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TITLE: Connecting Mechanical to Biomechanical Performance of Prosthetic Feet to Design Customized Passive Devices that Provide Improved Mobility

PRINCIPAL INVESTIGATOR: Amos Winter, Associate Professor of Mechanical

RECIPIENT: **Massachusetts Institute of Technology**
Cambridge, MA, 02139

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Fort Detrick, Maryland 21702-5012

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Amos Winter

E-Mail: awinter@mit.edu;

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Massachusetts Institute of Technology
77 Massachusetts Ave
Cambridge, MA, 02139

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U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT
The purpose of this project is to design high performance, low cost prosthetic feet that are optimized for multiple activities of daily living and tuned specifically for a user's height, weight, and activity level. The project involves a novel design metric, known as the Lower Limb Trajectory Error (LLTE), which we use to predict the biomechanical performance of prosthetic feet based on their geometry and stiffness. The LLTE can be used to optimize prosthetic foot designs for specific tasks, such as walking up ramps or on level ground. The major goals for this project are to: develop a clinical algorithm that will allow us to tune a prosthetic foot to a user's height and weight, create a single component, prototype foot design for level ground walking, validate the prototype foot's performance with amputees, collect reference data from able-bodied subjects walking up stairs and ramps, and designing a prosthetic foot optimized for these tasks. This year, we improved upon our single component prototype foot by adding an optimized heel component. We also validated this prototype with human subjects, and found that our prototype performed just as well or better than commercially available prosthetic feet. We also identified and eliminated a manufacturer defect in our equipment that interfered with our measurements.

15. SUBJECT TERMS
Prosthetics, Biomechanics, Design, Gait Analysis, Optimization, Rehabilitation

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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

   The motivation behind this project is to create high-performance, rugged, passive mechanical prosthetic feet that can drastically improve the lives of the active military and veteran populations who have below-knee amputations (BKAs). We have devised a novel optimization metric for prosthetic foot design, called Lower Leg Trajectory Error (LLTE), which provides a quantitative connection between the stiffness and geometry of a prosthetic foot and its biomechanical performance. **Through this research program, we will design single component, compliant feet that are optimized for various activities of daily living, can be manufactured at low-cost through injection molding or with high customizability with 3D printing, and are tunable for specific patients' body weight, size, and level of activity.** This project precisely addresses the 2016 U.S. congressional mandate for the Department of Veterans Affairs (VA) to provide improved prosthetic limbs: "veterans have a need for accessible, dependable, and affordable tools to overcome barriers to engagement, employment, and independent living. The continued development of 3D printing and other technological advances has the potential to make development and adaptation of devices faster and more affordable". **This project aligns with the FY16 PRORP Rehabilitation Focus Area: Prosthetic and/or Orthotic Device Function.**

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

   Prosthetics, Biomechanics, Design, Gait Analysis, Optimization, Rehabilitation

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?

   Major Goal 1: Validate Clinical Algorithm.
   Target Date: September 30, 2018
   Completion: 25%
   Major Goal 2: Design Single Part Foot Topology
   Target Date: September 30, 2018
   Completion: 100% for first generation prototype, more iterations may follow
   Major Goal 3: Experimentally Validate Single Part Foot Prototype
   Target Date: September 30, 2019
   Completion: 100%
   Major Goal 4: Collect Able-Bodied Gait Data for Multiple Activities of Daily Living
   Target Date: September 30, 2019
   Completion: 20%
   Major Goal 5: Design and Experimentally Validate a Multi-Activity Foot
   Target Date: September 30, 2020
   Completion: 0%

   What was accomplished under these goals?

   This year, we accomplished Major Goal 3 by improving and validating our single part foot prototype. We improved upon our single part foot design by optimizing its behavior over a

