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TITLE: Improved Training Program for Fall Prevention of Warfighters with Lower Extremity Trauma

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CONTRACTING ORGANIZATION: Mayo Clinic, Rochester, MN

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14. ABSTRACT

In the current military and healthcare environment, it is essential to focus on rapid but safe development of functional skills with a goal of early discharge from rehabilitation to return to active duty or civilian life. Although the U.S. military has access to state-of-the-art treatment and devices, warfighters with lower extremity trauma still struggle to regain full functional capabilities. A key factor that limits the ability of these individuals to achieve maximum functional capabilities is falls. Falls have serious consequences including loss of confidence, fear of falling, and injury. Warfighters with lower extremity trauma need to face the risk of falling and overcome that fear. After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay healing. When individuals trip or slip, they are likely to fall and injure themselves, in spite of advances in rehabilitation care. This project develops a secondary rehabilitation program, implemented after traditional therapy, and designed to reduce falls in warfighters with amputations or limb preservation procedures. The goals of this research effort are to augment existing rehabilitation with a novel, demonstrably successful fall-prevention training method to help warfighters return to full high-level functional capabilities and emotional wellness, and to decrease the time required to either return to active duty or to a productive, active civilian life. The training program utilizes a microprocessor-controlled treadmill designed to deliver task-specific training perturbations. The training consists of six, 30 minute sessions delivered over a 4-week period. In the current year, 35 subjects have completed training.

15. SUBJECT TERMS
Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy

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Table of Contents

1. INTRODUCTION

After standard rehabilitation for amputation or limb salvage, many warfighters still struggle with falls, which can exacerbate physical and emotional injury and delay return to active duty or to a productive, active civilian life. Following a trip or slip, many warfighters are still likely to fall and injure themselves, in spite of advances in rehabilitation care. Adaptations due to the loss of function, while necessary, may also limit physical performance and reduce quality of life. This research project is a secondary rehabilitation program, implemented after and as augmentation to existing rehabilitation by providing advanced fall-prevention training, to help warfighters return to as close to full high-level functional capabilities and emotional wellness as possible, and to decrease the time required to either return to active duty or to a productive, active civilian life. The proposed novel training method has the potential to change the standard of care for lower extremity limb trauma.

2. **KEYWORDS:** Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy

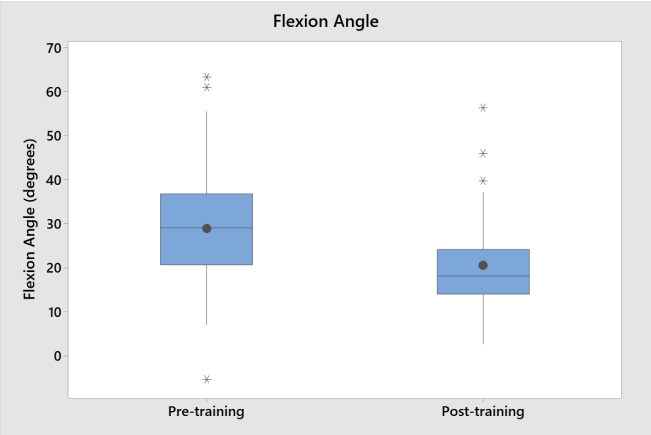
3. ACCOMPLISHMENTS

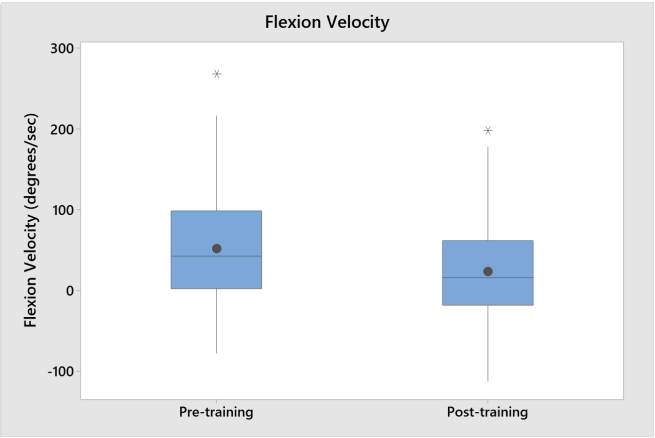
- **What were the major goals of the project?**
  This project has three main goals.
  (1) Implement a novel postural perturbation training program in the three DOD Medical Treatment facilities. This rehabilitation protocol will be provided to active-duty service members who have suffered combat-related lower limb trauma, specifically amputations or salvaged limbs.
  (2) Assess whether the benefits of improved motor skills induced by the rehabilitation protocols can be retained following training.
  (3) Identify, evaluate, and implement existing low cost methods for measuring trunk control that can be used in lieu of substantially more expensive fixed motion capture systems. This will ensure that the rehabilitation program can be transitioned to clinical settings.

