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“Raising the Bar” in Extremity Trauma Care: A Story of Collaboration and Innovation

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Today’s military health system is working in remarkable ways to provide complex extremity trauma care that helps injured service members reach their highest level of function. The difference in outcomes as a result is staggering. In the 1980s, only 2% of soldiers remained on active duty following limb loss, despite relatively minor injuries such as a partial hand amputation.1 By 2010, 19% of service members remained on active duty after suffering limb loss caused by major extremity trauma. About 25% of this group actually returned to theater, even though their injuries were much more devastating than those suffered during previous conflicts.2

Wounded soldiers now have access to cutting-edge technologies, multidisciplinary care, and research efforts aimed at realizing optimal outcomes for a population already used to performing at high levels. The approach is holistic and family centered, focusing more on the patient’s ability than disability. Best of all, advances in the care of these patients offer benefits to other injured service members as well as the civilian population.

This work is possible because of the synergies that exist between programs operating through the Department of Defense (DoD) and the U.S. Department of Veterans Affairs (VA) across the patient care spectrum. The result is complementary rather than competing care that begins at the point of injury and continues for the rest of a patient’s life.

Efforts to cultivate this collaborative approach to orthopedic rehabilitation care have been bolstered by three separate but interconnected programs that have identified and developed critical research capabilities and infrastructures that translate research advances into clinical care for patients with traumatic extremity injuries.

The Extremity Trauma and Amputation Center of Excellence (EACE) was created by Congressional mandate as a joint enterprise between the DoD and the VA to develop a comprehensive strategy to help service members with traumatic injuries optimize their quality of life.

The Center for Rehabilitation Sciences Research (CRSR) was established to advance the rehabilitative care for service members with combat-related injuries while also educating the next generation of military medicine professionals.

The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium was developed as a research capacity building program to further establish research infrastructures and investigators at DoD and VA sites and to launch a series of multiteam clinical research initiatives.

These programs operate independently, but they are designed to be interdisciplinary and collaborative in nature. This complementary approach is reflective of the efforts by the DoD to address the complex health needs of the combat wounded before they reach the VA, which has already had an established amputee and rehabilitation science program. Together, they provide a unique opportunity to strengthen DoD/VA research programs and influence the long-term direction of care for this unique patient population.

It is an approach that is working, as evidenced by a 2015 report by the Defense Health Board on the sustainment and advancement of amputee care.3 It found that the DoD is “leading the Nation and the world in extremity trauma and amputee science and care through its infrastructure, systems and approach.” That same report also reiterated the need for collaborations between institutions, practitioners, and researchers across disciplines and organizations in order to sustain these advancements.

Whether it is team members from the EACE and the BADER Consortium embedding at military treatment facilities (MTFs) to help answer clinically relevant questions and support research in high-priority areas or CRSR staff working to define and validate rehabilitation strategies for injured service members, the focus remains constant—to help these wounded warriors get back to the life they were living before their traumatic injuries.

By working collaboratively, researchers do not have to give up their autonomy. Indeed, each domain of rehabilitation care can and should be able to work independently.

The resultant creativity and energy is evidenced by the myriad of research projects already underway at MTFs and VA centers around the country. These researchers are not constrained by working toward the same goal—helping patients regain their highest functional levels—but rather, they are empowered to meet those goals in different ways.

One project funded by the Defense Medical Research and Development Program and supported by the EACE and BADER focused on preventing falls in service members with amputations through the use of advanced rehabilitation training.4 At CRSR, they are finding improvements in pain management strategies that can improve the quality of life for patients with severe combat injuries. The BADER Consortium supports the goal of optimal outcomes by providing needed administrative assistance and infrastructure support to help address important gaps in clinical orthopedic rehabilitation research and patient care.
MTFs and VA medical centers are uniquely positioned to undertake this mission of restoring function. The networks that already exist at these facilities enable the orderly adoption of cutting-edge technological devices and associated rehabilitation techniques to enhance patient function.

These advances are being developed, tested, and evaluated by the same high-performing, motivated population most likely to benefit from them. In this capacity, the MTFs and VA medical centers can serve as the nation’s premiere translational and clinical trial network for traumatic amputee rehabilitation, offering possibilities for personalized care and optimal function of these devices.

Microprocessor-controlled prosthetic knees offer tangible examples of how injured service members are getting access to cutting-edge care, but it is providing these devices with a well-designed rehabilitation program that truly offers the opportunity for patients to return to their busy lives and work, thereby making the goal of optimizing outcomes a reality. The Return-to-Run program pioneered at the Center for the Intrepid is one example of coupling high-tech with rehabilitation, resulting in long-term improvements in physical performance, pain- and patient-reported outcomes.

In the same vein, research has found that the body, mind, and spirit should be jointly considered following traumatic injuries. The Military Extremity Trauma Amputation/Limb Salvage study showed that service members who underwent amputation rather than limb salvage returned to full activity and had a lower likelihood of post-traumatic stress disorder.

There was a time when simply helping a patient regain some aspect of mobility was considered a success. But this generation of injured service members has more demanding medical and interpersonal needs than previous cohorts. These young men and women typically lived highly active and athletic lifestyles before their injuries. They want to return to their busy lives, whether it is through the use of prosthetic and orthotic devices that help them regain their mobility or specialized rehabilitation training that helps them adapt to changing terrains.

The needs of this unique population have spurred many stunning advancements in patient care over the past 15 years. It is why programs like the EACE, CRSR, and BADER have been able to thrive in a relatively short amount of time.

Much is still not known about the challenges injured service members will face in the future. Many of these patients are young, but so are the programs providing the resources to support these critical research efforts. These heroes, who face lifelong adaptations to the rigors of the world, need continued and dedicated teams of specialists trained in their unique challenges. As the research into these areas faces greater challenges, it is important for the centers and the collaborations to be allowed to grow and mature.

In the coming years, there needs to be an increased effort to develop research enterprises that will wield the greatest impact on current and future limb loss partners. Great research advances have been made during the recent 15 years of conflicts, but it is critical that these successes be sustained in peacetime.

Vagaries of combat—along with the fluctuations in the number of patients with traumatic extremity injuries who require care—present funding and staffing challenges that could threaten medical advancements and treatment breakthroughs in the future. Only when clinicians and researchers work together—along with the DoD and VA leadership—to develop programs and research capabilities with the greatest potential for impacting our wounded will these challenges be overcome.

It is through this larger coordination of effort we can ensure military health professionals will continue to raise the bar in the development and implementation of a new normal where service members who have experienced all kinds of extremity trauma can achieve their highest level of function and enjoy a better quality of life.

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REFERENCES

The Extremity Trauma and Amputation Center of Excellence: Overview of the Research and Surveillance Division

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ABSTRACT Congress authorized creation of the Extremity Trauma and Amputation Center of Excellence (EACE) as part of the 2009 National Defense Authorization Act. The legislation mandated the Department of Defense (DoD) and Department of Veterans Affairs (VA) to implement a comprehensive plan and strategy for the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputation. The EACE also was tasked with conducting clinically relevant research, fostering collaborations, and building partnerships across multidisciplinary international, federal, and academic networks to optimize the quality of life of service members and veterans who have sustained extremity trauma or amputations. To fulfill the mandate to conduct research, the EACE developed a Research and Surveillance Division that complements and collaborates with outstanding DoD, VA, and academic research programs across the globe. The EACE researchers have efforts in four key research focus areas relevant to extremity trauma and amputation: (1) Novel Rehabilitation Interventions, (2) Advanced Prosthetic and Orthotic Technologies, (3) Epidemiology and Surveillance, and (4) Medical and Surgical Innovations. This overview describes the EACE efforts to innovate, discover, and translate knowledge gleaned from collaborative research partnerships into clinical practice and policy.

INTRODUCTION

In 2009, Congress legislated the creation of the Extremity Trauma and Amputation Center of Excellence (EACE) as a joint enterprise between the Department of Defense (DoD) and Department of Veterans Affairs (VA) to optimize the quality of life (QoL) of service members and veterans who sustain extremity trauma or amputation.1 Congress directed the EACE to implement a comprehensive plan and strategy, conduct clinically relevant research, foster collaborations, and build partnerships across multidisciplinary international, federal, and academic networks. In accordance with this mandate, the EACE’s mission is focused on the mitigation, treatment, and rehabilitation of traumatic extremity injuries and amputations. The purpose of this editorial is to provide an overview of the EACE efforts to innovate, discover, and translate knowledge gleaned from collaborative research partnerships across established DoD, VA, and academic research programs.

BACKGROUND

At the time of the first EACE staff hire in September 2011, the U.S. military was engaged in nearly 10 years of continuous combat. As of October 1, 2015, data compiled from the Expeditionary Medical Encounter Database, Naval Health Research Center, indicate that approximately 26,000 traumatic extremity injuries resulted from deployments during Operations Enduring Freedom (OEF), Iraqi Freedom, (OIF) and New Dawn (OND). These injuries ranged in severity and complexity, with nearly 50% involving the lower limbs.2 From 2001 to 2015, 1,687 individuals with major limb amputations from OIF, OEF, and OND were documented in the EACE Amputee Registry. Of these individuals, 69% suffered a single limb loss injury and 31% lost multiple limbs. The overall incidence of extremity injuries from these operations is consistent with previous wars, comprising more than half of all combat wounds.2

With extremity injuries sharply rising early in the conflicts, leadership within the DoD and VA health care systems realized the need for specialized systems of care that could deliver concentrated, interdisciplinary health care required by
individuals with severe combat-related injuries. Together, the DoD and VA launched efforts to create these systems by both building upon existing resources and acquiring new capabilities in partnerships with academic institutions, veteran service organizations, industry, and other federal agencies.