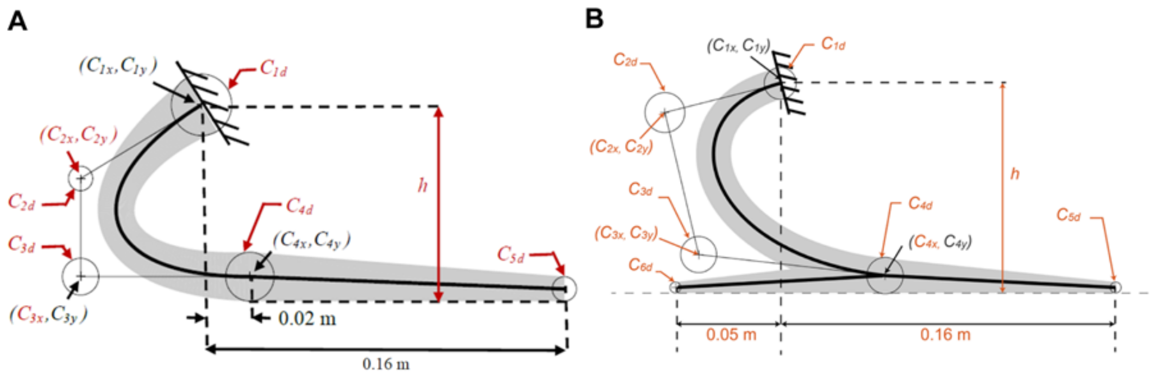

Figure 1: Improving the design of the single part prototype feet. **A)** Schematic of the original single part prototype foot described using a wide Bèzier curve. The shape was defined with 9 parameters. **B)** Schematic of the new prototype foot using 12 parameters to define the foot shape. The addition of the heel improved the LLTE by 60%

larger portion of the gait cycle. This improved prototype was tested by five human subjects with transtibial amputations and compared against commercially available prosthetic feet. **Our prototype performed as well or better than the commercially available prosthetic feet**. A manufacturer error in our test equipment severely hindered progress for Major Goal 4 where we would measure the biomechanics of ascending and descending stairs and ramps in able-bodied subjects. Fortunately, with the help of the manufacturer, we were able to fix the error, and data collection can rapidly proceed in year 3. No progress was made for Major Goal 1 in validating the clinical algorithm, as we prioritized lab time and subject availability for testing our prototype. However, the excellent performance of the prototype feet suggests that our current algorithm for designing feet for each user's height and weight works well. We plan to formally evaluate the clinical algorithm during quarters 1 and 2 for year 3.

Major Goal 2: Design Single Part Foot Topology

Although we accomplished Major Goal 2 during year 1, we have continued to improve the design. The previous design was optimized to match the motion of able-bodied people during the midstance phase of gait when the foot is flat on the ground, but we were unable to include early and late stance phases in the optimization because the constitutive models lacked enough constraints to calculate the LLTE during those phases. We found that constraining the predicted knee torque of the constitutive model to that of able-bodied gait during those phases allowed us to calculate the LLTE for the entirety of stance phase. This enhanced analysis enabled us to design feet that could better mimic the shock absorption of the human ankle foot complex during heel strike in early stance. We added more parameters to the Wide Bezier curve that defined the shape of our original prototype to include an optimized heel (Fig. 1), and used the LLTE design framework to find the optimal foot shape. The addition of the optimized heel reduced the LLTE of our design by 60% (from 0.816 to 0.319), which means that the new prototype is able to recreate able-bodied kinematics better than our original.

Major Goal 3: Experimentally Validate Single Part Foot Prototype

With IRB approval, we recruited five human BKA subjects to test our new single part prototype foot. We used the LLTE design framework to find the optimal foot shape that would provide an able-bodied like gait for each subject according to their weight, leg length, and foot length (Fig. 2). Then, we manufactured the feet from a single block of Nylon 6/6

User's Mass	55.9kg	79.6kg	61.1kg	72.5kg	85.6kg
Height	1.70m	1.57m	1.70m	1.67m	1.63m
Shank Length	0.440m	0.454m	0.505m	0.498m	0.459m
Foot Size	0.252m	0.270m	0.279m	0.290m	0.267m

Figure 2. High-performance, low-cost, customized plastic prosthetic feet. Each foot was optimized to facilitate able-bodied kinematics and kinetics, given the individual's body weight and leg segment size.

using a water jet cutting machine. The **MIT** prototypes were evaluated against the subjects' own prosthetic feet, **prescribed** before the study by their own prosthetist, to determine how our foot affected their motion. They were also compared against another commercially available energy storage and return foot that the subjects had not used before, the **College Park** Horizon LT, to serve as a control for the training and accommodation the subjects had with their prescribed foot. Each foot served as a different walking condition (denoted as MIT, Prescribed, and College Park, respectively) in a motion gait analysis where the subjects walked along a level 10 m walk way while wearing passive reflective markers strategically placed on their body. Infrared cameras tracked the motion of these markers to measure the position and orientation of the subjects' body parts as they walked, and force plates embedded in the ground measured the ground reaction forces (GRFs) acting on their feet and the corresponding center of pressure (COP). For each subject and condition, data were collected for steps from their biological (sound) foot and prosthetic foot. We also conducted surveys after each condition to assess the subjects' preference and perception of each foot.