- **What was accomplished under these goals?**
  The primary goal in this year of the study has been to finish recruitment and training.

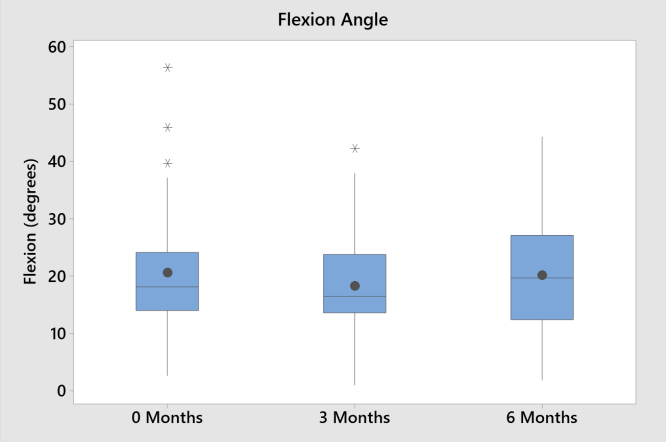
  Major activities:
  - 319 subjects have been screened, 55 subjects were eligible, 45 subjects have been enrolled, and 35 subjects have completed the training. The goal for the project was to enroll, train, and test 30 subjects.
  - 6 Abstracts have been presented at two national meetings and one regional meeting.

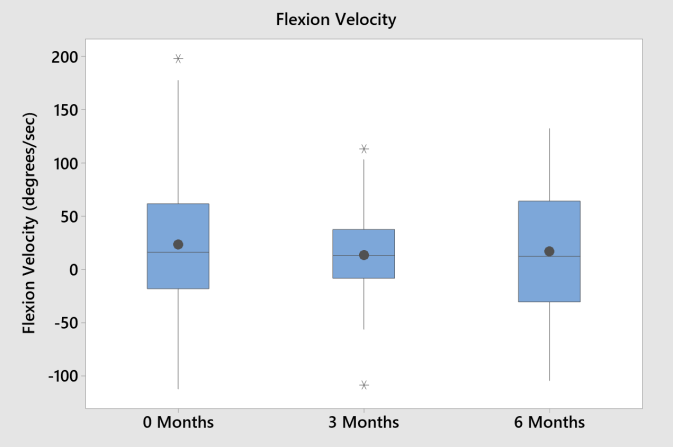
  Major findings
  - Post-training decreases in trunk flexion angle and velocity in an improvement in trunk control.





- Subject were evaluated immediately following training and then also at 3 and 6 months after training. The increased skill was retained at the 3 and 6 month assessments.





- **What opportunities for training and professional development has the project provided?**
  Nothing to report.

- **How were the results disseminated to communities of interest?**
  - 3 Abstracts presented at the Military Health System Research Symposium
  - 2 Abstracts presented at the American Society of Biomechanics Annual Meeting
  - 1 Abstract presented at the 12th Annual Joint National Capital Region Research Competition

- **What do you plan to do during the next reporting period to accomplish the goals?**
  - Finish analysis of all study results.
  - Submit papers describing the findings of the study.

4. IMPACT

- **What was the impact of the development of the principal discipline(s) of the project?**
  Nothing to report.

- **What was the impact on other disciplines?**
  Nothing to report.

- **What was the impact on technology transfer?**
  Nothing to report.

- **What was the impact on society beyond science and technology?**
  Nothing to report.

5. CHANGES/PROBLEMS

- **Changes in approach and reasons for change**
  No changes to report.

- **Actual or anticipated problems or delays and actions or plans to resolve them**
  There were significant delays in the beginning of the project. All issues have been resolved and we are nearing completion of subject enrollment.

- **Changes that had a significant impact on expenditures**
  Nothing to report.

- **Significant changes in use or care of human subjects**
  None.

6. PRODUCTS

- **Publications, conference papers, and presentations**
  Journal Publications:
  None

  Abstracts Presented:
  American Society of Biomechanics
  Title: Step Width Variables are not Meaningfully Correlated with Stumble or Fall Incidence in a High Functioning Population with Lower Limb Trauma
  Authors: Riley Sheehan, Mark Grabiner, Trevor Kingsbury, Brad Hendershot, and Kenton Kaufman

  Title: Evaluation of the Four Square Step Test as an Outcome Measure in a Fall Prevention Program
  Authors: Claire Z. Zai, Trevor D. Kingsbury, John-David Collins, Julianne Stewart, Riley Sheehan, Brad D. Hendershot, Christopher L. Dearth, Kenton Kaufman