**DoD Clinical Care**
In 2001, the U.S. Army designated Walter Reed Army Medical Center, now Walter Reed National Military Medical Center (WRNMMC), as the flagship location to provide extremity trauma and amputee care for the U.S. military. In 2003, the U.S. Army established the Armed Forces Amputee Patient Care Program to provide state-of-the-art surgical and rehabilitative care to patients with limb loss. This program leveraged resources and subject-matter experts across the Military Health System to optimize patient outcomes. By 2007, the DoD had established three state-of-the-art Advanced Rehabilitation Centers (ARC) to provide clinical rehabilitative care services and promote a return to high-level function: the Military Advanced Training Center (MATC) at WRNMMC, the Center for the Intrepid at San Antonio Military Medical Center (SAMMC), and the Comprehensive Combat and Complex Casualty Care (C5) Program at the Naval Medical Center San Diego. These DoD ARCs continue to deliver coordinated, patient-centered care and management through interdisciplinary teams.

**VA Clinical Care**
The VA health care system has well-established clinical rehabilitation programs for veterans experiencing a myriad of disabling conditions, including spinal cord injury, neurodegenerative diseases, mental health conditions, stroke, brain injury, low vision/blindness, and limb loss. While the majority of all veterans with amputation experienced new limb loss secondary to vascular disease and diabetes, the VA provides a lifelong continuum of care for patients with both disease- and trauma-related amputation. As a result of injuries suffered during OEF/OIF/OND, there was an increase in the number of veterans with combat-related limb loss seen by the VA. Of those, 50% also sustained concomitant traumatic brain, peripheral nerve, spinal cord, soft tissue, and/or psychological injuries such as post-traumatic stress disorder. This combination of multiple injuries resulting from the same traumatic event was termed “polytrauma” by the VA for the purpose of defining the system of care services that would be needed as combat operations continued. Public Law 108-422, also known as the Veterans Health Programs Improvement Act of 2004, charged the VA to create “centers for research, education, and clinical activities on complex multi-trauma associated with combat injuries.” In 2005, the Polytrauma System of Care (PSC) was established in conjunction with the designation of four Polytrauma Rehabilitation Centers (PRCs). The PSC is an integrated network of specialized rehabilitation programs dedicated to serving veterans and service members with both combat- and civilian-related traumatic brain injury and polytrauma injuries, including limb loss.

In 2008, emulating the PSC model, the VA established an Amputation System of Care (ASoC). The ASoC is committed to delivering a full range of amputation care and rehabilitation services, including use of telehealth technologies, to more than 80,000 veterans who have sustained an amputation. The ASoC consists of a hub-and-spoke system made up of 4 care components: 7 Regional Amputation Centers (RACs), 18 Polytrauma Amputation Network Sites (PANS), 108 Amputation Care Teams (ACTs), and Amputation Points of Contact (APoC) across the United States and Puerto Rico.

**DoD-VA Research Scope and Partnerships**
The need for innovative surgical and rehabilitation technologies and treatment strategies increased exponentially because of severe injuries sustained by service members throughout recent conflicts. In response to this demand, research programs within the DoD and VA redirected efforts toward caring for the combat wounded. These programs broadened their research scope to include traumatic brain injury, blast-related sensory loss, amputation, polytrauma, and the development of advanced prosthetics for combat-injured service members. These efforts were not performed in isolation—multiple partnerships and collaborations across federal agencies, academic institutions, and industry were created and/or expanded to address growing clinical needs. The DoD and VA increased collaborative efforts in many clinical research areas and coauthored a “guidebook” that provides suggestions for identifying collaborators with common research goals, summarizes administrative and funding mechanisms, and identifies procedures for establishing collaborations.

**DoD Research Support**
One core source of research support within the DoD is the U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP), which provides Defense Medical Research and Development Program (DMRDP) execution management support for the six Defense Health Program core research program areas ($452.6 million fiscal year [FY] 2010–2015, estimated $299.6 million FY 2016). Each major research program area is guided by a Joint Program Committee (JPC) comprised of DoD and non-DoD medical and military technical experts who translate guidance into research and development needs. They also have key responsibilities for making funding recommendations and providing program management support.

The EACE research efforts are most closely aligned with Joint Program Committee-8/Clinical and Rehabilitative Medicine Research Program (JPC-8/CRMRP), which seeks to find, evaluate, and fund cutting-edge research in reconstruction,
rehabilitation, and definitive care to improve outcomes, restore function, return to duty, and improve QoL for injured service members. Currently, research sponsored by the JPC-8/CRMRP ($180 million FY 2015) is focused on the following key areas: Neuromusculoskeletal Injury Rehabilitation, Pain Management, Regenerative Medicine, and Sensory Systems Traumatic Injury.

JPC-8/CRMRP funding comes from Army and Defense Health Program core dollars as well as Congressional Special Interest (CSI) program monies that are appropriated by Congress and executed by the CDMRP. Three CSI-affiliated research programs closely align with the mission of the EACE and include the Orthotics and Prosthetics Outcomes Research Program (OPORP) ($10 million FY 2016), Peer Reviewed Orthopaedic Research Program (PRORP) ($30 million FY 2016), and Reconstructive Transplant Research Program (RTRP) ($12 million FY 2016).

VA Research Support

In parallel to the DoD research programs, the VA Office of Research and Development (ORD) is an intramural, veteran-centric research program conducted throughout the VA health care system. For more than 90 years, ORD has had the mission “to discover knowledge and create innovations that advance health care for Veterans and the Nation.” In support of this mission, ORD’s Rehabilitation Research and Development (RR&D) Service supports and integrates preclinical, clinical, and applied rehabilitation research and seeks to translate research results into practice.

RR&D program areas most relevant to the EACE mission include regenerative medicine ($26 million FY 2015), musculoskeletal/orthopedic rehabilitation ($141 million FY 2015), and rehabilitation engineering prosthetics/orthotics ($80 million FY 2015). Supported clinical and preclinical studies span research domains ranging from improvements in foundational science techniques and systems to prevention and screening, treatment, and follow-up care. These programs within DoD and VA are some of the past and current funding streams for studies worked on by the EACE researchers.

THE EXTREMITY TRAUMA AND AMPUTATION CENTER OF EXCELLENCE

Over the past decade, DoD and VA realized a need to strengthen clinical and research ties between the two departments to reduce redundancy and maximize the impact of collective efforts. Pursuant to these complementary efforts, Congress directed the establishment of the EACE in 2008. Governance is jointly provided by the Army Surgeon General as the DoD lead component and the Director of the Rehabilitation and Prosthetics Service within the Veterans Health Administration’s (VHA) Office of Patient Care Services. At the time of writing, 41 EACE-funded staff members (37 DoD and 4 VA) are structured across 4 divisions of effort. These divisions include Clinical Affairs, Clinical Informatics and Technology, Global Outreach, and Research and Surveillance (R&S; Fig. 1).

The Clinical Affairs Division provides many deliverables and functions, including continuing medical education and training, assistance with the translation of current research findings into clinical practice through clinical practice guidelines and clinical policies for DoD and VA.

Through the Clinical Informatics and Technology Division, the EACE is developing the Defense and Veterans Extremity Trauma and Amputation Registry (DVEAR), an integrated health registry to support clinical care and research. The DVEAR will support the management of data and information reporting throughout DoD and integrate data from VA’s existing amputation repository. The DVEAR will capture and quantify key demographic, socioeconomic, and polymorbid characteristics, as well as outcomes of service members and veterans affected by traumatic extremity injury and amputation.

The Global Outreach Division strengthens international relationships through the DoD Secretarial Designation Program, which authorizes provision of amputation care for non-DoD beneficiaries. The EACE also serves as a resource for coalition nations desiring to enhance their extremity trauma and amputation care capability by providing patient consultation and developing plans for facilities and services.

Research and Surveillance Division

The EACE R&S Division implemented a comprehensive plan to conduct clinically relevant research, including the hiring of clinical researchers, the establishment of collaborations and partnerships, and the identification of clinical research gaps. The EACE R&S Division consists of 26 core team members embedded at point of care within the three ARCs; the Navy Health Research Center, San Diego; and the James A. Haley Veterans’ Hospital, Tampa (Fig. 2). The EACE core and affiliated researchers (e.g., those from academic and industrial settings) work collaboratively to identify and answer clinically relevant questions through externally funded research projects (Fig. 3). Together, they have been successful in receiving support from aforementioned research programs like CDMRP, JPC-8/CRMRP, and RR&D. In addition, the EACE core and affiliated researchers have conducted research projects with support from the National Institutes of Health, the Office of Naval Research, the U.S. Navy Bureau of Medicine and Surgery, the Center for Rehabilitation Sciences Research, and the Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium.

The EACE R&S Division embraces an evidence-based framework for clinical decision-making by gathering information from clinicians, patients, and research literature to identify high-priority areas for investigation. An initial clinical needs assessment conducted in 2012 by the EACE leadership identified four key research focus areas for investigations relevant to extremity trauma and amputation: (1) Novel
Rehabilitation Interventions, (2) Advanced Prosthetic and Orthotic Technologies, (3) Epidemiology and Surveillance, and (4) Medical and Surgical Innovations.