Kinetic and kinematic data suggest that our prototype performed just as well or better than commercial prosthetic feet in recreating able-bodied gait dynamics (Fig. 3). The LLTE design framework creates feet that move the shank along a target trajectory, defined by knee joint position and shank orientation, in response to a specific loading condition, defined by the GRF and its COP. For our prototype, the target shank trajectory and loading conditions were based on able-bodied dynamics; therefore, we compared the horizontal and vertical knee joint position, shank orientation, horizontal and vertical GRFs, and COP from the different foot conditions to that of the target able-bodied dynamics. While all the feet matched the target very well, for four out of the five subjects, the MIT foot had the lowest average normalized root mean square error over all of the target variables (Table 1). Additionally, the MIT foot saw greater horizontal forces during late stance, implying that our prototype provided a greater push off force the other prosthetic feet. The survey results indicated that in regards to comfort and performance, subjects rated their prescribed prosthetic foot the highest, with our prototype as a close second, and the College Park foot as the least preferred.

These favorable results suggest that our design framework is able to create high performance feet customized for users of different sizes through a quick optimization process. We can proceed confidently towards Major Goal 5 where we use the LLTE design framework to design multi-activity feet.

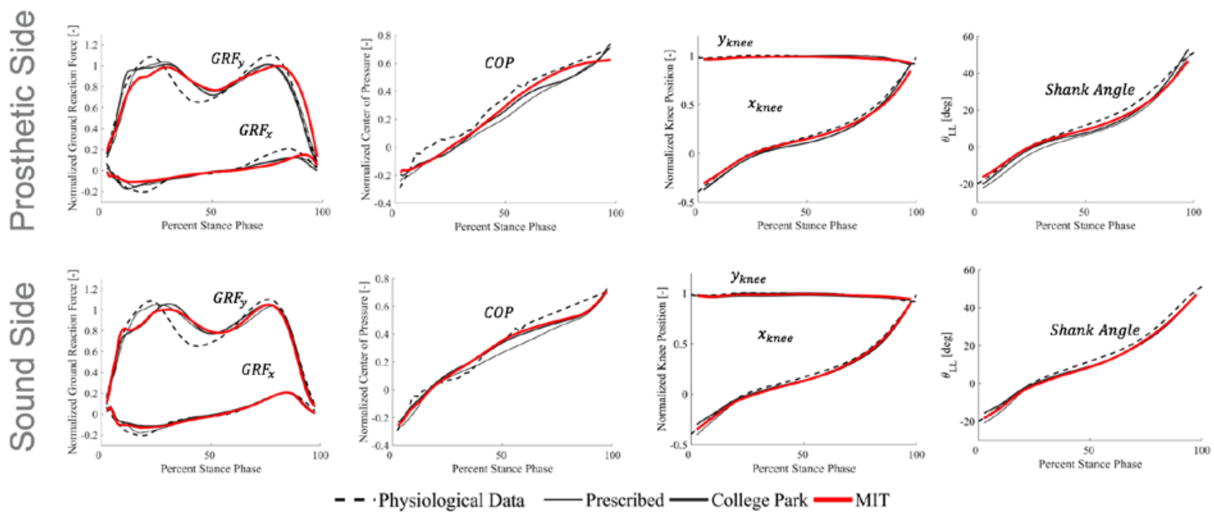

Figure 3. Gait data from five test subjects who tested MIT feet customized for their body size and weight using the LLTE framework (red line), their clinically prescribed feet (thin back line), and a common commercial foot made by College Park (the Horizon LT) (thick black line). All data are compared to the physiological reference data used to design and optimize the MIT with the LLTE framework (dashed line). GRF values are normalized by body weight, COP values are normalized by foot length, and *x* and *y* position data are normalized by shank length.

