plotted from toe off to toe off.

Ongoing efforts aim to reduce drift in joint movement estimation, extend the joint angle computations to the ankle, evaluate asymmetry between the feet, and develop adaptive methods for gait phase detection in all activities.

Significance

This study presents the first results of our study performing long-term, multi-activity tracking and reconstruction during everyday life with sensors built onto all of an individual's prosthetic legs. The ability to capture a variety of activities will enable the investigation of how different prostheses affect these activities. This information will contribute to better choices of which devices an individual will benefit from in each activity.

Acknowledgments

Funding provided by DOD W81XWH-19-2-0024. Project in collaboration with Walter Reed Medical Center, JA and BH.

References

- [1] Solà 2017 *arXiv*. [2] Wang et al, 2021, ASB
- [3] Seel et al, 2012, CCA [4] Ju et al, 2016, Meas Sci Technol

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Abstract Details:

Breakout Session: Advancements in Prosthetic and Orthotic Technologies

Submission Category: Oral Presentation

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

Abstract:

BACKGROUND.

Optimal selection of prosthetic devices for the rehabilitating warfighter should rely on understanding the effects of these devices during real-world, everyday use—not just laboratory tests. This abstract reports first-of-kind results comparing foot clearance and knee kinematics in two different prostheses, derived from long-term recordings of movement during daily life. We highlight new methods for estimating outcome metrics from recordings of this type and show how walking with a daily-use prosthesis versus a running-specific prosthesis affects movement differently.

METHODS.

EXPERIMENTAL PROTOCOL—One male Service member with unilateral transtibial amputation (time since amputation: 7 mo, MFCL K4) provided written informed consent to participate in this 20-day study. To monitor the participant's real-world activity, we instrumented his primary prostheses; an Össur Proflex foot for daily activities (pin suspension) and a Fillauer Obsidian running blade (suction suspension), with a custom sensor suite. This suite was composed of a Raspberry Pi Zero W, 5 Inertial Measurement Units (IMUs), an RTK-GPS module, and environmental sensors. We placed an IMU on the top of the prosthetic foot and on the shank and thigh. Another high-accuracy IMU was placed on the shank to provide a low-drift reference to reduce heading drift. A final IMU was placed on the participant's unimpaired foot and connected via Bluetooth. The total weight of the sensor suite was 217g. Quick clips enabled the system to be switched between the prostheses in about one minute. The system ran on a battery charge (5000 mAh, 5V) for roughly 9.5 hours, and a second battery was provided.

We 3D scanned each prosthetic foot with the sensor suite attached during the initial lab visit to enable reconstruction of detailed foot movement relative to the sensors. On the daily prosthesis, a 3D printed fixture was placed in the IMU pouch to provide clear, flat surfaces to identify the position and orientation of the IMU correctly.

MOVEMENT RECONSTRUCTION—The trajectory of the foot IMU was reconstructed using a Kalman Smoother, which computes position and orientation from raw acceleration and gyroscope data using pedestrian dead-reckoning techniques. To reduce drift due to sensor bias, we applied a Zero Velocity Update (ZUPT) at every footfall and Zero Attitude Rate Update (ZARU) for long stationary periods [1]. In addition, GPS data were used to align the reconstruction frame with the world frame.

Knee joint movement was reconstructed using data from the angular rate gyroscopes in the shank and thigh IMUs [2]. Based on a hinge joint assumption, we formulated a least-squares optimization problem to solve for the direction of hinge joint axis in each IMU's own reference frame. Joint angle was computed by projecting the angular velocity of both segments onto the joint axis and integrating the difference between the two segments over time. Knee joint movement was quantified by peak knee flexion in stance and swing.

WHOLE-FOOT (WF) GROUND CLEARANCE CALCULATION— Using CAD software (Autodesk), we imported scans of the participant's prostheses and defined landmarks at the IMU's centers and axes and the toes. We added a grid of points that covered the surface of the participant's prostheses. With the pose of the IMU in the world frame and the pose of the prosthetic relative to the IMU in the 3D scan, we reconstructed the location of all the points in the world frame throughout each stride.

