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TITLE: Direct Quantification of Balance Amongst Limited Community Ambulators Using Microprocessor Prosthetic Knees

PRINCIPAL INVESTIGATOR: Adam Goodworth

CONTRACTING ORGANIZATION: Westmont College, 955 La Paz Road, Santa Barbara, CA 93117

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

Westmont College
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Approved for public release; distribution is unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT. Our research determines how trans-femoral (TF) prosthesis users with limited mobility (K2 ambulators) can leverage control features in a microprocessor knee (MPK) to improve balance. We plan to test 13 K2 ambulators in both standing and walking before, during, and after use of an MPK and compare these results to control subjects. We also aim to complete a scoping review of microprocessor technology for prosthetic feet. In this 2nd year, our major accomplishments include: 1) Pilot testing and testing of control subjects, 2) Development of perturbation treadmill at Westmont Lab, 3) Development of analysis programs from both standing and walking, 4) Progress in recruitment efforts, 5) Analyzed data from a set of control subjects, 6) Trained graduate students in data capture and literature review, and 7) Disseminated results via abstracts and one article. Dr. Goodworth and Mr. Felmlee remain in close communication about data collection, analyses, and recruitment. One challenge remains recruitment of older TF amputees, which was negatively impacted by COVID-19. However, we were able test 1 amputee in October 2021 and have a couple amputees planned to enroll in our study in coming months.

15. SUBJECT TERMS
balance, prosthetics, prosthetic knee, veteran amputee, limited mobility ambulatory (K2), trans-femoral (TF) microprocessor knee (MPK), neural control, feedback modeling, perturbation

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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 ability to balance one's body is a fundamental requirement to many activities of daily living. Poor balance leads to falling. The consequences of falling can be very serious, including reduced future mobility, injury, and even death. The purpose of our research is to use state-of-the-art perturbations to determine how trans-femoral (TF) prosthesis users with limited mobility (K2 ambulators) can leverage control features in a microprocessor knee (MPK) to improve balance. We plan to test 13 K2 ambulators in both standing and walking before, during, and after use of an MPK and compare these results to 13 age-matched control subjects. We test the hypothesis that limited mobility patients are able to improve balance with an MPK. More importantly, we use detailed experimental methods that also allow us to characterize how and why limitations may exist in the ability of prosthesis users to leverage the MPK technology. By understanding the benefits and limitations, we propose our investigation could lead to 1) improvements in the design of MPKs for K2 users, 2) specific rehabilitation to help K2 ambulators better use existing MPKs or 3) a realization of some fundamental limitations in the suitability of MPKs for K2 ambulators.

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

balance, prosthetics, prosthetic knee, veteran amputee, limited mobility ambulatory (K2), trans-femoral (TF) microprocessor knee (MPK), neural control, feedback modeling, perturbation testing, frequency domain

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.

SITE 1: Westmont College
SITE 2: University of Hartford

	Percentage Complete
<u>Specific Aim 1.</u> Experimentally test the reactive balance control system in trans-femoral prosthesis users with and without a micro-processor knee (MPK)	35%
Major Task 1. Prepare balance equipment for delivery of transient and continuous perturbations	100% (2/15/21)
Subtask 1. *Design and complete minor modifications to exiting programs and equipment for the current project.*	100% (2/15/21)
Subtask 2. *Quality control - complete tests with several lab members.*	100% (12/1/20)
Subtask 3. *Quality control - preliminary analysis of data to verify integrity of equipment and protocol.*	100% (12/1/20)