AVERAGED NRMSE	SUBJECT 1	SUBJECT 2	SUBJECT 3	SUBJECT 4	SUBJECT 5
Prescribed Foot	**0.053** ± 0.009	**0.085** ± 0.011	**0.064** ± 0.020	**0.078** ± 0.007	**0.076** ± 0.015
College Park Horizon LT	**0.055** ± 0.013	**0.078** ± 0.014	**0.067** ± 0.018	**0.081** ± 0.010	**0.086** ± 0.016
MIT Foot	**0.049** ± 0.007	**0.066** ± 0.006	**0.055** ± 0.013	**0.073** ± 0.012	**0.085** ± 0.018

Table 1: Deviation from able-bodied gait for each subject and foot condition as described by normalized root mean square error (NRMSE). NRMSE values are shown as the mean ± standard deviation.

Major Goal 4: Collect Able-Bodied Gait Data for Multiple Activities of Daily Living

Progress on Major Goal 4 has been hindered by a manufacturer equipment error. The problem has been resolved, and we intend to quickly complete Major Goal 4 in the first quarter of Year 3. Please see the Changes/Problems section for more details.

Major Goal 5: Design and Experimentally Validate a Multi-Activity Foot

Work on Major Goal 5 is scheduled to begin in Year 3. While we will rely on data collected for Major Goal 4, the data can be collected quickly from a convenience sample of able-bodied subjects, so work can begin with minimal delay.

Major Goal 1: Validate Clinical Algorithm

A severe delay in obtaining IRB approval in Year 1 prevented the validation of the clinical algorithm using human subjects. After approval was finally obtained at the beginning of Year 2, limited subject availability and lab time required the prioritization of research activities, and we decided to prioritize activities for Major Goal 3 because they best aligned with the overall goal of the project: designing and testing high performance prosthetic feet. We will have time to complete Major Goal 1 in Quarters 1 and 2 of Year 3, because the human subjects research involving amputees for Major Goal 5 will not begin until later in Year 3.

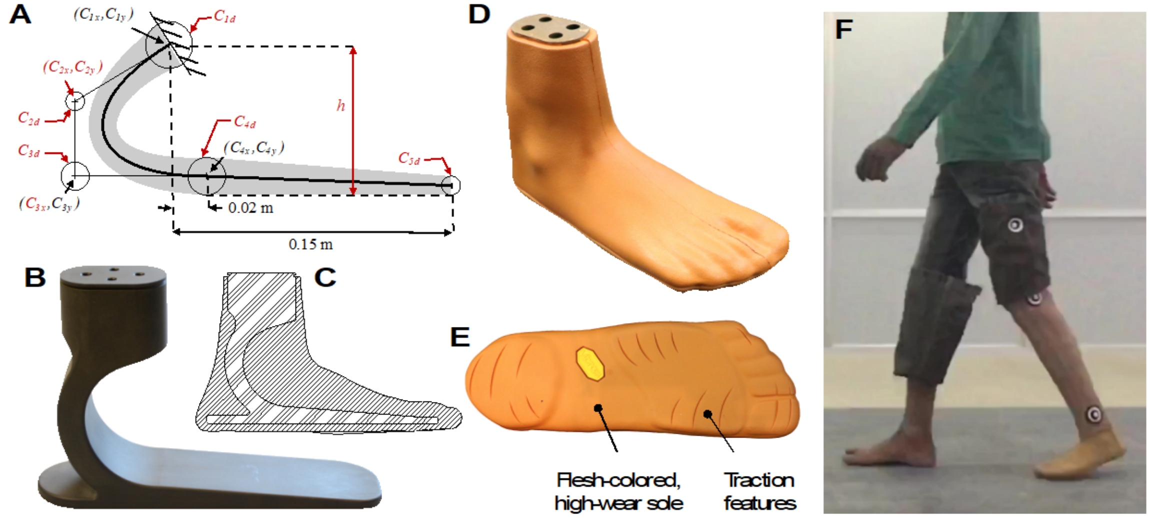

Figure 4. Creating a low-cost ESAR foot with the LLTE design framework. A) Single part foot geometry described by a wide Bézier curve with select variables shown in red. B) The resulting, optimized single part foot architecture, which can be packaged within C) a physiological envelope. D) The integrated single part foot and cosmesis, with E) foot sole by Vibram, designed to balance physiological aesthetics and traction. F) One of 15 subjects testing the foot in D) during 2019.

