## Introduction

I would first like to thank Chairwoman Barbara Comstock and Ranking Member Daniel Lipinski of the Research and Technology Subcommittee for the invitation to deliver testimony on this important topic, and thank Chairman Randy Weber and Ranking Member Marc Veasey of the Energy Subcommittee for participating in this joint hearing. My name is Matthew Major. I am a Research Health Scientist at the Jesse Brown VA Medical Center in Chicago, IL, and I also hold a joint appointment as Assistant Professor of Physical Medicine and Rehabilitation at Northwestern University in Chicago. I have been working in these institutions since 2010, but have been performing rehabilitation research for over twelve years. I earned Bachelor of Science and Master of Science Degrees in Mechanical Engineering from the University of Illinois at Urbana-Champaign, and earned a PhD in Biomedical Engineering from the University of Salford, Manchester in the United Kingdom. My expertise is in the application of engineering-based principles to rehabilitation science as it relates to the development and evaluation of prosthetic and orthotic technology. I have been fortunate to benefit from a five-year VA Career Development Award to support early investigators. As a Rehabilitation Scientist and Biomechanist, I am active in both rehabilitation and biomechanics scientific and professional societies. I am also an editorial board member for the journal which serves our clinical profession here in the US, the Journal of Prosthetics and Orthotics.

My testimony will focus on rehabilitation research as it relates to Veterans with neurological or musculoskeletal pathology who are able to benefit from prosthetic and orthotic technology to restore mobility and function.

## The Need

One of the highest priorities of the Veterans Health Administration is to provide superior healthcare to Veterans who experience limb loss or neurological trauma, such as stroke. The primary goal of rehabilitation for these Veterans is to restore the greatest level of independence and ambulation. There exists a large and growing number of

Veteran patients with neurological or musculoskeletal pathology who rely on access to the Veterans Health Administration rehabilitative care for functional restoration.

When medically indicated, these Veterans receive prosthetic and orthotic devices as fit by trained clinicians known as prosthetists and orthotists. These devices support the functional needs of these individuals and allow them to realize their full rehabilitation potential. Prostheses serve to replace lost anatomy for restoring walking ability or reaching and grasping, while orthoses serve to restore function of existing anatomy with impaired movement and control. These devices are custom-built for each patient and often assembled from commercial components. Physical therapists provide a critical service by training patients to effectively use these devices, ensuring long-term rehabilitation success. In this context, the responsibility of an interdisciplinary clinical team is to:

1) Best match a prosthetic or orthotic design to the patient user based on their health status, desired outcomes, and rehabilitation potential; and
2) Implement targeted physical and psychological therapies to encourage Veterans to maximize function when using rehabilitation technology.

According to this clinical framework, my research focuses on two primary tracks as a means to improve this clinical process and enhance Veteran care:

1) Development of prosthetic and orthotic rehabilitation technology; and
2) Evaluation of this technology and associated rehabilitation strategies.

The ultimate goal is to enhance quality of life for Veterans using the primary mechanism of supporting their functional needs such that they can have regular and unrestricted participation in leisure, domestic, and work activities. Leisure and domestic activities are of course critical to well-being, but I want to particularly emphasize the importance of gainful employment. The unemployment rate tends to be higher for Veterans than non-Veteran peers and the limitations associated with mobility and functional impairment exacerbates this challenge of return-to-work. My experience has led me to understand that community reintegration is a key component of successful rehabilitation of Veterans, and this objective is a main driver of my research efforts.

## The Solutions

My current research is primarily funded by the U.S. Department of Veterans Affairs and the U.S. Department of Defense, and is focused on the rehabilitation of Veterans with limb loss. I will discuss several of these projects relevant to the interdisciplinary clinical framework described previously, and note collaborations that are critical to the success of this research.

