

AWARD NUMBER: W81XWH-15-2-0071

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

PRINCIPAL INVESTIGATOR: Kenton Kaufman, PhD, PE

CONTRACTING ORGANIZATION: Mayo Clinic

REPORT DATE: October, 2019

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

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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, we have enrolled 35 subjects and 14 subjects have completed training | | | | | |
| 15. SUBJECT TERMS Amputation, Limb Salvage, Falls, Fall Prevention, Rehabilitation, Therapy | | | | | |
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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.

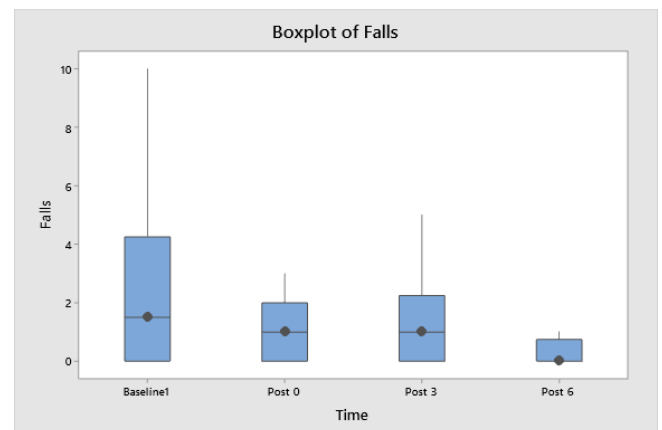
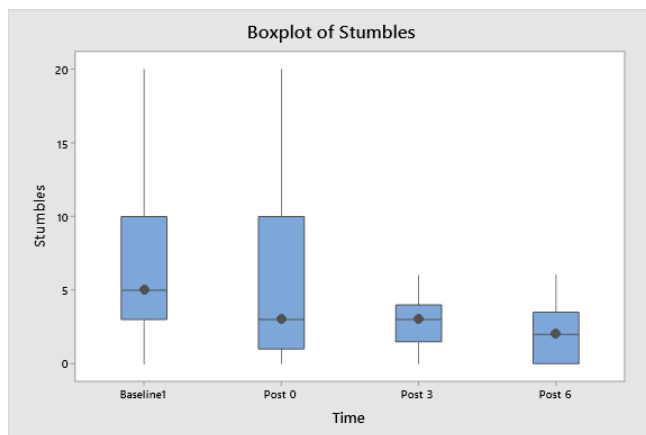
• What was accomplished under these goals?

The primary goal in this year of the study has been to recruit and enroll subjects.

Major activities:

- Data collection is well underway. 319 subjects have been screened, 72 subjects were eligible, 36 subjects have been enrolled, 22 are currently being trained, and 14 subjects have completed the training. The goal for the project is to enroll, train, and test 30 subjects.

The training has demonstrated a reduction in stumbles and falls.



- 4 Abstracts have been presented at two national and one international meeting.
- 2 manuscripts have been published this year.
- **What opportunities for training and professional development has the project provided?**
Nothing to report.
- **How were the results disseminated to communities of interest?**
 - 2 Abstracts presented at the Military Health System Research Symposium
 - 1 Abstract presented at Society of Clinical Research Associates
 - 1 Abstract presented at the International Society of Biomechanics
 - 2 Manuscripts published
- **What do you plan to do during the next reporting period to accomplish the goals?**
 - Complete data collection.
 - Analyze results.
 - Submit a paper 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:

Miller EJ; Kaufman KR. Comparison of overhead harness configurations for measuring trunk kinematics during treadmill disturbances. *Gait & Posture*. 68:15-17, 2019 Feb.

Miller EJ, Kaufman KR. Cross-sectional validation of inertial measurement units for estimating trunk flexion kinematics during treadmill disturbances. *Medical Engineering & Physics*, 70:51-54, 2019 Aug.

Abstracts Presented:

Kenton R. Kaufman, Joseph J. Wick, Christine M. Huyber, Riley Sheehan, Mark D. Grabiner, Marilynn Wyatt, Claire Z. Zai, Meghan L. Tullos, Brad D. Hendershot, and Christopher L. Dearth. Development of an Integrated Platform for Performing Multi-Center Extremity Trauma and Rehabilitation Research. Presented at 2019 Military Health System Research Symposium, August 19-22, Kissimmee, FL.

Brad D. Hendershot, Julian C. Acasio, Courtney M. Butowicz, Caitlin E. Mahon, Meghan Tullos, Riley C. Sheehan, Emily Miller, Marilynn Wyatt, Clair Z. Zai, Jules Stewart, Christopher L. Dearth, Mark D. Grabiner, and Kenton R. Kaufman. Clinical Assessment of Trunk Postural Control within a Fall-Prevention Training Program for Service Members with Lower Extremity Trauma and Limb Loss. Presented at 2019 Military Health System Research Symposium, August 19-22, Kissimmee, FL.