Other Activities

Although not listed in our statement of work, we have been developing a rugged cosmetic cover for our foot designs in collaboration with Vibram, the largest shoe sole manufacturer in America (Fig. 4). The cover consists of polyurethane foam molded over our prototype in the shape of a human foot. The cover also includes a durable rubber sole with grooves for traction that mimic the wrinkles in human feet. In January 2019, we began a field test of this cosmetic cover in Rajasthan, India in a partnership with the Jaipur Foot Organization, a charitable organization that provides free prosthetic care for people in India. Our original prototype was fitted with the cosmetic cover and distributed to twenty people with BKAs in India to use in their daily lives. In August 2019, we recovered five of the feet for a preliminary evaluation of their long term performance. We also interviewed the test subjects regarding the foot to better understand its advantages and limitations in activities of daily living. The feet showed no signs of breakage, and the users felt that they could walk faster on the prototype than their previous prosthesis. Subjects used the feet to perform manual labor such as working on a farm or pushing carts to and from markets and indicated that they were not too tired to complete their work while wearing our prototype. We will continue to recover more feet from the subjects so that we can perform a more thorough analysis in the future.

Additionally, we have begun a collaboration with Hanger, Inc., a leading distributor of prosthetic components in America and a major provider of prosthetic care. Hanger has expressed interest in both our design methods and prototypes, and they would make an excellent partner for distributing our technology to soldiers, veterans, and civilians, alike. They also provide valuable insights regarding the clinical and economic contexts our designs will need to operate within, which will be important for translating our technology to industry. Hanger has provided assistance in loaning us College Park Horizon LT feet for use in our evaluation of our prototype foot.

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

This project continues to provide Victor Prost with training in biomechanical research under the tutelage of Dr. Brett Johnson at MIT and Dr. Jenny Kent at Northwestern University. He has learned more about measurement systems and analysis techniques, including the calculation of mechanical flow of power through prostheses. Mr. Prost also continues to hone his presentation and writing skills through the preparation of informational slide shows, posters, and manuscripts.

Both Mr. Prost and Dr. Johnson have expanded their networks and knowledge in the field through conference attendance, including the Dynamic Walking Conference and the International Society for Prosthetics and Orthotics meeting.

Additionally, we are proud to announce that Prof. Amos Winter has received tenure at the Massachusetts Institute of Technology based in part on the work accomplished within this project.

How were the results disseminated to communities of interest?

Results from this research have been shared at conferences regarding biomechanics and prostheses, including Dynamic Walking and the International Society for Prosthetics and Orthotics.

Our work has also been featured on the O&P Edge website, which is a professional website and magazine for prosthetists and orthotists.

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

During Quarters 1 and 2 of Year 3, we will complete the measurements of able-bodied dynamics on stairs and ramps to accomplish Major Goal 4, as well as evaluate the clinical algorithm we use to customize our designs to user’s height and weight in accordance with Major Goal 1. During Quarters 2, 3, and 4, we will design and test a multi activity foot optimized for walking on level ground, stairs, and ramps.

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?

This project will likely have the largest impact on prosthetic foot design. The LLTE design method has the potential to revolutionize prosthetic foot design by providing evidence-based, quantitative principles to design feet for a desired biomechanical response, as opposed to empirically driven development cycles. **The results from this year strongly support the efficacy of the LLTE, where customized prostheses for individuals that perform as well as commercially available prosthetic feet were designed and manufactured in less than a day.** This project is also pushing the boundaries of passive prosthetic foot performance, where the goal is to provide a versatile passive prosthetic foot that can provide able-bodied like gait to persons with transtibial amputations for a variety of ambulatory tasks.

What was the impact on other disciplines?

This project will also further our understanding of passive dynamic walking, which is relevant to the field of biomechanics, by testing and evaluating the performance of passive prosthetic feet. The project will also contribute to the field of machine design by articulating how to create novel passive mechanisms and compliant structures that can generate complex reciprocating torque and kinematic profiles.

What was the impact on technology transfer?

One of the main goals of this project is to design high performance prosthetic feet that can be used to return soldiers with transtibial amputations to active duty, and transferring our technology to the US military will be a key outcome of this project.

The knowledge we generate in terms of customizing prosthetic feet to an individual's height and weight could also have a commercial impact, and we are actively exploring opportunities to incorporate our technology into the private prosthetic foot industry. Our new relationship with Hanger will help facilitate this process.

What was the impact on society beyond science and technology?