Major Task 2. Human subject testing of TF prosthesis users and control subjects.	40%
Subtask 1. *Local IRB/HRPO Approval.*	100% (7/1/2019)
Subtask 2. *Advertising and subject recruitment.* *If 7 TF and 7 control subjects are not recruited by month 8 of the grant, then we will expand our recruitment to additional facilities*	35%
Subtask 3. *Testing human subjects* *N=13 prosthesis users and N=13 younger non-prosthesis user control subjects and N=13 age-matched non-prosthesis controls*	35%
<u>Specific Aim 2.</u> Test the hypothesis that an MPK can improve reactive balance control in TF prosthesis users	30%
Major Task 3. Analyze & Interpret data for significant changes in dependent variables: prescribed knee vs MPK	25%
Subtask 1. *Create custom MATLAB program to analyze data*	90%
Subtask 2. *Analyze CoM dependent variables in continuous balance tasks* *Analyses are on-going, following the completion of testing each subject. This approach to analysis ensures rapid detection of any possible experimental error and ensures rapid progress in reaching goals.*	40%
Subtask 3*. Analyze individual body segment and stepping characteristics in both continuous and transient tests*	40%
Subtask 4*. Interpret, summarize, and disseminate results through a peer-reviewed journal (eg, J Biomechanics, Prosthetics and Orthotics International, Gait and Posture) and conference (eg, ISPGR, AOPA)*	25%
<u>Specific Aim 3.</u> Characterize human-device interactions and the balance control system with and without an MPK and correlate these results with clinical measures.	20%
Major Task 4. Develop and interpret results from a feedback model of standing posture control	30%
Subtask 1. *Modify existing feedback control models to account for prosthesis mechanics and control.*	80%
Subtask 2. *Use model to determine parameters across subjects and test conditions.*	40%
Subtask 3. *Interpret, summarize, and disseminate results.*	30%
Major Task 5. Correlate balance results with clinical measures and demographics	10%
Subtask 1. *Complete analysis with covariates, interpret, summarize, and disseminate results*	5%
<u>Specific Aim 4.</u> Identify state of the art effectiveness of human-device interaction in powered and microprocessor ankles (MPA)	60%
Major Task 6. Perform a systematic review of evidence surrounding MPA	60%
Subtask 1*. Identify search questions & gather articles*	90%
Subtask 2. *Extract relevant data*	60%
Subtask 3. *Interpret, summarize, and disseminate results*	20%

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.

Major Activities and Specific Objectives in Year 3:

In year 3, we made considerable strides in recruiting and testing amputee subjects and testing and analyzing data from healthy control subjects. In support of Aims 1-3, we tested three transformal amputees and completed testing of healthy controls. We trained a new set of research assistants and disseminated results to the scientific community. Analyses programs were refined to the point of high automation following clear data reduction protocols. We also modified the handrails of the treadmill to include a dual force sensor to measure the many instances where subjects need to grab the rail during the perturbation testing. During year 3, we also modified our testing protocol to overcome some of the challenges of a lengthy longitudinal design with K2 ambulators. Our new protocol still answers the main research questions but is more realistic for recruitment. Finally, in support of Aim 4, Mr. Felmlee and his students progressed in their systematic review related to the state of advanced/powered prosthetic ankle and foot componentry.

Significant Results:

Aims 1-3
We tested 3 transfemoral amputees in during perturbed treadmill walking, perturbed quiet standing, and clinical tests (eg, over ground walking), Figure 1.