My primary project is supported by a Department of Veterans Affairs Career Development Award and involves collaboration with the Edward Hines Jr. VA Hospital and Northwestern University Department of Physical Therapy. The project goal is to better understand the physiological factors that underlie balance issues in Veterans with lower limb loss, such as sensory feedback and motor control. We do not yet fully understand why half of community-living individuals with a single lower limb amputation experience at least one fall per year. For those individuals who do fall, two-thirds fall more than once and forty percent experience a fall-related injury. These issues have considerable implications on quality of life and healthcare costs. The long-term objective of my project is to inform prosthesis designs and physical therapies that enhance balance and reduce the risk of falls and fall-related injuries. In this study we characterize the differences in walking behavior, standing balance, muscle strength, and sensation between non-impaired individuals and persons with limb loss. Through the use of rehabilitation robots, we observe the motor responses of prosthesis users when exposed to a sudden pull to the side. These robots are a unique type of rehabilitation technology that use a system of motors, pulleys, and cables to simulate a gait disturbance by applying controlled pulls to the pelvis while an individual walks on a treadmill. Although useful as a method to assess how persons with limb loss respond to walking disturbances and maintain balance, this same technology can be used to deliver patient-specific, targeted therapies for improving balance. For instance, a Veteran might undergo a series of training sessions with a therapist to explore strategies for managing a disturbance when walking to ultimately promote safe community ambulation.

My second project is supported by the Department of Defense and involves collaboration with the Captain James Lovell Federal Health Care Center and Rosalind Franklin University. This project assesses the efficacy of an integrated therapeutic intervention that combines cognitive behavioral therapy and physical therapy to improve balance confidence in persons with limb loss. Similar to an increased prevalence of falls, individuals with limb loss experience low levels of balance confidence, which is linked to reduced activity levels. Low activity levels and a more sedentary lifestyle have negative consequences on general health and quality of life. The long-term aim of this research is to assess an integrated therapy that can be implemented into the VA and DoD system-of-care for Veterans with lower limb loss to improve balance confidence and increase participation in daily activities. Promotion of community activity and independence increases the likelihood of return-to-work and maintaining employment. In this study, we enroll persons with limb loss in a therapy program that provides multiple sessions of combined cognitive behavioral therapy and step training over several months. The cognitive behavioral therapy is delivered by trained psychologists and aims to increase a person's self-awareness and their confidence in maintaining balance during various forms of daily activity. The physical therapy employs unique rehabilitation technology incorporating virtual and augmented reality environments for individuals to explore strategies to control their body in response to walking disturbances. These disturbances come in the form of targets projected onto a treadmill belt or a virtual environment displayed on a monitor, both of which demand controlled weight shifting and limb movements from the patient. Disturbances are presented in the form of a game to encourage engagement and therapy compliance.

My third project is supported by the Department of Veterans Affairs and investigates the prevalence of falls and the factors related to fall risk in Veterans with upper limb loss. My findings thus far have revealed that similar to individuals with lower limb loss, nearly fifty percent of persons with upper limb loss experience at least one fall in a year. For those individuals who do fall, almost two-thirds fall more than once and a third experience a fall-related injury. We are now investigating the biomechanical and physiological factors that contribute to increased fall prevalence. We are beginning to understand that use of an upper limb prosthesis can affect an individual's balance based on their perceptions of the device and its inherent characteristics. The ultimate goal of this research is to improve screening procedures that can identify Veterans at risk of falling, and design upper limb prostheses and therapies that enhance balance and safe ambulation.

My fourth project is supported by the Department of Defense and involves collaboration with the Brooke Army Medical Center, VA Puget Sound Health Care System, and the Minneapolis VA Health Care System. This project assesses the prosthetic needs of women Veterans with lower limb loss, a subgroup of Veteran patients that historically has not received as much attention as their male counterparts. Uniquely, women use specific types of footwear and heel heights that interact with prostheses in ways less common than men's footwear. Many commercially-available prostheses are unable to accommodate to the variety of footwear that women might like to wear, thereby restricting their choice of both prosthetic technology and footwear. In this study we are assessing the prosthetic needs and services available to women with lower limb loss, and characterizing the influence that women's footwear has on the function of prostheses. The long-term goal of this project is to make the prosthetic solutions available to women with limb loss more relevant to their needs, and develop clinical guidelines to support their unique clinical care and community integration. A parallel project began recently to develop a new prosthetic foot design that better accommodates to different types of footwear, thereby expanding opportunities for leisure, domestic, and work activities using a single prosthesis.