**Novel Rehabilitation Interventions**

The EACE researchers are executing studies aimed at developing and determining the most efficacious treatment interventions for optimizing an individual’s level of function and reintegration back to military and/or civilian communities while mitigating comorbidities and secondary health effects. These interventions are specific to impairments, functional limitations, activity restrictions, and assistive devices.

One such EACE-supported intervention focuses on preventing falls in service members with transtibial amputations through advanced rehabilitation training using a microprocessor-controlled treadmill.\(^{21}\) The study demonstrated a significant improvement in stumbles and falls. After receiving the advanced rehabilitation training, 60% of the subjects (\(N = 11\)) reported a decrease in stumbles and falls, and all subjects reported that their uncontrolled falls had decreased to zero. This reduction of stumbles and falls was maintained over the 6-month follow-up period.

The EACE researchers have also used high-end virtual reality environments (Computer Assisted Rehabilitation ENvironment, Motekforce Link) to develop task-specific assessments and treatment interventions related to participation in military and civilian activities. Assessment applications were created to quantify function and identify deficits related to walking stability and mechanics during perturbations,\(^{22,23}\) cognitive tasks,\(^{24}\) and/or military-specific tasks.\(^{24}\) Investigational treatment interventions within the virtual reality environments include utilization of direct and indirect visual feedback during gait, visual-vestibular habituation techniques,\(^{24}\) and military task-specific rehabilitation.

The EACE researchers are collaborating with industry and academic partners to leverage motion-tracking game technology to extend virtual reality therapy into patients’ homes through interactive and entertaining game experiences. Finally, while
many inventions focus on functional limitations and participation restrictions, new studies are looking at strategies such as blood-flow restriction resistance training to increase muscular strength. Through this form of training, individuals may be able to experience muscular strength and hypertrophic gains at a lower resistance than conventionally employed. The EACE researchers are investigating whether lower resistance with blood-flow restriction should reduce the pain associated with rehabilitation, increase patient compliance, and result in greater strength gains at discharge. Preliminary results in the lower extremities are promising and clinical trials for individuals with upper limb injuries are planned.

Advanced Prosthetic and Orthotic Technologies
Following the physical or functional loss of their limb(s), service members and veterans are often reliant on prosthetic and orthotic devices to return to activities of daily living, recreation, and occupation. Throughout the recent conflicts, advances in technology have led to the availability of novel devices such as improved microprocessor-controlled prostheses, active power-producing prostheses, myoelectric-controlled prostheses, and exoskeletal orthoses. The functional demand and complexity of these systems necessitated studies to examine the efficacy of advanced prosthetic and orthotic devices, specifically ease of fitting and operation, improved safety and/or function, and optimal prescription parameters to meet specific patient needs. The EACE researchers leveraged advanced assessment tools within the three ARCs and the James A. Haley Veterans’ Hospital to amass nearly a decade worth of data from patients who use advanced prosthetic and orthotic devices.

These efforts have contributed to a global medical body of knowledge on emerging and maturing prosthetic technologies, such as myoelectric upper-limb prostheses, microprocessor-controlled prosthetic knees, powered prosthetic knees, and powered prosthetic ankle-foot systems. The underlying intent of these investigations was to determine if the technologies provide benefit to patient function across a
variety of activities including level-ground gait, slope and stair ambulation, walking during destabilizing conditions, transitions from standing, and common activities of daily living. Since many service members with amputation are young and fit at the time of injury, the EACE researchers have re-examined factors that may influence function later in life, such as metabolic costs and stability during gait. Previous literature often describes older groups of dysvascular amputees. However, this cohort does not offer adequate comparisons for young, blast-related traumatic amputees. Studies conducted with this younger population of amputees provide reference data and begin to establish the prevalence and predictive factors that may lead to the onset of secondary health conditions later in life, such as low back pain, cardiovascular disease, and osteoarthritis. For example, factors such as asymmetric limb loading and short residual limb lengths may impact long-term outcomes and the prescription of prosthetic devices.

New orthotic technologies also continue to emerge. The Intrepid Dynamic Exoskeletal Orthosis (IDEO) is a carbon fiber ankle-foot orthosis developed at the Center for the Intrepid. It is designed to support ankle and foot structures in a posture that minimizes pain while also storing energy before releasing it at push off. It is prescribed to those with functional limb loss following severe injury to muscle, nerve, or bone. Through collaborative efforts in research and education, this orthosis is now available for service members, veterans, and the private sector. Current and future research efforts with the IDEO focus on determining optimal device properties and evaluating patient function during both recreational and military-specific activities.

**Epidemiology and Surveillance**

Researchers in the Epidemiology and Surveillance research focus area track service members and veterans with severe limb trauma and amputation to evaluate the effectiveness of treatment inventions and to monitor subsequent short- and long-term health and QoL outcomes. This initiative is imperative to thoroughly characterize patients and their responses to care and also to identify predictors of optimal rehabilitation outcomes. Descriptive characteristics, prevalence, and incidence of short- and long-term secondary conditions, health care utilization, QoL, and the resulting economic impact are all quantifiable factors that EACE stakeholders may use to guide health care policy and direct resources to facilitate optimal outcomes. While providing a continuously evolving view of the extremity trauma and amputation population, research in the Epidemiology and Surveillance research focus area informs, supports, and unifies efforts throughout the R&S Division lines of research.

The need for comprehensive outcome measures that can assess high-level mobility and agility has encouraged collaboration between DoD and VA to develop the Comprehensive High-Level Activity Mobility Predictor (CHAMP). The CHAMP was assessed for reliability and validity and recommendations for its clinical application disseminated through published manuscripts and training seminars for DoD and VA clinicians. Reference standards from uninjured male service members along with those who sustained limb loss are provided for both the CHAMP and the 6-minute walk test to establish a guideline for goal setting and expectations. The CHAMP is one example of an outcome measure that can be used to longitudinally characterize the function of male
service members as they age. The EACE researchers are continuing to develop and validate the CHAMP for female service members as well as other novel outcome measures that will improve the health of injured service members and veterans.

The EACE researchers are currently focused on conducting epidemiologic studies to evaluate the morbidity and mortality rates of two core patient cohorts with the long-term goal of maximizing their health and QoL outcomes. Specifically, individuals with severe extremity injuries have been stratified into those with (1) “acutely threatened limbs” that required immediate consideration for amputation and (2) “functionally impaired limbs” that do not require immediate consideration for amputation but cause significant limitations. The EACE researchers use local clinical data records, Defense Manpower Data Center records, the Expeditionary Medical Encounter Database (EMED), the Medical Health System Data Repository, the VA Corporate Data Warehouse, and multiple other data sources to conduct research. Central to the EACE epidemiological efforts is the ability to access the EMED, a gold standard repository of high-quality, verified, and validated combat casualty data spanning the spectrum of care and rehabilitation.\textsuperscript{71,72} Within the EMED, each casualty injury record is coded by in-house Naval Health Research Center clinical staff on diagnoses (International Classification of Diseases-9/10 codes) and on injury severity, using both the Abbreviated Injury Scale and Abbreviated Injury Scale-2005 Military. Coded injury data are then mapped to tactical data describing the characteristics of the casualty event, descriptions of treatments administered within the chain of evacuation, predeployment- and postdeployment-related health information, personnel data with career and dependent history data, and finally, with longitudinal, prospective QoL outcome data.

In addition to performing retrospective epidemiologic studies, the EACE researchers have begun prospective longitudinal efforts to examine rehabilitative and QoL outcomes. Another key facet to the EACE R&S directorate is the Wounded Warrior Recovery Project (WWRP). The WWRP is a 16-year, longitudinal, prospective, informed-consent study being conducted through Naval Health Research Center, which tracks long-term QoL, mental health outcomes, pain experiences, social support, and prosthetic/orthotic use and satisfaction.\textsuperscript{73} Funding for the WWRP is through U.S. Navy Bureau of Medicine and Surgery.

Complementary to the WWRP, additional surveillance studies are aimed at understanding the prevalence and prevention of developing secondary health conditions following severe extremity trauma, such as osteoarthritis, obesity, cardiovascular disease, and low back pain. These secondary conditions may exacerbate an existing disability caused by the initial extremity injury.\textsuperscript{74,75} Among these secondary conditions, delayed amputations receive particular attention as individuals may eventually choose or require an elective amputation to recover function. Delayed amputations, occurring more than 90 days after initial injury, account for 10 to 15% of all combat-related amputations\textsuperscript{76} and correlate with adverse physical and psychological diagnoses.\textsuperscript{72} Future studies will work to identify early predictors of delayed amputations including the specific injury, wound complications, and rehabilitation therapies that may increase or decrease the likelihood of amputation.

Findings from the EACE Epidemiology and Surveillance research focus area support EACE-specific needs related to rehabilitating and reintegrating injured service members and veterans. This research will help inform DoD and VA clinical practice recommendations, guidelines, and policy on extremity trauma and amputation care.