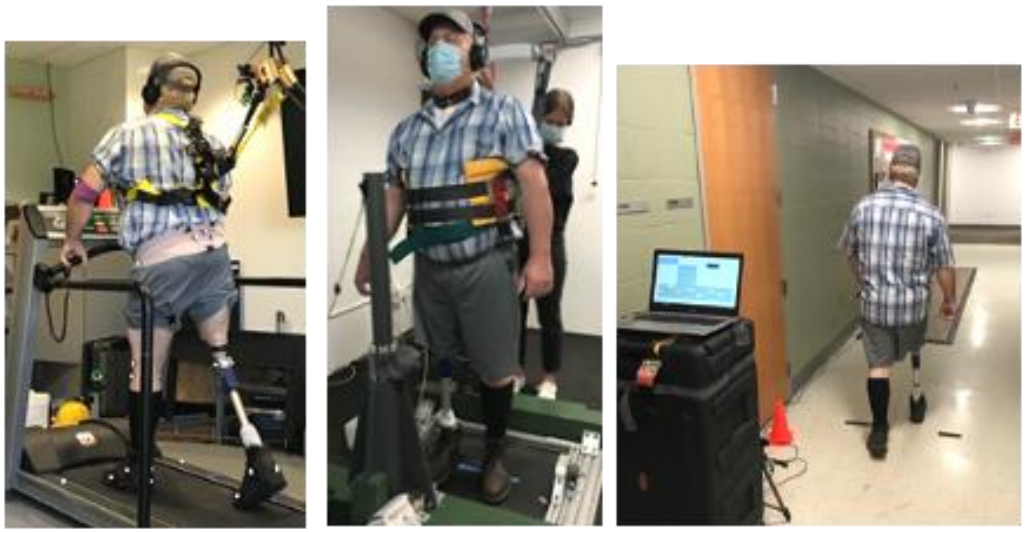

Figure 1: Photos of testing one TF amputee with a mechanical prosthetic knee. Left photo is the treadmill test where the platform rotates to elicit balance responses. The middle photo is the standing balance lab where the platform rotates up and down eliciting standing responses. The right photo is a clinical test with an instrumented mat.

Standing balance data has been analyzed using frequency domain methods and feedback control systems modeling (systems identification). To our knowledge, this is the first frequency based characterization of TF amputees in balance. We found one amputee exhibited adaptions (drift away from prosthesis) while using his prescribed knee but not his mechanical knee (Figure 2). This was only present during the perturbations trials.

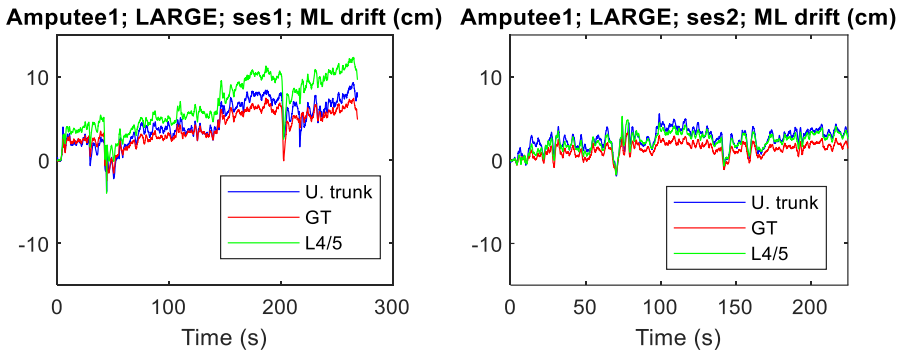

Figure 2. Medial-lateral drift through trial evident with MPK in session 1.

Figure 3 is a frequency response function for one amputee. Red lines are responses to small stimuli and blue are responses to large stimuli. Left plots are responses with MPK and the right are the mechanical knee. Changes in gain between stimulus amplitude means an adaptation occurred with both knees, such that the subject swayed relatively less during higher stimulus trials. The mechanical knee was associated with sharper increase in gains around 0.1Hz (note the log scale).

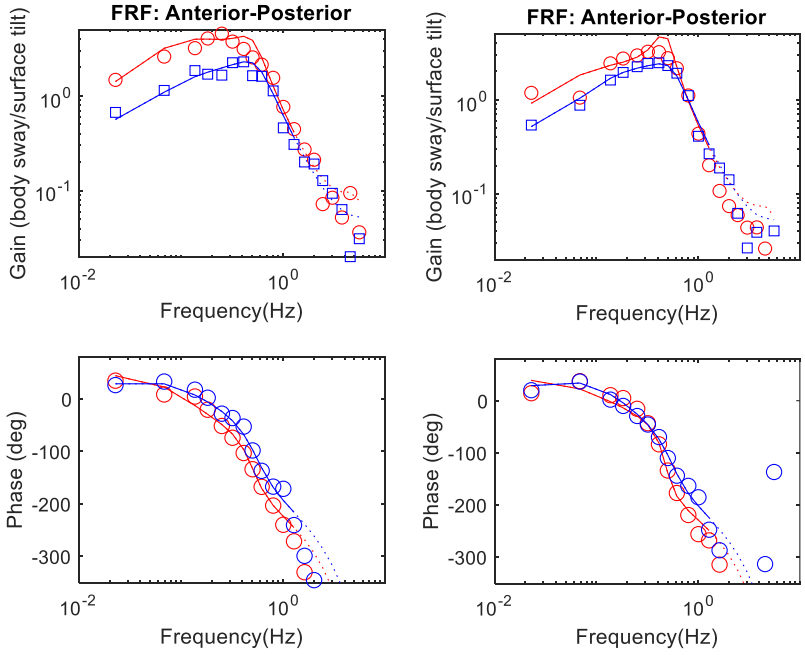

Figure 3. Frequency response functions for one amputee. Session 1 (MPK) on LEFT and Session 2 (Mechanical) on RIGHT. Red curves are small stimulus and blue are large stimulus.