  Military Health System Research Symposium
  Title: Fall-Prevention Training Program for Service Members with Lower Limb Trauma and Loss
  Authors: Kenton R. Kaufman, Emily J. Miller, Christine M. Huyber, Riley Sheehan, Mark D. Grabiner, Marilynn Wyatt, Claire Z. Zai, Trevor Kingsbury, Meghan L. Tullos, Brad D. Hendershot, and Christopher L. Dearth

  Title: Trunk neuromuscular control assessed in the lab is not correlated with perturbation recovery improvement following a trip training intervention
  Authors: Noel Guerrero, Riley Sheehan, Brad D. Hendershot, Trevor Kingsbury, Kenton Kaufman

Title: Evaluation of the Four Square Step Test as an Outcome Measure in a Fall Prevention Program
Authors: Claire Z. Zai, Trevor D. Kingsbury, John-David Collins, Julianne Stewart, Riley Sheehan, Brad D. Hendershot, Christopher L. Dearth, Kenton Kaufman

12th Annual Joint National Capital Region Research Competition
Title: Clinical Assessment of Trunk Postural Control within a Fall-Prevention Training Program for Persons with Lower Limb Trauma
Authors: B.D. Hendershot, J.C. Acasio, C.M. Butowicz, C.E. Mahon, M. Tullos, R.C. Sheehan, E. Miller, M. Wyatt, C.Z. Zai, J. Stewart, C.L. Dearth, M.D. Grabiner, K.R. Kaufman
[Finalist for Robert A. Phillips Award (top 4 of 209 submissions)- 2nd Place]

- **Website(s) or other Internet site(s)**
  Nothing to report.

- **Technologies or techniques**
  Nothing to report.

- **Inventions, patent applications, and /or licenses**
  Nothing to report.

- **Other products**
  Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Kenton Kaufman, PhD, PE
Project Role:	Principal Investigator, Mayo Clinic
Nearest person month worked:	2
Contribution to Project:	Dr. Kaufman held regular meetings with the Co-Investigators. He has prepared materials for the Mayo IRB and HRPO. He has developed the standard operating procedures for the research protocols. He has served as the liaison with the Grants Officer's Representative and has provided the required quarterly and annual reports.
Funding Support:	

Name:	Emily Miller, MS
Project Role:	Research Engineer, Mayo Clinic
Nearest person month worked:	2
Contribution to Project:	Emily Miller attended regular meetings with the Co-Investigators. She has worked to improve data analysis code and assure quality data.
Funding Support:	

Name:	Christine Huyber, CCRP
Project Role:	Kinesiologist, Mayo Clinic
Nearest person month worked:	1
Contribution to Project:	Christine Huyber attended regular meetings with the Co-Investigators. She has continued to provide expertise for REDCap data collections from all institutions performing subject recruitment and training.
Funding Support:	

Name:	Marilynn Wyatt, MA, PT
Project Role:	Site Principal Investigator, NMCSD
Nearest person month worked:	1
Contribution to Project:	Ms. Wyatt is the NMCSD site principal investigator for the project. She has attended all study meetings with the other Co-Investigators and coordinates the work being accomplished at Naval Medical Center San Diego (NMCSD). The focus this year has been on data verification, subject follow-up questionnaires in lite of the Covid-19 shutdown and work towards dissemination.
Funding Support:	Grant/Geneva Foundation sub award

Name:	Taylor Henderson, BS
Project Role:	Engineer, NMCSD
Nearest person month worked:	1
Contribution to Project:	Ms. Henderson served as an engineer for the project. She has served as needed to keep the hardware and software in order for data collection. Ms. Henderson transitioned off the project after the first quarter of this fiscal year.
Funding Support:	Grant/Geneva Foundation sub award

Name:	John-David Collins, MA, ATC
Project Role:	Biomechanist/AI, NMCSD
Nearest person month worked:	1
Contribution to Project:	Mr. Collins served as an Associate Investigator for the project working as the research biomechanist for NMCSD. His role was to oversee the recruitment, data collection, training and long term follow-up for the project. He transitioned off the project after the first quarter of this fiscal year.
Funding Support:	Grant/Geneva Foundation sub award

Name:	Claire Zai, MS
Project Role:	Clinical Research Coordinator/ Researcher, NMCSD
Nearest person month worked:	4
Contribution to Project:	Ms. Zai serves as the protocol coordinator for NMCSD. Ms. Zai has attended all meetings, teleconferences and training sessions. She has coordinated all testing sessions and subject contact. She has completed all IRB documentation including but not limited to deviations, amendments and personnel changes and documents for HRPO reviews and IRB renewals. She had documented all session data and organized it

	appropriately in online databases. A major focus has been on long term follow-up mostly by way of digital questionnaires due to Covid-19 pandemic. She has been instrumental in the data verification process. Specifically, she has reprocessed all the data from the site to increase data accuracy and reflect all changes made in post processing.
Funding Support:	Grant/Geneva Foundation sub awards