Medical and Surgical Innovations

In recent years, significant efforts have been devoted toward developing advanced medical therapies and surgical techniques to improve the restoration of tissue form and function following traumatic composite tissue injury. The EACE, collaborating with ongoing research efforts at WRNMMC and the Uniformed Services University of the Health Sciences, is in the early stages of building a capability to conduct preclinical and clinical research in the broad area of medical and surgical innovations. The overarching goal of the EACE Medical and Surgical Innovations research focus area is to foster the development of next-generation regenerative medicine therapeutics and innovative surgical approaches and to accelerate the translation of the best-performing technologies to the clinic.

Regenerative Medicine (RM) focuses on replacing or regenerating human cells, tissues, or organs to restore or establish normal form and function.\textsuperscript{77} Next-generation regenerative medicine therapeutics focused on restoring tissues of the extremities (i.e., muscle, bone, tendon, ligament, nerve) are particularly relevant for service members and veterans with extremity trauma and/or amputation. Additionally, many of these therapeutics that have been developed and/or investigated were supported, at least in part, by DoD and/or VA, such as the Armed Forces Institute of Regenerative Medicine. Examples of topics currently under investigation by the EACE researchers include the clinical evaluation of a biologic scaffold material to aid in the restoration of tissue structure and function following volumetric muscle loss; the preclinical evaluation of the mechanisms that drive biomaterial mediated tissue regeneration as a means to facilitate rational design of next-generation RM materials and therapeutics; the development of 3-dimensional bio-printing; and whole organ engineering capabilities, among others.

Several innovative surgical approaches have been developed to facilitate tissue reconstruction and improve limb function for individuals with traumatic extremity injuries. Examples include targeted muscle reinnervation\textsuperscript{78} for prosthetic control and osseointegration, in which a prosthesis is attached directly to the skeleton of a patient with an amputation.\textsuperscript{79} The EACE researchers are currently participating in several osseointegration studies, led by clinicians at WRNMMC,
whose ultimate goal is to improve the QoL for individuals with limb loss, especially those who cannot tolerate conventional, socket-based prostheses.

These RM therapeutics and innovative surgical approaches offer immense potential to promote tissue restoration, improved function, and/or enhanced QoL; however, they vary in their stage of development, with relatively few technologies having reached commercialization and/or widespread clinical implementation. Thus, continued investment by the DoD in future research and development activities is needed to realize true clinical success in re-establishing optimal function and QoL for service members and veterans with severe extremity trauma injuries. These future directions should encompass activities that span the full spectrum of the research continuum—from basic science to preclinical animal models to human clinical trials conducted by teams of clinicians and researchers from multidisciplinary fields including orthopedic surgery, regenerative medicine, bioengineering, and rehabilitation.

**CONCLUSION**

Military medical research often paves the way for changes in civilian and global clinical practice, partly because of the nature of high-impact innovations and discoveries. At the time of establishment, the EACE entered richly developed clinical and research environments comprised of federal, academic, clinical, and industry leaders. Through its R&S Division, the EACE is able to leverage and expand upon existing research efforts, funding, and infrastructure to establish research in four key focus areas. Together with their collaborators and partners, the R&S Division strives to conduct research that influences clinical practice guidelines throughout the Military Health System, VA, and civilian health care networks. The EACE researchers actively compete for intramural and extramural research funding to execute scientific investigations that improve the clinical outcomes of our injured service members and veterans as they return to the highest-possible level of physical, psychological, and emotional function. The EACE R&S Division will continue to conduct relevant research and translate findings into clinical practice to improve QoL for service members and veterans. The EACE will continue to innovate and discover so that our nation’s service members and veterans are provided the highest level of care.

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The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium: Reaching in Partnership for Optimal Orthopaedic Rehabilitation Outcomes

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ABSTRACT The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium began in September 2011 as a cooperative agreement with the Department of Defense (DoD) Congressionally Directed Medical Research Programs Peer Reviewed Orthopaedic Research Program. A partnership was formed with DoD Military Treatment Facilities (MTFs), U.S. Department of Veterans Affairs (VA) Centers, the National Institutes of Health (NIH), academia, and industry to rapidly conduct innovative, high-impact, and sustainable clinically relevant research. The BADER Consortium has a unique research capacity-building focus that creates infrastructures and strategically connects and supports research teams to conduct multiteam research initiatives primarily led by MTF and VA investigators.

BADER relies on strong partnerships with these agencies to strengthen and support orthopaedic rehabilitation research. Its focus is on the rapid forming and execution of projects focused on obtaining optimal functional outcomes for patients with limb loss and limb injuries. The Consortium is based on an NIH research capacity-building model that comprises essential research support components that are anchored by a set of BADER-funded and initiative-launching studies. Through a partnership with the DoD/VA Extremity Trauma and Amputation Center of Excellence, the BADER Consortium’s research initiative-launching program has directly supported the identification and establishment of eight BADER-funded clinical studies, BADER’s Clinical Research Core (CRC) staff, who are embedded within each of the MTFs, have supported an additional 37 non-BADER Consortium-funded projects. Additional key research support infrastructures that expedite the process for conducting multisite clinical trials include an omnibus Cooperative Research and Development Agreement and the NIH Clinical Trials Database. A 2015 Defense Health Board report highlighted the Consortium’s vital role, stating the research capabilities of the DoD Advanced Rehabilitation Centers are significantly enhanced and facilitated by the BADER Consortium.

INTRODUCTION

The significant traumatic injuries to limbs sustained by service members during combat deployments in Operations Enduring Freedom, Iraqi Freedom, and New Dawn posed new challenges to Department of Defense (DoD) Military Treatment Facilities (MTFs) and U.S. Department of Veterans Affairs (VA) sites. During active periods of conflict, the number and complexity of injuries resulting in limb loss and limb salvage grew substantially relative to past conflicts. This is attributed to advancements in the effectiveness of body armor, rapid evacuation, and early medical attention programs.

To address the new clinical challenges associated with combat-related limb injuries and loss, DoD and VA officials established specialized clinical programs for extremity trauma care and research, technology development initiatives in orthotics and prosthetics, and the development of consortia to conduct and support clinically focused research programs related to orthopaedics and rehabilitation.

The Bridging Advanced Developments for Exceptional Rehabilitation (BADER) Consortium, started in September 2011, is part of that collaborative effort. Its overall goal is to strengthen evidence-based orthopaedic rehabilitation care to achieve optimal functional outcomes for wounded warriors and civilians with traumatic limb loss and limb differences.

The purpose of this article is three-fold. First, we highlight the BADER Consortium’s model system and methods for supporting the establishment of impactful and sustainable research capabilities. This includes research capacity-building components, research support infrastructures, and initiative-launching studies. Second, we demonstrate results indicating
the effectiveness of BADER Consortium activities. Finally, we present a discussion containing insights gained to date.

**Orthopaedic Rehabilitation Research Efforts**

A review of related research programs is needed to provide context for best understanding the BADER Consortium’s central role in developing these critical research infrastructures. In 2001, following an assessment of the Army Medical Department’s ability to care for large populations of combat amputees, Walter Reed Army Medical Center, now Walter Reed National Military Medical Center, was established as the first specialized amputee care center.

In 2007, three DoD Advanced Rehabilitation Centers (ARCs) were established for military amputees with specialized clinical programs in orthopaedics and orthopaedic rehabilitation. These centers are the Military Advanced Training Center at Walter Reed National Military Medical Center; the Center for the Intrepid and the San Antonio Military Medical Center at the Brook Army Medical Center; and the Comprehensive Combat and Complex Casualty Care (C5) Program at Naval Medical Center San Diego. In concert with DoD efforts, the VA established an Amputee System of Care across the United States with regional amputation centers and polytrauma amputation network sites.

The ARCs implemented advanced motivational and therapeutic rehabilitation care models that utilized intensive rehabilitation, peer dynamics, and advanced rehabilitation technologies with the goal of obtaining unprecedented outcomes and quality of life (QoL) following rehabilitation. As a result, service members with salvaged and amputated limbs began returning to active duty, including redeployment to combat zones.

Efforts of the ARCs to obtain high functional and QoL outcomes have led to a series of orthopaedic technology development initiatives. The Telemedicine and Advanced Technology Research Center, a component of the U.S. Army Medical Research and Materiel Command (USAMRMC), expanded their Advanced Prosthetics and Neural Engineering Program to include a Lower Extremity Gait Systems–integrated research team. In addition, the Defense Advanced Research Projects Agency (DARPA) established the Revolutionizing Prosthetics Program in 2006. The Revolutionizing Prosthetics Program developed “two anthropomorphic advanced modular prototype prosthetic arm systems, including sockets, which offer increased range of motion, dexterity and control options.”

Stemming from a joint agreement involving multiple government agencies, the Armed Forces Institute of Regenerative Medicine (AFIRM) was launched in 2007 to accelerate research and the delivery of regenerative medicine therapies to treat the most severely injured service members. The primary focus of AFIRM research has been seeking fundamental breakthroughs in basic scientific domains at the cellular and tissue levels.

As a natural extension of the AFIRM Consortium, the Major Extremity Trauma Research Consortium (METRC) was established in September 2009. METRC consists of a national network of clinical centers and one data-coordinating center that work together with the DoD to conduct multicenter clinical research studies relevant to the treatment and outcomes of orthopaedic trauma sustained in the military. The overall goal of the METRC is to “produce the evidence needed to establish treatment guidelines for the optimal care of the wounded warrior and ultimately improve the clinical, functional, and QoL outcomes of both service members and civilians who sustain high-energy trauma to their extremities.”