Kenton R. Kaufman, Joseph J. Wick, Christine M. Huyber, Riley Sheehan, Mark D. Grabiner, Marilynn Wyatt, Claire Z. Zai, Meghan L. Tullos, Brad D. Hendershot, and Christopher L. Dearth. Development of an Integrated Platform for Performing Multi-Center Extremity Trauma and Rehabilitation Research. Presented at Society of Clinical Research Associates Annual Conference, September 27-29, 2019, San Antonio, TX.

Miller EJ, Kaufman KR. Cross-sectional validation of inertial measurement units for estimating trunk flexion kinematics during treadmill disturbances. Presented at XXVII Congress of the International Society of Biomechanics, July 31 – August 4, 2109, Calgary, Canada.

- **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: | |

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|------------------------------|--|
| 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 conducted tests to validate the trunk kinematics from the IMUs vs motion capture. She has published two manuscripts. She presented these findings from one of the manuscripts at the 2019 International Society of Biomechanics meeting. |
| Funding Support: | |

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| 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: | |

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| Name: | Marilynn Wyatt, MA, PT |
| Project Role: | Site Principal Investigator, NMCS D |
| Nearest person month worked: | 1 |
| Contribution to Project: | Ms. Wyatt is the NMCS D 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 (NMCS D). The focus this year has been on treadmill issues and once resolved, subject recruitment, training and long term follow-up. |
| Funding Support: | Federal Employee (11 months)/transitioned to Grant/Geneva Foundation sub award 1 September 2018. |

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| Name: | Taylor Henderson, BS |
| Project Role: | Engineer, NMCS D |

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| Nearest person month worked: | 1 |
| Contribution to Project: | Ms. Henderson serves as an engineer for the project. She has worked on technical aspects of the project for NMCS D and attends meetings with co-investigators. Her effort has focused on resolving belt slipping issues with the NMCS D treadmill. |
| Funding Support: | Grant/Geneva Foundation sub award |

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| Name: | John-David Collins, MA, ATC |
| Project Role: | Biomechanist/AI, NMCS D |
| Nearest person month worked: | 1 |
| Contribution to Project: | Mr. Collins serves as an Associate Investigator for the project working as the research biomechanist for NMCS D. His role is to oversee the recruitment, data collection and training for the project. Additionally he has contributed to any troubleshooting efforts and any administrative duties needed. He worked with Taylor Henderson to resolve treadmill issues. |
| Funding Support: | Grant/Geneva Foundation sub award |

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| Name: | Claire Zai, MS |
| Project Role: | Clinical Research Coordinator/ Researcher, NMCS D |
| Nearest person month worked: | 1 |
| Contribution to Project: | Ms. Zai serves as the protocol coordinator for NMCS D. 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 subject recruitment and long term follow-up. |
| Funding Support: | Grant/Geneva Foundation sub awards |

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| Name: | Julianne Stewart, PT, DPT |
| Project Role: | Research Physical Therapist, NMCS D |
| Nearest person month worked: | 1 |
| Contribution to Project: | Dr. Stewart serves as the research physical therapist for this project. She has attended all in-person meetings and teleconferences with co-investigators. She assists with subject screening and scheduling as well as REDCap data entry. During subject assessments at NMCS D she is 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. |
| Funding Support: | Grant/Geneva Foundation sub awards |

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| Name: | Trevor Kingsbury, MS |
| Project Role: | Biomechanist/AI, NMCS D |
| Nearest person month worked: | 1 |
| Contribution to Project: | Mr. Kingsbury, a DoD civilian employee, has been involved in |

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| | the project since inception. He has attended all investigator meetings. Mr. Kingsbury has provided project support as a biomechanist and onsite supervisor providing day-to-day oversight of staff, scheduling and recruitment. He is the site PI for all IRB matters. He has assisted during subject data collection, has assisted with the troubleshooting of the treadmill, and has assisted in the preparation of the IRB documents. He worked with others to resolve treadmill issues. |
| Funding Support: | Federal Employee |

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| Name: | Pinata Sessoms, PhD |
| Project Role: | Site Principal Investigator, Naval Health Research Center |
| Nearest person month worked: | 1 |
| Contribution to Project: | Dr. Sessoms is the NHRC site lead for the project. During the current reporting period, Dr. Sessoms has participated in the regularly scheduled meetings with Co-Investigators and has served as liaison to key personnel at NHRC, helping to obtain the needed approvals from NHRC personnel for the multi-site IRB protocol. |
| Funding Support: | BUMED |