A two-step process was implemented to determine the minimum clearance during swing; first, the zero-height plane for each stride was matched to the lowest point of the previous stance phase. Second, instantaneous WF ground clearance was determined as the lowest height of any point on the foot during the forward-swing period, defined as the time between the two maxima of the IMU's trajectory. For comparison, we calculated toe clearance (minimum height of the toe point) and virtual IMU clearance (minimum height of the IMU above a line connecting its positions at successive footfalls). Data are reported as mean±standard deviation.

RESULTS.

In this study, data for over 50,000 strides were collected. This preliminary analysis includes 12 strides on each prosthesis for foot clearance, and minimum 47 on each prosthesis for joint movement.

Minimum WF ground clearance was lower than toe clearance estimated only from the toe marker (TOE) and lower than the virtual clearance of the IMU (VIMU) that approximates mid-foot clearance (Daily foot—WF: 8.6 ± 15.3 mm; TOE: 24.0 ± 15.7 mm; VIMU: 12.9 ± 13.1 mm; Running blade—WF: 18.7 ± 13.5 mm; TOE: 56.0 ± 14.6 mm; VIMU: 36.0 ± 11.0 mm). Overall, the daily foot

resulted in lower minimum clearance than the running blade.

Peak knee flexion in mid-stance was minimal on the running blade compared with that on daily foot (Daily foot—ANGLE: $11.2 \pm 4.4^\circ$ flexion; TIME: $21.7 \pm 0.2\%$ stride; Running blade—ANGLE: $0.7 \pm 0.5^\circ$ flexion; TIME: $18.9 \pm 3.4\%$). There was essentially no stance-phase knee flexion with the running blade; thus, the timing of peak value was highly variable. Peak knee flexion in swing phase was also lower with the running blade (Daily foot—ANGLE: $69.7 \pm 9.7^\circ$ flexion; TIME: $70.1 \pm 0.03\%$ stance; Running blade—ANGLE: $55.1 \pm 4.5^\circ$; TIME: $70.3 \pm 0.02\%$).

DISCUSSION

The difference between WF, TOE, and VIMU clearance arises as the new method incorporates the entire geometry of the foot, allowing its shape and angular motion, including inversion and eversion, to affect which point is lowest. Both the minimum clearance and the location of the minimum clearance point can be affected by footwear, prosthesis, alignment, and gait style. Several factors could cause the daily foot to have a lower clearance than the running blade, for example absence of a heel on the running blade, the blade's curvature, differences in gait strategy by the user, and potential differences in the location of the prosthesis' "toe" relative to the residual limb. The increased clearance with the running blade may be surprising because such prostheses are commonly aligned to make the prosthetic-side leg slightly longer than the natural leg—a change that would be expected to reduce, not increase, ground clearance. Further investigation into more data and additional participants would clarify this phenomenon.

One explanation for the minimal peak knee flexion on the running blade is that the running blade does not have a heel to push the tibia forward during heel strike; instead, the knee remains straight, and the whole running blade deforms and absorbs and returns energy throughout the stance phase. A similar phenomenon occurs in running with running-specific prostheses: users often keep the knee straight and "bounce" on the prosthesis instead.

Similarly, peak knee flexion during swing phase was lower with the running blade. Given that the participant exhibits greater foot clearance when walking on the running blade, this reduced knee flexion must still be enough to create a safe foot clearance. This phenomenon might vary based on the shape and length of the running blade.

CONCLUSIONS.

The preliminary results of minimum WF clearance and knee joint flexion demonstrate the capabilities of capturing and reconstructing lower limb motion in real-world settings over prolonged durations. The novel approach to determining WF clearance and proximal joint motions can enable precise identification of anatomical locations that most likely lead to tripping, scuffing, or falls during walking. 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.

[1] Solà, arXiv, 2017

[2] Seel et al, 2012

Disclaimer: The authors would like to thank and acknowledge Todd Sleeman, CP, for their expertise and assistance in this study. Funding provided by DOD W81XWH-19-2-0024. The views expressed are those of the authors and do not reflect the positions of the Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc., Uniformed Services University of the Health Sciences, Departments of the Army/Navy/Air Force, Department of Defense, nor the U.S. Government. The identification of specific products does not constitute endorsement by the authors, Department of Defense, or any component agency.

Learning Objectives

1. Discuss the proposed approach to evaluate different prostheses during everyday activities for the rehabilitating warfighter.
2. Analyze a novel method of calculating ground clearance when walking with different prostheses.
3. Describe changes in knee joint movement when walking with a daily foot versus a running blade.

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