Also in 2009, the Extremity Trauma and Amputation Center of Excellence (EACE) was legislated by Congress as a collaborative organization to enhance research partnerships between the DoD, VA, academia, and industry. One unique aspect of the EACE is a congressional mandate to “conduct research to develop scientific information aimed at saving injured extremities, avoiding amputations, and preserving and restoring the function of injured extremities.” The primary mission of the EACE is to coordinate multidisciplinary teams to conduct scientific research at the ARCs and VA sites that improves clinical outcomes and returns patients to the highest possible level of physical, psychological, and emotional functions. The scope of the EACE mission includes treatment, research, education and training, and mitigation following traumatic extremity injury and/or amputation.

With the burgeoning increase in clinical research and advanced patient care activities, the need soon became apparent for specialized “infrastructures” that would enhance the capacity to conduct and sustain world-class orthopaedic rehabilitation research. In 2010, the DoD Congressionally Directed Medical Research Programs (CDMRP) Peer Reviewed Orthopaedic Research Program established the Orthopaedic Research Clinical Consortium Award (ORCCA). The goal of the ORCCA was to “establish a strong infrastructure for continuing clinical studies on combat-related musculoskeletal injuries and products that result in changes to, or validation of, current clinical practices that lead to better outcomes for our injured warriors.”

Following that, the Center for Rehabilitation Sciences Research (CRSR) was established in 2011 to advance the rehabilitative care for service members with combat-related injuries through synergistic research projects that promote successful return to duty and community reintegration. Housed in the Uniformed Services University of the Health Sciences, CRSR is an academic arm of rehabilitation activities within the DoD and well positioned to expedite the translation of advancements into patient care settings via the education and training of future health care providers within the military healthcare system.

**The BADER Consortium**

In September 2011, the BADER Consortium, based at the University of Delaware (UD), received the ORCCA award. A partnership was formed with four MTFs (the three ARCs and the Naval Medical Center Portsmouth), the EACE, VA Centers, the National Institutes of Health (NIH), academia,
and industry to rapidly conduct innovative, high-impact, clinically relevant orthopaedic rehabilitation research. Using an NIH capacity-building model approach that provides essential infrastructures and project funding to conduct impactful research, the BADER Consortium has further strengthened MTF/VA efforts to establish and support a growing orthopaedic rehabilitation research culture.

The mission of the BADER Consortium is to help establish sustainable world-class programs in orthopaedic rehabilitation research at MTFs and VA sites that result in evidence-based orthopaedic rehabilitation care. Our vision is for wounded warriors and civilians with limb loss and limb difference to routinely benefit from significant orthopaedic rehabilitation advancements, and as a result obtain optimal functional clinical outcomes and fully re-engage in life and work activities. These goals are being realized through three primary objectives:

1. Establish infrastructures to support the advancement of orthopaedic rehabilitation research capabilities at ARCs and VA sites that promote optimal functional outcomes and QoL;
2. Conduct a variety of innovative, high-impact, and clinically relevant BADER-funded initiative-launching studies that lead to sustainable externally funded research programs; and
3. Preserve advancements in orthopaedic rehabilitation research by establishing an externally funded, self-sustaining clinical research enterprise.

METHODS
The BADER Consortium framework (Fig. 1) is modeled on the Institutional Development Award (IDeA) Network of Biomedical Research Excellence (INBRE) program—a component of the research capacity-building IDeA program of the NIH.12 Established in 1993 by congressional mandate, the IDeA program aims to increase research competitiveness and sustainment of select states. This is accomplished through support for two major programs: Centers of Biomedical Research Excellence and INBREs. The INBRE program creates infrastructure to administratively support a broad research network—typically multiple disparate research, academic, and patient care centers geographically dispersed across a state or region. The activities conducted by an INBRE Program—while broad in nature and containing policies and procedures to ensure full compliance with human subject protection, scientific integrity, and administrative federal regulations—generally reside in three categories: research capacity-building, research-support, and INBRE-funded studies for launching scientific careers in research focus areas. The BADER Consortium used this unique model to enhance the capacity at MTFs and VA sites, making it possible for more innovative, high-impact research to be conducted.

Research Capacity-Building Infrastructures
General principles of the INBRE Program were implemented by the BADER Consortium to construct a broad, nationwide orthopaedic rehabilitation clinical research network across
government, academic, and industrial partners. The Consortium’s research capacity-building components consist of three Scientific and Technical Cores; a Clinical Research Core (CRC); a Research Advisory Committee (RAC)—groups of scientific experts providing research reviews, advice, and expertise; and access to graduate training in Biomechanics and Movement Science.

Three Scientific and Technical Cores provide strategic support to orthopaedic rehabilitation scientists and partnering clinicians at the MTFs and VA sites. The Biomechanics Core provides the Consortium expertise and support in biomechanics and human movement analysis methodologies. The services of the Core include assistance with solving on-site problems with hardware and software, expert advice for research proposals and the development of new strategies and methods in support of clinical research areas. The Biostatistics Core at Christiana Care Health System provides episodic biostatistics support under a fee-for-service mechanism—where BADER pays the costs of incurred fees in order to be cost-effective. The Core provides pre- and postaward support to BADER-supported investigators, including but not limited to power analysis, statistical modeling, and specialized data analyses. Located at UD, the Rehabilitation Outcomes Measurement Core works directly with Principal Investigators to ensure that adequate outcomes measurement techniques are introduced and followed in the research process. The specific aim of the Rehabilitation Outcomes Measurement Core is to assist investigators in the selection, use, implementation, analysis, and interpretation of relevant outcomes variables for studies that are proposed and implemented within the BADER Consortium.

The CRC provides on-site staffing support necessary to develop, conduct, and monitor clinical studies under the direction of MTF administrative directors and clinical research leaders in support of MTF, the EACE, and/or CRSR scientific staff. The CRC is central, offering “boots on the ground” support staff to assist with research efforts at MTFs and VA sites. It is the Consortium’s central body of study execution and provides MTF-led research teams with resources to develop, conduct, and monitor clinical studies, as well as day-to-day support, education, and training. Two full-time, on-site CRC staff members are dedicated to each of the MTFs. The highly skilled individuals provide MTF staff with on-site technical assistance, protocol management, and human subject recruitment support. The CRC research support infrastructures are further organized to develop and support a research-intensive culture by assisting MTF investigators with establishing a uniform and sustainable research capability that facilitates ongoing and new clinical research protocols across all participating study sites.

Research expertise and mentorship are provided through the RAC, comprising experts specializing in DoD research and priority clinical gap areas. The overall purpose of the RAC is to assure the quality and impact of BADER Consortium research. The team conducts scientific reviews of proposed projects and performs reviews of research project progress reports. Efforts of the RAC are bolstered by an extensive group of BADER Consortium affiliates from which MTF and VA research partnerships are formed.

Access to a graduate training program in Biomechanics and Movement Science has been made available to MTF and VA center staff. Under an agreement with the College of Health Sciences at UD, the BADER Consortium provides graduate stipends for select MTF and VA research staff to enhance their skills and research expertise through the pursuit of graduate education degrees.

Research Support Infrastructures

The Consortium’s research support components are designed to ease the burden of administrative overhead, ensure data safety, and facilitate the forming of research partnerships. They consist of a single, Consortium-wide master Cooperative Research and Development Agreement (Consortium CRADA), a centralized protocol and data management system (PDMS), and administrative support for forming and sustaining DoD and VA research partnerships with academia and industry.

To accelerate the establishment of clinical research projects and research partnerships, BADER Consortium leadership worked with the Medical Research Law Office of the Staff Judge Advocate, USAMRMC to develop the BADER Consortium CRADA. The goal of this initiative was to jettison the traditional project-specific CRADA format—where CRADAs are customized to each project—in favor of a single consortium CRADA model that outlined the breadth of policies and procedures encountered by the activities of a national consortium.

To establish the Consortium CRADA, a selection of CRADAs from the Navy, Army, and the NIH were gathered. The content of each example CRADA was reviewed and categorized. Like categories were then combined and systematically reduced to generalized guidelines in each CRADA activity category. Each category was then tested against applicable federal regulations and active policies. The resulting “master” Consortium CRADA was virtually exercised using an array of Consortium-related scenarios. The resulting policy and implementation procedures, such as on-boarding projects and the declaration and approval of amendments, were developed. Before full implementation, the Consortium CRADA was trialed at two government sites.

Implemented via a collaborative agreement with the NIH Eunice Kennedy Shriver National Institute for Child Health and Human Development, the NIH’s Clinical Trials Database serves as a rehabilitation outcomes data collection tool with patient self-report and a secure centralized web-based portal for the management of clinical study data and tissue repository information. This PDMS is a Federal Information Security Management Act–compliant tool that simplifies data sharing among member sites by standardizing research methods while simultaneously facilitating protocol tracking and compliance monitoring. While fully customizable, it uses standardized forms, common data elements, and a common vocabulary.
The centralized administrative core provides valuable support for the establishment and sustainment of research partnerships. This includes support for grand rounds presentations, site visits by potential collaborators, and scientific planning meetings at MTF and VA sites.