Name:	Julianne Stewart, PT, DPT
Project Role:	Research Physical Therapist, NMCSD
Nearest person month worked:	8
Contribution to Project:	Dr. Stewart served as the research physical therapist for this project. She has attended all in-person meetings and teleconferences with co-investigators. She assisted with subject screening and scheduling as well as REDCap data entry. During subject assessments at NMCSD she was responsible for the subject consent process as well as questionnaire administration, PT Evaluation completion, and providing clinical supervision of the patient's status during treadmill assessments. She transitioned off the project August 31, 2020.
Funding Support:	Grant/Geneva Foundation sub awards

Name:	Trevor Kingsbury, MS
Project Role:	Biomechanist/AI, NMCSD
Nearest person month worked:	1
Contribution to Project:	Mr. Kingsbury has provided project support as a biomechanist and onsite supervisor providing day-to-day oversite of staff, scheduling and recruitment. He is the site PI for all IRB matters. He has attended all project meetings and has supervised the staff collecting the data and maintaining the regulatory records. He is involved in the data verification process and work towards dissemination.
Funding Support:	Federal Employee

Name:	Riley C. Sheehan, PhD
Project Role:	Site Principal Investigator, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	5
Contribution to Project:	Dr. Sheehan serves as the site lead at the CFI. During the current reporting period, Dr. Sheehan has participated in regular teleconferences with Co-Investigators. He has assisted with successfully completing data collection. He also coordinated data processing efforts. He has also prepared conference abstracts and manuscripts based on study findings. He has also coordinated the administration of the Henry Jackson Foundation sub-award for the effort at the CFI.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Noel Guerrero, BS
Project Role:	Research Assistant, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	4
Contribution to Project:	Mr. Guerrero is the Research Assistant at the CFI for the project. During the current reporting period, Mr. Guerrero has participated in regular teleconferences with Co-Investigators. He has also assisted in scheduling of participants, data collection, and data processing. Additionally, he has prepared a conference abstract based on study findings.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Jonathan Wilson, PT, DPT
Project Role:	Research Physical Therapist, Center for the Intrepid, Brooke Army Medical Center
Nearest person month worked:	4
Contribution to Project:	Mr. Wilson is the Research Physical Therapist at the CFI for the project. During the current reporting period, he has assisted with data collection and training sessions.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Christopher L. Dearth, PhD
Project Role:	Site Principal Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Dr. Dearth serves as the WRNMMC site lead for the project. During the current reporting period, Dr. Dearth has participated in all study meetings, and engaged in discussions with WRNMMC clinical and research staff to ensure successful continuation of study activities. He has also co-authored two manuscripts that are pending peer review.
Funding Support:	Federal Employee

Name:	Bradford D. Hendershot, PhD
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Dr. Hendershot serves as an Associate Investigator for the project. During the current reporting period, Dr. Hendershot has participated in all study meetings, and engaged in discussions with WRNMMC clinical and research staff to ensure successful continuation of study activities. He has also co-authored two manuscripts that are pending peer review.
Funding Support:	Federal Employee

Name:	Julian Acasio, MS
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	4

Contribution to Project:	Mr. Acasio serves as an Associate Investigator for the project. Mr. Acasio has been crucial in the data processing and re-processing efforts. Mr. Acasio co-authored two manuscripts that are pending peer review. Mr. Acasio has assisted clinical staff in most data collections during this reporting period.
Funding Support:	Henry M. Jackson Foundation Sub-Award

Name:	Caitlin Mahon, MS
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	1
Contribution to Project:	Ms. Mahon serves as an Associate Investigator for the project. During the current reporting period, Ms. Mahon has assisted clinical staff with data collection and patient coordination. She has also co-authored two manuscripts that are pending peer review.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Meghan Tullos, PTA, CBDT
Project Role:	Associate Investigator, Walter Reed National Military Medical Center
Nearest person month worked:	7
Contribution to Project:	Ms. Tullos serves as an Associate Investigator for the project. During the current reporting period Ms. Tullos has been the primary clinician for the WRNMMC study site. She has co-authored two manuscripts that are pending peer review. Ms. Tullos has led the effort in patient coordination and scheduling.
Funding Support:	Henry M. Jackson Foundation Sub-award

Name:	Mark D. Grabiner, PhD
Project Role:	Site Principal Investigator, University of Illinois-Chicago
Nearest person month worked:	1
Contribution to Project:	Dr. Grabiner attended the regularly scheduled meetings with the research team. The project-based work at UIC is focused on post-collection analysis of biomechanical data collected at and transferred from Mayo, NMCSD, CFI, and WRNMMC.
Funding Support:	

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  No.

- **What other organizations were involved as partners?**
  Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

- **Collaborative Awards**

- **Quad Chart**

9. APPENDICES