Develop and demonstrate a technology that can be easily implemented in a clinical setting to provide advanced fall-mitigation training and accelerate recovery to the highest possible levels of performance for Warfighters with lower limb trauma and/or loss.

DESCRIPTION: Even after participating in advanced rehabilitation and receiving state-of-the-art prosthetic and orthotic devices, Warfighters with lower limb trauma and/or loss are still at risk for falls. Warfighters with lower limb trauma and/or loss are often young and capable of high performance at the time of their injuries, and may be at increased risk of injury causing falls following rehabilitation due to their continued active lifestyle, sometimes including remaining on active duty and deployment [1].

Previous research on fall mitigation training has demonstrated success. However this research is often conducted on cost prohibitive systems requiring significant space and operator training [2-3]. These systems are not feasible for use in a clinical setting. A solution is sought that is clinically accessible, and easy to use for both clinicians and patients. As a use-case example, a regimen for the technology could be prescribed by a physical therapist based on individual patient needs and goals, executed by a physical therapy assistant or technician, and completed by the patient over the course of their treatment.

PHASE I: Conceptualize and design an innovative solution for a technology that optimizes the performance and mitigates the risk of falls in Warfighters with lower limb trauma and loss. The technology must be feasible for use in clinical settings and easy to use by clinical staff. The required Phase I deliverables will include: 1) a research design for engineering the device and 2) a preliminary prototype with limited bench-top testing to demonstrate proof-of-concept evidence, and 3) evidence that the technology, used in a clinical setting by a trained clinician, will result in the mitigation of falls and improved performance in those with lower limb trauma and/or loss. Other supportive data may also be provided during this 6-month Phase I effort.

PHASE II: Design, develop, test, finalize and validate the practical implementation of the prototype system that implements the Phase I methodology towards a technology that can be easily implemented in a clinical setting to provide advanced fall-mitigation training and accelerate recovery to the highest possible levels of performance for Warfighters with lower limb trauma and/or loss, over this Phase II effort. A plan for meeting FDA requirements toward regulatory approval is required. Plans for translation in rehabilitation clinics including end-user requirements, training and use guidelines/documentation, and operating standards are required. The testing and practical implementation of the prototype technology should be relevant to Warfighters who have experienced lower limb trauma and/or loss, and are undergoing rehabilitation to meet their goals. These patients are often young and active and may have the desire to remain on active duty. Roughly 15-20% of Warfighters with major limb trauma from the most recent conflicts remained on active duty following discharge from rehabilitation. Some re-deployed to theater. Others who separated from the military have engaged in high demand occupations (police, fire fighter, first responder, etc.). The developed technology should be implemented as part of the rehabilitation process and should result in outcomes related to mitigation of falls and increased performance or participation in injured Warfighters with lower limb trauma and/or loss.

PHASE III DUAL-USE APPLICATIONS: Work with commercial partners, military subject matter experts (e.g. a military treatment facility that treats patients with limb trauma and/or loss), and/or the civilian marketplace to move towards a final commercial product. Ensure that the final product can be incorporated into clinical practice including ease of use, appropriate coding/billing, cost/benefit, and training, education, socialization, and outreach. While the technology should be focused on optimizing performance and mitigating falls in Warfighters with limb trauma and loss, there are other military, veteran and civilian populations that may benefit. The military’s highest priority is readiness. Musculoskeletal injuries are one of the greatest factors limiting readiness. There is potential that this technology could extend to Warfighters with lower limb musculoskeletal injuries (e.g. chronic ankle instability, knee/ankle tendon or ligament injury, etc.) to accelerate recovery and return to duty. Additionally, it is envisioned that this technology could be applied...
within VA and civilian rehabilitation facilities to mitigate falls and improve performance, participation and quality of life for patients with stability and mobility issues following injury/illness.

REFERENCES:

KEYWORDS: Stability, Limb Loss, Limb Trauma, Performance, Falls, Rehabilitation