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14. ABSTRACT

The U.S. military is currently fitting amputees with state-of-the-art prosthetic devices. In addition to walking and changing direction on a variety of surfaces, amputees must be able to manage uneven terrain, crowded environments, stairs, ramps, and hills. The largest problem for a lower extremity amputee is falls. Among individuals with a lower extremity amputation, 52% reported having fallen in the previous 12 months, 49% reported being fearful of falling, and 65% had low balance confidence scores. Falling history and balance confidence are associated with reduced mobility capability and social activity. As a result, lower extremity amputees with limited balance and stability are at risk for diminished quality of life. The goal of this research effort is to rehabilitate lower extremity amputees to reduce falls using a novel training method. In this first year of the research effort, we have developed a novel experimental method to induce unexpected trips to amputees under controlled laboratory conditions. We have identified objective biomechanical variables that are causally related to the success or failure in avoiding a fall after a trip, objective tests to quantify functional outcomes, and a subject-specific questionnaire to determine if the training method is effective. Enrollment has begun. Our target is to deliver a quantitatively derived, deployment-ready, advanced gait rehabilitation system that can improve functional outcomes and/or shorten the time required for injured servicemen and women to return to active duty or to a productive civilian life.

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Introduction

The US global war on terrorism has resulted in many US warfighters sustaining extremity injuries. The US military is currently fitting amputees with state-of-the-art prosthetic devices. While amputees may try to focus on the advanced technology to try to solve some of the adjustment issues, “high tech” does not always equate to “high function”. In addition to walking and changing direction on a variety of surfaces, amputees must be able to manage uneven terrain, crowded environments, stairs, ramps, and hills. The key factor that limits the ability of amputees to achieve maximum functional capabilities is falls. Among individuals with a lower extremity amputation, 52% reported having fallen in the last 12 months, 49% reported being fearful of falling, and 65% have low balance confidence scores. Falls in lower extremity amputees can have serious consequences, including loss of confidence, fear of falling, and injury. As a result, lower extremity amputees with limited balance and stability are at risk for diminished quality of life. The goal of this research effort is to rehabilitate lower extremity amputees to increase trust in their prosthesis and reduce falls by using a novel training method. Deliverables include a quantitatively derived, deployment ready, advance gait rehabilitation system and method that can improve functional outcome and/or shorten the time required for injured service men and women to return to active duty or to a productive civilian life.

Body

This was the first year of a research effort to develop and test a novel training technique aimed at increasing and/or accelerating the functional capabilities of lower extremity amputees and enhancing their return to active duty or a productive civilian life. An interdisciplinary group from four institutions was formed to collaborate on this project. Our study has three main objectives. First, we will determine if the rehabilitation protocol improves the dynamic stability during postural disturbances in individuals who have previously completed a conventional training protocol. Second, we will determine if the new rehabilitation protocol can reduce the time required for rehabilitation of amputees to reach maximum functional improvement. Third, we will assess if the training can be retained.

Our efforts in this first year have been to install the equipment necessary for conducting this study, determine the appropriate training protocol for amputees, educate research personnel on the theory and application of the training protocol, and establish appropriate measureable outcome measures. The training protocol is based on a treadmill platform that can deliver a postural disturbance to an individual under static, e.g. standing, or dynamic, e.g. walking, conditions. The treadmill was ordered and installed. A user’s manual was developed to instruct research personnel on the treadmill platform and training protocol. The manual consists of an introduction to the theory and background and serves as a foundation for the rehabilitation of lower extremity amputees, introduction to the treadmill capabilities, introduction to the rehabilitation protocol, and a step-by-step standard operating procedure to conduct the training protocol. Research personnel were hired and trained. A CRADA was established for data sharing between the institutions. A research protocol was written and submitted for review. The protocol has been approved by the Institutional Review Board of all four institutions involved and the Office of Human Research Protection at USAMRC.

The test methods to evaluate primary and secondary outcome variables have also been developed. The primary outcome variable will be whether the outcome of an induced tripping protocol is a recovery or a fall. The testing protocol was developed using a virtual reality environment in the Human Performance Laboratory at the Naval Health Research Center-San Diego. Gait kinematic characteristics are analyzed to assess dynamic postural stability. These outcome variables include trunk kinematics, fractal analysis of walking characteristics, and the dynamic stability margin. In addition, the comprehensive high-level mobility predictor (CHAMP) test is being used as a functional outcome measure. This test was previously developed collaboratively with the DoD Medical Treatment Facilities. It is designed as a performance-based outcome measure for high-level activity and to determine readiness to return to duty. This testing method has several advantages. First, it

has been developed specifically for military amputees. Second, there is no floor or ceiling effect. Third, it tests 3-D movement. Both objective outcomes measures have been fully developed and are ready for use.

Patient centered information is also collected several questionnaires. The Prosthesis Evaluation Questionnaire (PEQ) is used to quantify patient satisfaction. The Activity-Specific Balance Confidence Scale (ABC) is being used to assess the subject's perceived balance confidence. A falls questionnaire is being used on a bi-weekly basis to investigate if the proposed training method will decrease the incidence of stumbles and falls during locomotion. Monitoring with electronic mail or text messaging is used to determine if the individual has stumbled or fallen. If the answer is "yes" then the cause and circumstance of the fall are determined from the subject's descriptions in a follow-up telephone call.

The protocol calls for subject functional capabilities to be collected at four time points. Subjects are tested before starting the training protocol to establish their baseline capabilities. The training then consists of 6 training sessions over a 2-week timeframe. The subjects are evaluated again following their training. They are then be followed for six months and assessed for functional outcomes at 3 and 6 months after completing training to determine if the training effect is maintained.

Enrollment has begun. Currently, three subjects have been enrolled into the study. The first subject has completed a three-month follow up. Importantly, the first two subjects have reported improvements in their personal recovery from stumbles and falls. Moreover, they have both reported an improved reliance on the prosthetic limb. These comments provide strong support for the ongoing research study.

Key Research Accomplishments

- Equipment has been purchased, delivered and installed.
- Research personnel have been hired.
- A User's Manual has been developed to provide the theory and background for the rehabilitation of lower extremity amputees as well as the operating procedures for the treadmill platform.
- The training protocol has been developed.
- Personnel have been trained to conduct the rehabilitation training and data collection.
- The test methods, both subjective and objective are developed.
- Regulatory approval has been received.
- A CRADA agreement has been signed.
- Study design and flow are operational.
- Redcap database set up and data being entered
- A recruitment method has been established.
- Enrollment has begun.

Reportable Outcomes

- Three subjects are enrolled.
- The first two subjects in this study report improvement in functional abilities and increased reliance on the prosthetic limb.

Conclusion

We have designed, developed, and have begun to test a clinically relevant and scientifically based method for increasing and/or accelerating the progressive adaptation of lower extremity amputees to their prosthesis. This rehabilitation method uses a novel and innovative treadmill training method. The training method is aimed at increasing the ability for amputees to rely on their prostheses, particularly in a challenging environment, and thus, improve their functional capabilities. Enrollment in the study has begun. Amputees who have received the advanced training to date have reported improved dynamic stability and increased functional performance.