By providing high performance prosthetic feet, we can enhance the quality of life for soldiers and civilians alike. By improving the design of passive prosthetic feet, we are also providing feasible technologies for persons in developing countries to improve their quality of life. The need for high performance prostheses is large in developing countries, where stigmas around disabilities can limit employment opportunities for persons with amputations, as well as disrupt their social bonds and hinder them from forming new ones. Accessible prosthetic foot technology can significantly improve the lives of people in this group.

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

Nothing to report

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

Our progress on Major Goal 4 was severely delayed by a manufacturer error in the instrumented stairs that were purchased for this experiment. When struck, the stairs would vibrate at a frequency under 15 Hz, which is part of the band of frequencies that the biomechanical signals we measure occupy (Fig. 5). The vibrations from the stairs are transmitted to the force plates and add unwanted noise to the GRF and COP signals. Because the noise has a similar frequency to the signals of interest, it cannot be filtered out post processing. The staff at Northwestern University spent months documenting and identifying the source of the noise, as well trying to dampen the unwanted vibrations using foam and other materials. When no immediate solution was found they contacted the stairs manufacturer, AMTI, for assistance. AMTI had the stairs shipped to their facilities where they conducted tests to see if they could reproduce the errors that we reported. After verifying the error, AMTI's engineers stiffened the structure of the stairs by adding steel plates between the supports. These plates increased the frequency at which the stairs vibrated to above 40 Hz. The noise could then be filtered out of the force plate signals using a digital low pass filter in post processing. We are now confident in the accuracy of the measurements from the instrumented stairs and able to proceed with the collection of able-bodied gait data.

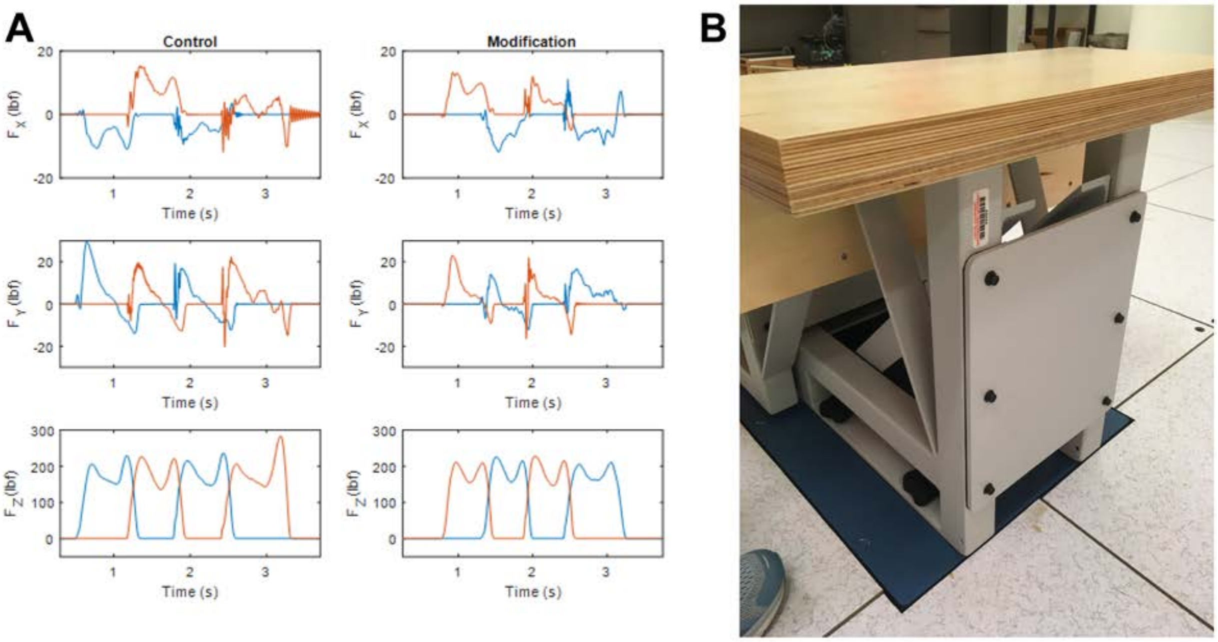

Figure 5: Correcting the error in measurements from instrumented stairs. **A)** Plots of the GRF components in the lateral (Fx), forward (Fy) and vertical (Fz) directions as measured from the instrumented stairs. Plots in the left column show data from the unmodified stairs, while plots in the right column show data after the stairs were modified. The sharp peaks and damped osciliations in Fx and Fy plots in the left column are errors introduced by vibrations from the stairs. After making the stairs more rigid, the peaks and oscillations are greatly diminished, as shown in the plots in the right column. **B)** Photograph of steel plates bolted across the stairs to increase their rigidity. Making the stairs more rigid caused them to vibrate at a higher frequency than the frequency band of the GRF signal, so that the vibration artifact could be filtered out of the measured signal during post processing.