We also used systems identification to determine the underlying feedback control processes used by participants during the test. This process involves using a parametric model that represents various processes where the parameters in the model are determined by fitting the model to experimental frequency-response function data. Figure 4 provides a schematic and basic overview of the model.

This overall process of data collection and analysis was repeated with healthy controls as a benchmark comparison. After collecting data from 22 control subjects, strong results emerged from the control subjects alone and we decided to concentrate efforts on preparing and submitting a major manuscript to Journal of Neurophysiology. In this manuscript, we showed how inter-subject variation in feedback control was a function of plane of motion and stimulus amplitudes, Figure 5.

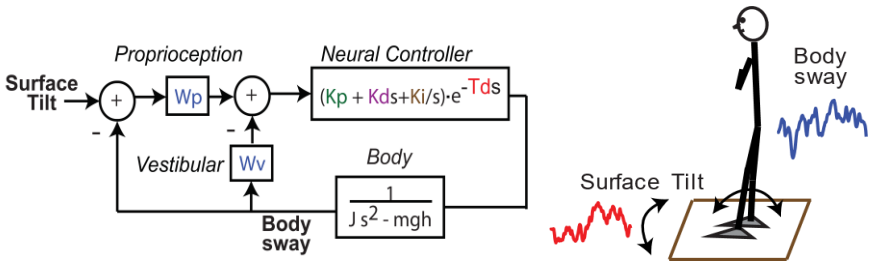

Figure 4. Standing balance and feedback model. Note the following interpretation of parameters.

Wp = proprioceptive feedback reliance (moves body toward feet)
Wv = vestibular feedback reliance (moves body upright)
Kp = "stiffness" causes torque in proportion to body sway.
Kd = "damping" causes torque in proportion to body sway velocity.
Ki = "integral" causes torque from body sway summed over time.
Td = time delay ("lumped", incl. neurological and passive effects)
J = inertia of body (measured through anthros)
mgh = mass (m) x g x center of mass height (h)

We found that subjects with a lower reliance on vestibular feedback and lower scaling of sensory to motor output (stiffness) had more sway and more sway velocity. Subjects with longer neural time delays also had more sway during perturbed standing balance tests.

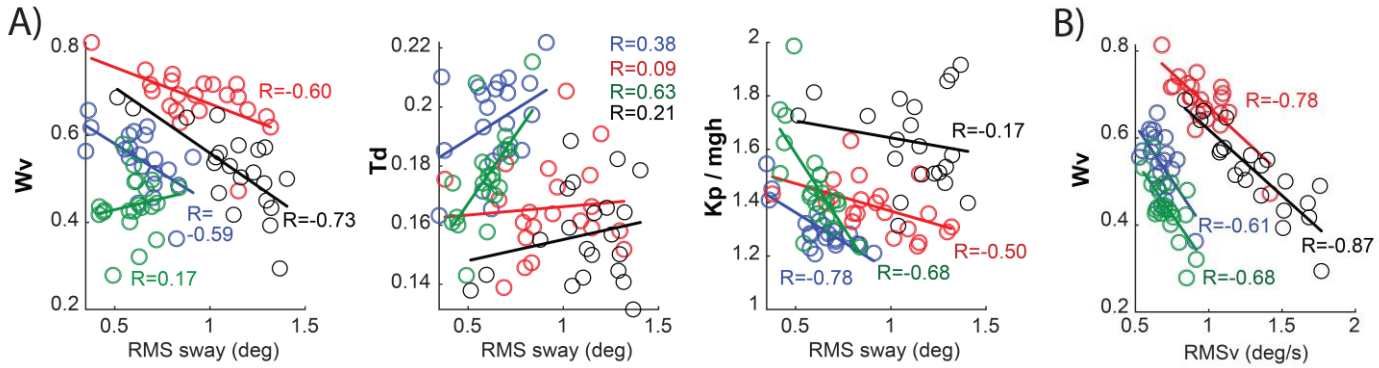

Figure 5. Sample of control parameters and how they correlate with observed body sway (zero mean root-mean-square, RMS) and body sway velocity (RMSv). Sensory reliance and stiffness (normalized by body size, mass x height x g = mgh) was generally negatively correlated while time delay was positively correlated.