**Initiative-Launching Studies**

The initiative-launching component contains a set of BADER Consortium-funded clinical research studies aimed at launching impactful clinical research initiatives in partnership with the MTFs and VA sites. BADER-funded projects are awarded via a peer-reviewed, limited competition award program open to the BADER Consortium Affiliates responding to a Consortium-generated call for proposals. The proposals are scientifically reviewed by the BADER RAC and ultimately selected by the Consortium’s Government Steering Committee. The goal of these initiative-launching projects is to establish sustainable multiteam system partnerships and generate clinically focused results that advance patient care paradigms in critical patient care gap areas. Furthermore, this BADER-supported program is designed to provide necessary funding to propel new and early-career scientists into independent researchers leading sustainable research programs at MTF and VA sites. This funding mechanism is also ideally suited for establishing a technology translation pipeline, based on a multiteam system model, by taking emerging technologies from Telemedicine and Advanced Technology Research Center and DARPA programs and rapidly transitioning the technology across research activity category teams into clinical trials and patient care paradigms (Fig. 2).

**RESULTS**

The BADER Consortium became operational in 2013 following an initial 12-month “discovery” phase. During that phase, a total of eight CRC on-site research support staff were identified in collaboration with MTF staff, hired by UD, trained and on-boarded at the MTFs. Development and testing of the Consortium CRADA was completed on September 19, 2012. Within four months of its implementation, six partner institutions completed on-boarding to the Consortium CRADA. At the time of this report, the BADER Consortium contains nine industrial partners, eight government sites, 21 BADER-supported employees (10 are stationed full time at MTF sites), and 99 BADER-affiliated experts located at academic research sites across North America. Recently, a generic version of the Consortium CRADA was provided to CDMRP officials, upon request, for use by other CDMRP-funded consortia.

By 2014, the BADER Consortium completed two rounds of BADER-funded calls for proposals and identified its eighth BADER-funded clinical study. The earliest studies received clearance from the USAMRMC Human Research Protection Office to begin study activities in June of 2013. The Administrative Core provided critical support for these activities by coordinating efforts, in partnership with the EACE, to identify research gap areas used to solicit proposals for BADER-funded projects and assist with the scientific review process. Totaling $7.6 million in direct project funding, the eight BADER-funded studies have a net planned enrollment greater than 1,400 subjects.

Topic areas covered by BADER-funded projects and their emerging team research initiatives include the following: assessing new, clinically relevant research areas in DoD-identified critical gap areas to reduce the incidence of falls; retraining to improve walking and running after amputation; prescribing prosthetics for work and carrying heavy loads; and determining the impact of robotic prosthetics on functional outcomes and QoL. Additional projects focus on improving measures of functional outcomes and determining the effectiveness of current rehabilitation care trajectories.

In addition to their assignments on BADER-funded research projects, members of the CRC on-site staff have provided support for 37 non-BADER-funded studies at MTF sites. The nature of CRC staff contributions has been broad. Their responsibilities have included completing literature reviews in preparation of project presentations and publications; recruiting human subjects; assisting with the preparation of grant proposals; monitoring regulatory documents and processes; engagement with clinical staff to promote systematic outcomes assessment; loading research data into the PDMS; and contributing to the evaluation and acquisition of laboratory equipment.

The Scientific and Technical Cores demonstrated the capacity to provide support for orthopaedic rehabilitation research. The cores have supported BADER-funded research projects and provided valuable support and expertise for research ideas that become new research proposals and research areas. The Biomechanics Core supported a multicenter CRSR project to enhance data sharing. The Biostatistics Core provided statistical modeling support for seven external grant applications in the fall of 2014. The Outcomes Core spearheaded two clinical research initiatives and provided assistance to nearly all projects and grant proposals.
At the time of this report, one BADER-funded study has been completed. BADER research efforts have led to five published manuscripts, six pending publications, and 44 published abstracts. Thirteen grant proposals have been submitted to various agencies for external funding. These submissions have resulted in six externally funded projects having a net value of $3.5 million and an additional $7.9 million in pending grant submissions.

In 2013, the Defense Health Board (DHB) was tasked with reviewing the full spectrum of amputee care and defining a strategy for preserving and continuing the advancements.1 BADER Consortium leadership provided one of many DHB briefs and support materials leading to the April 8, 2015, DHB report titled, “Sustainment and Advancement of Amputee Care.” Following an extensive review, the DHB described BADER Consortium as “central to the ARCs’ research capabilities and current efforts.” The DHB also found that the Consortium “significantly enhanced and facilitated” the research capabilities of the ARCs.1

DISCUSSION

The BADER Consortium is uniquely positioned among its partner programs to advance the orthopaedic rehabilitation research agenda. It uses a clinical research capacity-building component that supports research team building and the successful identification and establishment of impactful and sustainable research initiatives. Key research infrastructures have been established in support of BADER-funded, externally funded, and MTF-supported clinical research projects. However, not all partner organizations have uniformly embraced Consortium-centric components.

The Consortium CRADA is a Consortium-centric mechanism that is used to rapidly onboard study sites and research projects. It provides a uniform standard operating procedure that addresses the broad range of policies related to research partnerships. Adoption of the Consortium-centric CRADA has been mixed across branches of the military, although readily embraced by academic, industrial, and select government partners. As a result, natural separations have begun to form between Consortium CRADA partners and nonpartners. Such divisions are disadvantageous and Consortium activities would be enhanced by the broad acceptance of a unified CRADA mechanism.

While BADER Consortium’s research infrastructures and project activities are seen as “central” to the ARCs’ mission, they should not be viewed as complete. BADER’s operational model was originally designed to focus primarily in three component areas—capacity-building, research-support,
and initiative-launching studies. As the result of our observations and direct requests for assistance, BADER support has transitioned limited resources to assist with technology translation, research subject recruitment, and research partnership activities (Fig. 3). Clearly, the development and sustainment of large-scale research subject recruitment capabilities focused on military personnel and civilians is an additional desired infrastructure, considering the goal of sustaining world-class research and patient care efforts during periods of reduced conflict.1

Streamlining the transition of new technologies into clinical research and patient care is facilitated by an understanding and implementation of the science behind team science.13 As the breadth of orthopaedic rehabilitation gap areas grows to encompass critical outcomes determinants in clinical acute care and early intervention focus areas, infrastructures for the rapid establishment and sustainment of dynamic research partnerships are also warranted.

CONCLUSION
The BADER Consortium is a highly effective network for enhancing orthopaedic rehabilitation research capacities at MTF and VA sites, establishing research areas in key gap areas and supporting an array of clinical studies in partnership with government, academia, and industry. Through its partnership with the EACE and cooperative agreement with CDMRP, the BADER Consortium is addressing important gaps in clinical orthopaedic rehabilitation research and patient care. Structures and activities of the BADER Consortium have become “central” to the ARC’s research capabilities and current efforts to strengthen and sustain evidence-based orthopaedic rehabilitation care that results in optimal functional outcomes for wounded warriors.1

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The Center for Rehabilitation Sciences Research: Advancing the Rehabilitative Care for Service Members With Complex Trauma

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ABSTRACT The Center for Rehabilitation Sciences Research (CRSR) was established to advance the rehabilitative care for service members with combat-related injuries, particularly those with orthopedic, cognitive, and neurological complications. The center supports comprehensive research projects to optimize treatment strategies and promote the successful return to duty and community reintegration of injured service members. The center also provides a unique platform for fostering innovative research and incorporating clinical/technical advances in the rehabilitative care for service members. CRSR is composed of four research focus areas: (1) identifying barriers to successful rehabilitation and reintegration, (2) improving pain management strategies to promote full participation in rehabilitation programs, (3) applying novel technologies to advance rehabilitation methods and enhance outcome assessments, and (4) transferring new technology to improve functional capacity, independence, and quality of life. Each of these research focus areas works synergistically to influence the quality of life for injured service members. The purpose of this overview is to highlight the clinical research efforts of CRSR, namely how this organization engages a broad group of interdisciplinary investigators from medicine, biology, engineering, anthropology, and physiology to help solve clinically relevant problems for our service members, veterans, and their families.

OVERVIEW Between 2001 and 2015, there have been approximately 327,000 cases of traumatic brain injury (TBI), 138,000 incidents of post-traumatic stress disorder (PTSD), and 1,645 service members who have sustained one or more major extremity amputations while serving in Operations Iraqi Freedom, Enduring Freedom, and New Dawn.¹ The majority of these severe injuries occurred from the effects of blasts,² most commonly the result of improvised explosive devices and rocket-propelled grenades.³ Improved trauma care on the battlefield and throughout the military health care system (MHS) has resulted in historic survival rates,³ with service members now surviving injuries that in previous wars would have been fatal. Because of the complexity of these wounds and the frequency of multiple, coexisting injuries and impairments, greater challenges now exist for rehabilitation practices.³⁻⁶

Battlefield survival is only the first step to recovery after a war injury. It is the responsibility of the MHS, the Department of Veterans Affairs (VA), and—arguably—the entire nation to help service members not only survive after injury but thrive as well. Recovery from complex wounds is extremely challenging for patients and families alike. Rehabilitation practices focus on goal setting and improving function through retraining, adaptive strategies, or utilizing novel equipment and assistive technology. The clinics emphasize restoring basic mobility for activities of daily living (e.g., dressing, bathing, and feeding); encompass cognitive training in order to restore speech and communication; focus on return to recreational and sports activities; and provide tools for emotionally reconnecting to one’s family, friends, and community. Given the uniqueness of war-related trauma and the desire to see patients thrive after injury, new rehabilitative methods and technology that focus on the military population must be explored.