My fifth project is supported by the Department of Defense, National Institutes of Health, and National Science Foundation and involves collaboration with the Massachusetts Institute of Technology. This project seeks to develop a novel method by which the mechanical function of a prosthesis can be optimized based on a person's individual characteristics. Through clever integration of computer simulation and rapid prosthesis fabrication, we can provide more personalized prosthetic interventions to maximize rehabilitation outcomes, such as walking dynamics and metabolic economy. Much of my previous research helped define the relationships between prosthesis mechanical function and biomechanical performance to improve evidence-based practice. This research project continues that work by designing prosthetic feet and knees that can be mechanically tuned for each Veteran based on their body characteristics and desired activity levels. The long-term objective of this project is to develop a powerful platform for individualized prosthetic solutions that enhance the quality of clinical care by reducing or eliminating limitations imposed by existing commercial device options. An important aspect of our technology is that it is based purely on a mechanical solution and does not require battery power. This expands application of our technology to situations where durability and reliability are critical, such as rugged terrain for military service members and resource-challenged areas where prosthetic services are limited. The intention is to integrate this technology into the VA and DoD system-of-care, thereby streamlining prosthetic delivery.

Finally, my sixth project was initially supported by the Department of Defense and I am currently seeking further funding from the Department of Veterans Affairs to continue this work. This project involves collaboration with the Minneapolis VA Health Care System, Northwestern University, and industry partners. The objective of this project is to develop new prosthetic technology for maintaining a secure connection between the prosthesis and amputated limb. This concept builds upon existing technology that creates a vacuum between the limb and prosthetic socket to suspend the prosthesis. This vacuum suspension method has demonstrated advantages over other methods by improving limb health and mobility. Our novel technology integrates software and hardware features that expand application of this suspension technique to Veterans of different ages, activity levels, and health status. Having already been awarded one patent, we recently filed a second application on this technology to the U.S. Patent and Trademark Office.

This selection of projects demonstrates how research can address primary aspects of rehabilitative care for Veterans such as the delivery of appropriate prosthetic technology and therapies that ensure long-term restoration of function and mobility. An important takeaway is that rehabilitation technology can assume the form of prosthetic devices as well as interactive systems for physical therapies.

**The Gaps**

My research activities describe only a few examples of the various methods by which rehabilitation technology can be applied to improve Veteran quality of life. Prosthetic and orthotic technology is advancing at an impressive pace. We are constantly inventing new devices, methods by which to fit these devices to the Veteran user, and therapies to enhance long-term rehabilitation outcomes. Prosthetic and orthotic devices now include computer control and can learn to work with the user to recognize intent. Prosthetic hands include multiple articulations and degrees of movement for enhanced function. Prosthetic feet can adapt to changes in terrain and have motors for putting a “spring in your step”. Techniques for less expensive manufacturing are becoming available and device durability is improving. The application of advances in robotics and material science are responsible for some of this evolution. We have come a long way in what technology is available, but still have a long way to go in understanding how best to use it.

It is important to emphasize that the most critical component to successful rehabilitation and community reintegration is the Veteran using these devices. Research and development grants us the ability to rehabilitate and empower Veterans with functional impairments, but understanding the interaction between Veterans and the devices they depend on is crucial. While prosthetic and orthotic technology will continue to advance with sufficient funding and support, clinicians will always be an integral part to the rehabilitation process. Historically, restoring function through prosthetic and orthotic intervention was largely accomplished via subjective and experience-driven decisions of clinicians as opposed to the application of scientifically rigorous quantitative information in clinical decision-making. This process is evolving as we continue to generate knowledge via clinical studies of how devices and therapies influence rehabilitation outcomes, thereby elevating evidence-based clinical practice. We must also address

Veterans' needs from a holistic perspective, considering both the physical and psychological condition, as this will ultimately yield more accurate personalized interventions. Consequently, we need to support parallel research efforts on technology development and best-practice clinical application of this technology.

As an example, the growing availability and cost-effectiveness of 3D printers has led to the exciting advancement of 3D-printed prosthetic hands as a solution to upper limb loss. However, as with traditional prostheses, these devices need to be fit to the patient by a clinical professional and patients require training to use these prostheses effectively. We see here an opportunity where joint contributions from technology development research and clinical application research can impact rehabilitative care. Part of my responsibility as a rehabilitation scientist is to help determine best-practice guidelines through controlled clinical studies. Clinical studies of prosthetic and orthotic technology inform clinical practice and guide health professionals on how to effectively implement this technology.