We also examined the correlation between parameters because feedback control is not expected to result in just one individual parameter change. We found most combinations of parameters were not correlated. However, two parameters were highly correlated (stiffness and time delay). In particular, subjects with larger stiffness also exhibited shorter time delays, Figure 6.

Subjects were also tested in the perturbed walking protocol and their body sway, joint angles, and stepping characteristics were quantified. In some trials the platform was stationary (normal treadmill walking) and other tests the treadmill was perturbed with a small or large amplitude consisting of a sum of sine waves that appeared random to

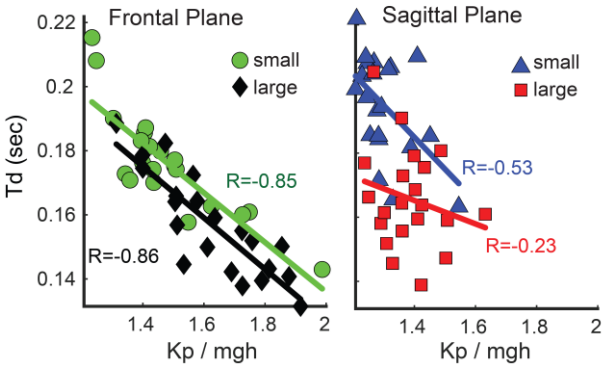

Figure 6. Correlations between time delay (Td) and stiffness (Kp) were strongest during frontal plane surface tilts.

subjects. Figure 3 shows a sample of our MATLAB program reconstruction of several key landmarks on the body and a sample output of the knee joint angle for one subjects. We calculated many metrics of gait and balance.

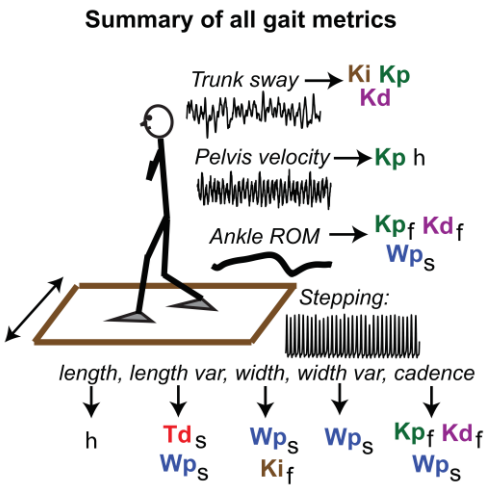

Figure 7. Summary of regression analysis showing the standing parameters that most accounted for gait metrics. "s" stands for sagittal plan and "f" is frontal.

Finally, we compared standing metrics to walking metrics and presented asked which feedback parameters are predictive of gait behavior. This project was presented at the International Society for Posture and Gait Research. We found as perturbation amplitude **increased**, there was found an **increase in trunk sway** (variability in frontal and sagittal planes), **increase in stance width** (variability and mean). This suggest subject responded to the surface stimulus by increasing variability of trunk with a wider and less consistent stance width. With increasing perturbation amplitude, there was **less knee and ankle range of motion** (peak-peak of average knee joint cycle) and **smaller step lengths**. Mapping these strategy changes in gait is a key benchmark to understanding transfemoral amputee results. Using regression analyses, we were not able to find a single model control parameter that accounted for across subject variability in gait parameters. We needed height (h) plus a combination of control parameters (Wp, Kp, Kd, Ki, or Td) to obtain R>0.7 in our regression analysis. Below in Figure 8 is a summary of the standing feedback parameters most associated with each gait metric. For example, variance across subejct in walking trunk sway most accounted for by the variance across subjects in standing control parameters Kp, Kd, and Ki (the sensory-to-motor scaling).