Wounded service members represent a patient cohort that is relatively young, had high fitness levels before injury,² and is highly motivated to return to high-demanding activities.⁵ Careful thought and consideration must be given to mitigate the long-term risks of living with a disability for this population, given their relatively young age at time of injury. For example, the incidence rates of diabetes, heart disease, arthritis, and chronic pain are significantly higher in veterans with limb loss than in
age-matched population controls.\textsuperscript{7,8} Thus, research strategies must focus on both the immediate and long-term impacts of wellness and quality of life to mitigate these increased risks.

The Center for Rehabilitation Sciences Research (CRSR) was developed in 2011 to facilitate innovative research projects that promote service member recovery and rehabilitation (Fig. 1). CRSR provides efficient dissemination of research knowledge gained from supported projects to military treatment facilities (MTFs) and the Department of Defense (DoD) Centers of Excellence (CoE). Headquartered at the Uniformed Services University (USU), CRSR has succeeded in developing a well-coordinated interdisciplinary team, primarily forged through partnerships between Walter Reed National Military Medical Center (WRNMMC), Brooke Army Medical Center, the Center for the Intrepid (CFI), Naval Medical Center Portsmouth, and Naval Medical Center San Diego (NMCSD) (Fig. 2). These sites have been the principal MTFs caring for the majority of injured service members returning from combat operations overseas. In addition, CRSR is well positioned, together with the Extremity Trauma and Amputee Center of Excellence (EACE) and other DoD CoEs, to fill the critical gaps in military relevant rehabilitative research identified by the Defense Health Agency and the U.S. Army Medical Research and Materiel Command (USAMRMC). As new discoveries are made, CRSR has the ability to influence the education and training of future health care providers and offer guidance for rehabilitating injured service members and their families.

CRSR is directed by U.S. Army Colonel (Ret.) Paul Pasquina, who served as the Chief of the Integrated Department of Orthopedics and Rehabilitation at both Walter Reed Army Medical Center and the Naval Medical Center in Bethesda, Maryland, before and during their merger to become WRNMMC. Dr. Pasquina is currently serving as the Chief of Rehabilitation for WRNMMC and the inaugural Chairman of the Department of Physical Medicine & Rehabilitation at USU, which serves as the medical academic institution of the MHS. This new USU department promotes the academic growth of all rehabilitation professionals within the MHS and ensures that the knowledge gained through CRSR and other rehabilitative research centers directly influences resilience and recovery planning.

Although a thorough description and detailed report about CRSR-sponsored projects and its investigators is beyond the scope of this overview, a summary of noteworthy scientific contributions has been included from each of the four research focus areas. This article will highlight CRSR clinical research efforts and how this organization engages a broad group of interdisciplinary investigators and connects them directly with clinicians, patients, and families to help solve clinically relevant problems.

**RESEARCH FOCUS AREA 1: IDENTIFYING BARRIERS TO SUCCESSFUL INTEGRATION**

This research area, led by Dr. Seth Messinger, focuses on the use of ethnographic interviewing to identify the current barriers to social reintegration for warfighters with neurological and orthopedic-related trauma. One of the paradoxical challenges facing military clinicians who work in outpatient rehabilitation programs is assessing the quality and effectiveness of intervention strategies. Recent research conducted in the U.S. Armed Forces Amputee Care Program has explored the ways in which the duration of rehabilitation, sense of patient and family autonomy, and locus of control influence the rehabilitative trajectory of severely injured service members. One study compared two patients with similar upper extremity amputations, ages, branch of service, and regional origins. Although both patients excelled at achieving functional goals in rehabilitation, only one had enduring success with his prosthesis;\textsuperscript{9} the other abandoned his device. The differing outcomes were attributed to the sense of autonomy/control experienced by the more successful patient in contrast to the less successful one. A follow-on study investigated lengths of stay and expectation concurrences between patients and clinicians and the influence on outcomes.\textsuperscript{10}

Dr. Messinger identified a critical point beyond which protracted outpatient care may be disruptive as patient concerns shift to other issues and no longer align with those of the therapists. Although these studies are limited in sample size, the depth of ethnographic and qualitative interviewing allows clinical researchers to explore factors that would not otherwise be apparent to the clinical staff.\textsuperscript{9}

Limited evidence also is available to understand how the brain is cognitively and psychologically altered after experiencing severe trauma, particularly for those who have sustained both
limb damage and TBI. This gap has been bridged by investigating the nexus of psychiatry and biomedicine as well as their influence on patient participation and success with rehabilitation. To date, 40 patients with both mild TBI and PTSD have been enrolled with unexpected findings discovered. Many subjects self-report that their symptoms of PTSD (e.g., hyper vigilance) could be viewed positively and assist some patients with their transition back into the civilian community.11

Finally, ongoing research is focused on understanding the aspects of rehabilitative care that help injured service members develop resilience as they subsequently leave the rehabilitation program and return to duty or their communities. Early results indicate that the relationships these patients form with their providers and peers have long-lasting effects as they encounter adversities and challenges once resuming life after injury. Their sense of accomplishment during rehabilitation, which they attribute to the knowledge, skills, and motivation given to them by their providers and peers, continues to be a source of inner strength. In addition, patients note that their access to high technology, particularly in prosthetics, not only improves functional abilities but also provides a sense of symbolic commitment that the military and their nation support their recovery. Although many patients report being less physically active in the years after leaving a rehabilitation program, they still greatly applaud the robust clinical focus on sports and athleticism that the rehabilitation program provided. Individuals note that this focus on high levels of performance adds tremendously to their successful community reintegration.12

RESEARCH FOCUS AREA 2: IMPROVEMENTS TO PAIN MANAGEMENT STRATEGIES

This research area focuses on pain management strategies critical to recovery and quality of life after severe combat injuries. Drs. Steven Cohen, Jack Tsao and Brad Isaacson lead this area to assist wounded service members with orthopedic and neurological pain relief. For the past several years, research efforts have concentrated on main complications: (1) axial spine pain (2) phantom limb pain (PLP).

Axial Spine Pain: Lower Back and Neck Pain

Debilitating conditions such as neck and back pain occur more frequently in individuals with limb amputation and trauma and have a more pronounced negative impact on an individual’s mobility and quality of life. Low back pain (LBP), in particular, remains a significant challenge to treat in clinical practice. Several studies have demonstrated that LBP is the leading cause of injury in active duty service members and one of the most common reasons for disability worldwide in people under the age of 45.13,14 By some estimates, the economic costs of treating LBP approach $100 billion per year in the United States.15 Similarly, chronic neck pain is a major cause of disability in the world,16 with a 12-month prevalence rate between 30 and 50%.16–18 Injured service members also suffer from these conditions at high rates and currently there is no “gold standard” for the treatment of neck pain and LBP. To address this lack of standardization and potentially reduce the economic burden of neck pain and LBP for the DoD and VA, Dr. Cohen has led several double-blinded studies to determine the efficacy of the current standards of care for LBP.

The purpose of one study was to evaluate the best approach for treating patients with lumbar and cervical radicular pain. Considerable debate exists as to the benefits of epidural steroid injection (ESI) versus gabapentin prescription.19 To address these conflicting opinions, Dr. Cohen led a multisite prospective-blinded study to assess whether ESI, conservative treatment, or combination treatment provided the highest patient satisfaction for treating cervical radicular pain. Data from 169 patients suggested no significant differences between these treatment options, but combination therapy improved outcomes compared to stand-alone methods.20 Dr. Cohen’s findings highlight the importance of an interdisciplinary approach to management of pain. These outcomes have implications for treating both injured service members and the general population.

Phantom Limb Pain

Almost immediately after the loss of a limb, 90 to 95% of all patients with major limb amputations experience a vivid phantom limb sensation such as warmth, cold, itching, pressure, or sense of position.21 When the sensations become intense enough to be defined as painful, they are referred to as PLP. PLP occurs in 80 to 90% of individuals with limb amputation and usually appears immediately following awakening from anesthesia, though pain onset may be delayed for up to a few days or weeks in 25% of patients. The presence of PLP does not seem to correlate with the cause or location of amputation.22 In most cases, PLP gradually fades with time, particularly with prosthetic use; however, a significant percentage of patients (30–70%) report having pain that persists for years or decades. Since evidence indicates that pain continuing for longer than 6 months is the most difficult to treat,22,23 better evidence is needed to identify effective treatment strategies.

The causes of PLP and nonpainful phantom sensation are not known; however, both peripheral and central processes are implicated.24 Memories of the limb’s posture and form before amputation often survive in the phantom.25,26 After a period of several weeks, a patient’s phantom limb may fade from consciousness and/or disappear completely. However, PLP is remarkably difficult to treat, and there are several reports of failed drug trials in clinical literature.23,24

Dr. Jack Tsao leads CRSR’s PLP research using a combination of virtual reality-based training, simulators, biological assays, and advanced neuroimaging to further understand this debilitating condition. He and his team completed the first randomized, sham-controlled prospective trial of mirror therapy for the treatment of PLP. Mirror therapy functions by having the amputee place a mirror between the intact and amputated limbs while simultaneously moving the phantom limb to mimic the movements of the intact limb viewed in the mirror. Dr. Tsao’s team is currently performing a functional magnetic resonance imagining study to determine activation patterns in the brain before and following mirror therapy.