Changes that had a significant impact on expenditures

Nothing to report

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

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Other publications, conference papers and presentations.

Conference Poster Presentation

Prost, V, Johnson, WB, Kent, J, Major, MJ, and Winter, AG. "Design and Testing of Passive Prosthetic Feet Optimized Using the Lower Leg Trajectory Error Metric." Proceedings from Dynamic Walking, June 3-6, 2019, Canmore, Canada

Conference Podium Presentation

Prost, V, Johnson, WB, Kent, J, Major, MJ, and Winter, AG. "Design and Testing of Passive Prosthetic Feet Optimized Using the Lower Leg Trajectory Error Metric." International Society for Prosthetics and Orthotics Congress, October 5-8, 2019, Kobe, Japan

- **Website(s) or other Internet site(s)**

  http://gear.mit.edu – This is the website for Prof. Winter's laboratory, the Global Engineering and Research (GEAR) Laboratory, where he lists his labs activities, accomplishments, and publications.

  https://opedge.com/Articles/ViewArticle/2018-08-22/field-trials-ready-for-custom-passive-prosthetic-foot. "Field Trials for Custom Passive Prosthetic Foot" Aug 22, 2018. *Not listed in the 2018 annual report*

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: *Amos Winter*
Project Role: *Principal Investigator*
Researcher Identifier: *ORCID ID: 0000-0002-4151-0889*
Nearest person month worked: *1.5*
Contribution to Project: *Oversaw the research for the design and development of the prototype test foot and prototype single part foot*

Name: *Matthew Major*
Project Role: *Principal Investigator*
Researcher Identifier: *ORCID ID: 0000-0002-2330-4619*
Nearest person month worked: *4*
Contribution to Project: *Oversaw Data Collection for major goal 3.*

Name: *Rebecca Stine*
Project Role: *Principal Investigator*
Research Identifier: *NA*
Nearest person month worked: *3*
Contribution to Project: *Facilitated subject recruitment and data collection.*

Name: *Jenny Kent, PhD*
Project Role: *Post-Doctoral Associate*
Research Identifier: *NA*
Nearest person month worked: *3*

Contribution to Project:	*Assisted with data collection, processed motion capture data, and analyzed the error in the instrumented stairs, liaised between MIT and Northwestern teams to facilitate data collection.*
Name:	*Victor Prost*
Project Role:	*Graduate Student*
Research Identifier:	*NA*
Nearest person month worked:	*12*
Contribution to Project:	*Improved prototype test foot design, manufactured the prototype test feet for subjects, assisted with data collection, analyzed data, managed the testing of a rugged cosmetic cover.*
Name:	*Brett Johnson*
Project Role:	*Research Engineer*
Research Identifier:	*NA*
Nearest person month worked:	*6*
Contribution to Project:	*Assisted with data collection and analysis, advised Mr. Prost in biomechanics, professional writing, and study design. Liaised between MIT and Northwestern teams to facilitate data collection.*

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

Nothing to Report

What other organizations were involved as partners?

Organization Name:	Vibram Corporation
Location of Organization:	18 School St, North Brookfield, MA, 01535
Partner's contribution to the project:	Designed cosmetic cover and rugged sole for prosthetic foot, and developed the manufacturing techniques to produce the foot and cover.
Organization Name:	The Jaipur Foot Organization
Location of Organization:	India, 13-A, Guru Nanak Path Malviya Nagar, Jaipur-302017, Rajasthan
Partner's contribution to the project:	Assisted with recruitment of subjects for field testing in India
Organization Name:	Hanger, Inc.
Location of Organization:	10910 Domain Drive, Suite 300, Austin, TX 78758
Partner's contribution to the project:	Provided College Park feet for prototype testing, and consultation on the clinical and economic contexts of the prosthetic industry

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.