Aim 4

Mr. Felmlee's team has screened 3737 articles returned by our search strategy. We are currently in process of a full text review of the 134 peer-reviewed/published articles that meet our criteria. After quality scoring and risk-of-bias assessment, 74 full-text articles are being screened for theme extraction. The current categories (as extracted from 15 articles) for advanced foot/ankle classification are: non-microprocessor, microprocessor controlled, and powered. Sub-themes are at this time: gait speed, level and sloped walking, stumble/fall prevention, and patient perception. The next steps in this project are to continue to extract remaining themes and aggregate findings. Meta-analysis of objective and quantified characteristics is being considered for variables such as gait speed and clinically reported outcome measures such as the 10-meter walk test.

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.

During year 3, a total of 15 graduate students in the MSPO and DPT program at U of Hartford learned about 3D motion tracking, experimental design, data collection, and literature reviews. Three students also attended and presented at the national AOPA conference. Mr. Felmlee is a PhD student at University of Connecticut. He was progressed in his training on MATLAB programming and interpretation. He continues to lead the data collections and interface with clinical stakeholders. We also trained a new clinical faculty member in research data collection, Steve Charry, at the U of Hartford.

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.

1) One peer-reviewed manuscript submission: Goodworth A.D. & Felmlee. (in revision) Characteristics of inter-subject variability in feedback control of standing balance *Journal of Neurophysiology.*
2) Two external presentations: International: ISPGR (June 2022) and regional AAOP (Nov 3-5, 2021).
3) One internal presentations (U of Hartford).

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.

We will continue testing transfemoral amputees and a sample of older adults. Our analyses will focus on amputees data. We intend to prepare an abstract summarizing the amputee data to the ISPGR for the summer of 2023. In the fall each year, we also re-train a new group of research assistants in data collection and data reduction (marker tracking and labeling from our 3D motion capture system).

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

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

In examining inter-subject variance, we found several key correlations in feedback control with postural sway. These are an important contribution to the field of balance in their own right and provide a benchmark for comparisons with amputees. We also demonstrated that perturbed posture data can be reliably collected and interpreted in mid-to-low mobility transfemoral amputees. We discovered that many transfemoral amputees labeled K3 require a substantial amount of support when walking on the treadmill. This result has clinical implications in that a broad categorization of K3 can be misleading for an individual. As such, we incorporated a custom force sensor to measure hand forces on the rail and provide walkers biofeedback that may be helpful future researchers.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report during this project year

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to report

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

One piece of equipment (an old computer) failed in August of 2022. This computer contained programs that controlled out motion platform. Thus, testing was temporarily halted in order to recover the program files and install on a new computer with appropriate software. The update is nearly complete and we anticipate testing to resume Nov 1st, 2022.

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.

Cost for prosthetics componentry and travel was less than anticipated in year 3. Therefore, we requested and were approved a no-cost extension for 9/2022-9/2023. When this next period is complete, we will likely have some funds remaining to request a final extension into 9/2024.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report.

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

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

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Goodworth A.D. & Felmlee. Characteristics of inter-subject variability in feedback control of standing balance *Journal of Neurophysiology* (Submitted in Aug 2022, currently in revision)

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.*

Two external presentations: International: ISPGR (June 2022) and regional AAOP (Nov 3-5, 2021).

One internal presentations (U of Hartford).

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

  Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

  Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

  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".

Adam Goodworth (PI) worked about 2.7 person months during year 3 of the grant. Dr. Goodworth oversaw the analyses and overall project objectives.

Duffy Felmlee (PI on subcontract at Hartford) worked about 2.8 person months during year 3 of the grant. Mr. Felmlee oversaw the data collection and clinical collaborations.

Other undergraduate and graduate researchers worked on the project, but none reached the level of 1 person month.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

In year 3, a researcher associated with Ottobock continued collaborating on our Aim 4 – literature review. He will likely be a co-author on any publication that arises from that work.

8. SPECIAL REPORTING REQUIREMENTS

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

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

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