Moreover, the process of Veteran rehabilitation does not end once an individual is fit with a device and deployed into the community. Real-world use of this technology and progressive changes in health status provide a window into rehabilitation progress and quality of life. Knowledge of community-based outcomes outside of the laboratory, such as activity level and participation, is challenging to capture. However, advances in wearable technology and the miniaturization of sensors have improved our ability to collect these real-world data in addition to other biosignals such as heart rate. Research is needed to explore ways in which we can integrate sensor technology into prostheses and orthoses to continuously and remotely monitor user status over extended periods of time and with minimal interruption to daily activity. The VA Clinical Prosthetics Services is already making use of activity monitors to quantify device utilization. Accordingly, research must also answer how real-world data can be used in practice by clinicians to optimize device designs or rehabilitation strategies to consistently and fully restore independent function to Veterans while protecting patient privacy.

Overall, Veteran rehabilitation research must continue to be interdisciplinary to accelerate its progress and remain competitive, integrating science from multiple domains including robotics, motor control theory, material science, biomechanics, physical therapy, prosthetics and orthotics, and psychology. We need to encourage interdisciplinary research efforts to advance rehabilitation science for Veterans so that they can achieve their full rehabilitation potential. I argue that we still lack a thorough understanding of the interaction between the human element and rehabilitation technology, whether that is prostheses and orthoses or therapeutic interventions. More progress is needed to better understand how the body acutely and chronically responds to different prosthesis and orthosis designs, which therapies are most effective, and what the long-term outcomes of rehabilitation are on Veteran health, community participation, and quality of life. Filling in the gaps linking the human, rehabilitation technology, and rehabilitation strategies will increase the effectiveness of personalized rehabilitation interventions and help close the loop between technology and clinical practice.

**The Horizon**

Based on the research activity and gaps I have detailed here, I recently published a proposed framework describing an interdisciplinary approach to maximizing long-term rehabilitation outcomes through shared-decision making. This process that I envisage would be integrated into the VA system-of-care and functions through continuous input from Veterans, engineers, physical and psychological therapists, and prosthetists/orthotists. With this theoretical framework, we will begin integrating physical and cognitive patient-specific health factors to offer fully personalized, holistic-based interventions. We must be mindful that not every Veteran is the same, and neither is their condition. Furthermore, the interventions we apply must not be static, but must constantly adapt to the Veteran user and their changing condition to fully support rehabilitation progress.

While prostheses and orthoses have long been custom-made devices, I believe that technology is driving us towards a future where we can fine tune rehabilitation interventions with extreme precision, accuracy, and speed. Devices and therapies will be personalized based on individual patient characteristics, and "smart" prostheses and orthoses will collect diagnostic data through on-board sensors. Clinicians will use these data to continuously monitor rehabilitation progress and design interventions, while the devices will automatically adjust in real-time to meet the demands of daily activity. Combined with advances in telehealth, therapies will be administered remotely without travelling to a clinic, thereby improving access to care. Real-time monitoring and remote intervention delivery will promote rehabilitation of Veterans while permitting continued community engagement. Our end goal is to restore the greatest level of independence, ambulation, and quality of life to Veterans with neurological and musculoskeletal pathology, which reflects a main priority of the VHA and fuels my passion for this work.

In conclusion, I would like to summarize this testimony with four key points:

1. Prosthetic and orthotic technology to support the rehabilitation of Veterans with functional impairments will continue to rapidly advance with further improvements in robotics and material science.
2. As technology advances, we must continue to explore the clinical application of these devices and holistic therapeutic interventions to elevate the quality of evidence-based practice.
3. We have a unique opportunity to develop interdisciplinary approaches to rehabilitation involving shared decisions of Veterans, clinicians and engineers.
4. Parallel research on technology development and rehabilitation strategies is necessary to fully address the functional needs of Veterans and design personalized interventions to maximize long-term rehabilitation outcomes.

I once again thank the Research and Technology and Energy Subcommittees for this opportunity to testify and highlight research that is being supported by the VA and DoD to empower U.S. Veterans through rehabilitation technology.

Matthew J. Major, PhD