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| Name: | Riley C. Sheehan, PhD |
| Project Role: | Site Principal Investigator, Center for the Intrepid, Brooke Army Medical Center |
| Nearest person month worked: | 6 |
| 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 data collection and training sessions. 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 |

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| Name: | Andrea Ikeda |
| Project Role: | AI, Center for the Intrepid, Brooke Army Medical Center |
| Nearest person month worked: | 2 |
| Contribution to Project: | Ms. Ikeda has participated in regular teleconferences with Co-Investigators as well as assisting with participant recruitment and data collection. |
| Funding Support: | Federal Employee |

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| Name: | Noel Guerrero, BS |
| Project Role: | Research Assistant, Center for the Intrepid, Brooke Army Medical Center |
| Nearest person month worked: | 6 |
| 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 recruitment and scheduling of participants, and data collection and processing. |

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| 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: | 5 |
| Contribution to Project: | Mr. Wilson has assisted with data collection and training sessions. |
| Funding Support: | Henry M. Jackson Foundation Sub-award |

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| 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, coordinated equipment orders/deliveries/install, and engaged in discussions with WRNMMC clinical and research staff to ensure continued subject enrollment and data collection in the upcoming year. Dr. Dearth has submitted all paperwork in order to obtain approval for a no cost extension for project. Dr. Dearth was an author on two poster presentations (noted above) that were presented at the Military Health System Research Symposium. |
| Funding Support: | Federal Employee |

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| 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, assisted with the coordination of equipment orders/deliveries/install, and engaged in discussions with WRNMMC clinical and research staff to ensure continuation of subject enrollment and data collection in the upcoming year. He has also led the development and validation of a trunk postural control assessment device and testing protocol with corresponding SOP to be used at all sites. Dr. Hendershot was an author on two poster presentations (noted above) that were presented at the Military Health System Research Symposium. |
| Funding Support: | Federal Employee |

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| Name: | Elizabeth Husson, CCRC |
| Project Role: | Associate Investigator, Walter Reed National Military Medical Center |
| Nearest person month worked: | 1 |
| Contribution to Project: | Ms. Husson serves as an Associate Investigator for the project |

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| | working as the research coordinator for WRNMMC (until employment ended 04/01/2019). During the current reporting period Ms. Husson has participated in all study meetings, assisted with the coordination of equipment orders / deliveries / install and assisted with the creation of documentation for the clinical research protocol that was submitted to the NMCS D IRB and HRPO and subsequent modifications to the IRB protocol. |
| Funding Support: | Federal Employee |

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| 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 with data collection during training and assessments of research subjects. She has helped with training of RA staff to ensure appropriate coverage during data collections for collections she was unavailable. Ms. Mahon was an author on a poster presentation ("Clinical Assessment Of Trunk Postural Control Within A Fall-prevention Training Program For Service Members With Lower Extremity Trauma And Limb Loss") that was presented at the Military Health System Research Symposium. |
| Funding Support: | Henry M. Jackson Foundation Sub-award |

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| Name: | Meghan Tullos, PTA, CBDT |
| Project Role: | Associate Investigator, Walter Reed National Military Medical Center |
| Nearest person month worked: | 12 |
| Contribution to Project: | Ms. Tullos serves as an Associate Investigator for the project. During the current reporting period Ms. Tullos has participated in all study meetings, coordinated and assisted with Treadmetrix treadmill troubleshooting to ensure it is working properly for training. Ms. Tullos has recruited 14 participants (12 of which are actively enrolled). Additionally, Ms. Tullos has had 11 of 12 subjects complete training and 6 of 12 subjects have completed the entire protocol to date. Ms. Tullos has set up and facilitated run throughs with RAs to ensure all staff are able to assist with data collection as needed. Ms. Tullos has completed all data processing as outlined in the protocol and worked with Emily Miller to troubleshoot processing code in MatLab. Ms. Tullos was an author on two poster presentations (noted above) that were presented at the Military Health System Research Symposium. |
| Funding Support: | Henry M. Jackson Foundation Sub-award |

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| Name: | Mark D. Grabiner, PhD |
| Project Role: | Site Principal Investigator, University of Illinois-Chicago |

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| 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, NMCSO, CFI, and WRNMMC. |
| Funding Support: | |

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| Name: | Jason Wilken, PT, PhD |
| Project Role: | Collaborator, University of Iowa |
| Nearest person month worked: | 1 |
| Contribution to Project: | Dr. Wilken previously was the Site Principal Investigator at CFI. He participated in all regularly scheduled meetings. He supervised treadmill acquisition and worked on obtaining regulatory approval. He is now at the University of Iowa. He will continue to participate in regularly scheduled meetings. |
| 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