This team has also extended the theory that visual observation is the key to mirror therapy by demonstrating that bilateral amputees with PLP may experience pain relief by observing someone else’s limbs moving. In a study of 20 bilateral lower limb amputees with PLP, direct visual observation significantly reduced PLP in both limbs, whereas mental visualization methods were not significant.27 This inexpensive technique may assist service members with limb loss reduce their pain thresholds and positively influence their ability

to participate in rehabilitation regimens. Additional work is being conducted by Dr. Tsao’s team to determine if genetic factors influence PLP since some individuals do not develop this debilitating condition following limb amputation, whereas others are severely affected. Lastly, studies are being conducted to determine how many sessions of mirror therapy are needed for pain relief and whether existing neuropathic pain models are applicable for treating PLP.

**Heterotopic Ossification**

Heterotopic ossification (HO) is a pathologic process characterized by ectopic osseous growth in muscle and/or periarticular regions. Although HO may develop from rare genetic disorders, abnormal bone growth has been most frequently reported following trauma, arthroplasty, burns, spinal cord injury, and traumatic brain injury. While most cases of HO in the general population are clinically asymptomatic, and do not require surgical intervention, military service members injured by blasts in Afghanistan and Iraq, have much different prognosis. Armaments such as improvised explosive devices (IEDs) and rocket propelled grenades (RPGs) generate extensive polytrauma, and approximately 63% of war fighters with limb loss have developed post-traumatic HO (with 20% to 40% requiring surgical excision). Symptomatic HO is problematic for service members since it delays rehabilitation regimens, causes pain, limits range of motion, and requires modifications of prosthetic limbs.

The CRSR is committed to understanding the etiology of these ectopic osseous masses and improving surgical planning for servicemen and women. Dr. Brad Isaacson is the lead investigator and received two Congressionally Directed Medical Research Programs (CDMRP) grants (W81XWH-12-2-0017 and W81XWH-16-2-0037) and private donations from the Wounded Warrior Amputee Softball Team to advance this field of orthopedics/rehabilitation. Data from his laboratory has demonstrated a link between bench top research and bedside care, with the mineral apposition rate (MAR), a hallmark for bone growth, computed to be 1.7 times faster in trauma-induced HO compared to non-pathological human bone. Further, when data from this cohort of wounded warriors was limited to patients with no more than a two-year period from injury to excision, and known correlates (traumatic brain injury and nonsteroidal anti-inflammatory drugs), the MAR and recurrence severity were significantly related.

Research by Dr. Isaacson and his team will now focus on developing a translatable animal model to investigate combat-related factors which have been associated with ectopic bone growth (tourniquets, wound vacuum usage, bioburden, and trauma).

**RESEARCH FOCUS AREA 3: APPLICATION OF NEW TECHNOLOGIES TO ADVANCE REHABILITATION AND PERFORMANCE**

CRSR supports and enhances existing clinical programs at the MTFs by facilitating the use of new technologies for rehabilitation and performance optimization. A strong partnership has been forged with the MHS, VA, and EACE to help provide infrastructure and personnel support for research projects. Efforts within this research area are led by a team of principal investigators, including Drs. Erik Wolf, Brad Hendershot, Alison Pruziner, Jason Wilken, Christopher Rabago, Elizabeth Russell Esposito, and Ms. Marilyn Wyatt. Advanced evaluation and treatment techniques are applied to help service members regain functionality after physical and cognitive injuries and to understand the longer-term implications of such injuries and rehabilitation processes.

Novel rehabilitation techniques applied in multisensory virtual reality environments (VRE) promote resilience and recovery to improve physical and cognitive skills in wounded service members. There are four high-end VRE (Computer Assisted Rehabilitation Environment, Motekforce Link, The Netherlands) used in the MHS to provide a safe, interactive setting for clinicians to simulate community, recreational, or occupational tasks.

Dr. Wolf led a CRSR effort to determine the most beneficial bio-mechanical and physiological feedback modalities within a VRE for delivering physical therapy to injured service members. Preliminary results indicate that a game-style application that provides feedback to the patient in an indirect manner produces the most positive outcomes. In collaboration with Dr. Wolf’s efforts, Drs. Pruziner and Hendershot are utilizing a VRE to identify how dual tasking with increased cognitive demand affects walking ability for people with unilateral lower limb amputation. Previous research has shown that performing tasks requiring divided attentional resources result in abnormal gait mechanics. Preliminary analyses suggest individuals with amputations may differentially prioritize cognitive and motor processes when walking. This study has potentially important implications regarding the ability to fully participate in a person’s natural environment after limb loss, and also may relate to an increased risk of falling. Additional ongoing efforts are aimed at evaluating biomechanical and cognitive responses to walking in more ecologically valid VRE, as opposed to game-style environments, which will include additional challenges to working memory, decision-making, and navigational skills.

Optimizing performance and maximizing functional outcomes are critical components of a rehabilitation program and are synonymous with returning to active duty for many wounded service members. Drs. Wilken and Rabago implemented an assessment battery within a militarized VRE to identify functional and cognitive deficits that emerge when performing military-specific tasks. This study incorporates load carriage, variable terrain negotiation, and quick decision-making. Physiological and biomechanical data collected during these tasks can guide future therapies and the prescription of prosthetic or orthotic devices for service members with lower extremity injuries. This study is the first step in developing a military-relevant assessment battery with objective performance metrics that correlate to return to duty rehabilitation goal. Follow-up studies supported by CRSR will incorporate the knowledge gained from the assessment study into a VRE-based, military-specific treatment intervention aimed at returning injured service members to duty and increasing military readiness.

In addition to VRE-based rehabilitation, other studies within this focus area seek to understand secondary musculoskeletal complications of limb loss and the influences of various technologies and rehabilitation paradigms. As noted, LBP is especially prevalent among persons with amputation(s), perhaps related to altered gait and movement patterns. To better understand these specific risk factors, Dr. Hendershot has performed several retrospective studies using the large biomechanical database at WRNNMC to directly quantify how gait deviations influence trunk and spine motion among service members with lower limb loss. Notably, larger and asymmetric trunk
motions with amputation were associated with increased loading at the lower back during walking\textsuperscript{35} and sit-to-stand movements.\textsuperscript{36} Although these increases were of small-moderate magnitude, repeated exposures over time may predispose these individuals to LBP onset and recurrence.\textsuperscript{37} Ongoing and future research will investigate the origins of altered trunk motion and subsequently assess methods or devices to minimize these loads in an effort to mitigate the prevalence of LBP among service members with lower limb amputation.

Another secondary musculoskeletal complication of unilateral limb loss is osteoarthritis (OA) within joints of the intact limb. Persons with unilateral lower limb amputation tend to preferentially use their intact limb during gait and movement, which leads to larger and more prolonged forces applied to the intact knee and/or hip joints. CRSR has funded two retrospective studies to assess gait mechanics in individuals with transtibial and transfemoral limb loss to determine how the intact limb is loaded at various time points during the rehabilitative process. Excessive intact limb loads (relative to controls) were only present at early time points among people with transtibial amputation, but persisted through late rehabilitation for persons with transfemoral amputation.\textsuperscript{38} Such evidence suggests an increased risk for early onset of OA and supports the development and assessment of interventions to correct modifiable gait mechanics in this population. A prospective evaluation of knee loading has been initiated to begin to address this gap.

In order to assist with multisite efforts aimed at sharing and combining commonly used biomechanical data across the MTFs, CRSR supported a project to evaluate the intra- and interlab reliability of gait data obtained at WRNMMC, CFI, and NMCSD.\textsuperscript{39} Ten participants traveled to each site to complete three biomechanical gait evaluations according to each laboratory’s standard operating procedures. Data were analyzed by a third party to eliminate bias. Results indicated that these measurements were highly reliable both within and between laboratories, with mean kinematic errors less than 5 degrees across all joints and planes of motion, and mean kinetic errors less than 10\% for all joint moments. The ability to collect reliable biomechanical data at these three major facilities will support future multisite studies and data sharing.

**RESEARCH FOCUS AREA 4: TRANSFER OF NEW TECHNOLOGY TO IMPROVE INDIVIDUAL PERFORMANCE AND FUNCTIONALITY AFTER INJURY** Novel devices, including prosthetics and orthotics, help return service members with cognitive and physical trauma to independent function. Previous research supported by CRSR and USAMRMC compared passive energy-storing and return (ESR) prosthetic feet with a powered ankle-foot orthosis to identify optimal design and prescription criteria for various terrains.\textsuperscript{31,43}

Because of the high incidence of upper limb loss occurring in combat casualties, focused research has been needed to improve prosthetics and control strategies for individuals with upper limb amputation. CRSR partnered with the Alfred Mann Foundation (http://uumf.org) to conduct a clinical trial through the Food and Drug Administration (FDA) entitled, “First-in-man demonstration of a fully implanted myoelectric sensors system to control an advanced electromechanical prosthetic hand.”\textsuperscript{43} A significant limitation to current myoelectric devices is their dependence on surface skin sensor electrodes to control their actuation. Unfortunately, these sensors are often unreliable, especially when individuals perspire or when their prosthetic socket moves in different positions. In addition, surface electrodes are limited in that they can only detect superficial muscle activity and do not provide the user with enough intuitive control.

This collaborative study demonstrated the feasibility of implanting wireless electrodes in the forearm of service members with transradial amputation to control a 3-degrees-of-freedom prosthetic hand. Future work will include expanding the use of this technology for individuals with transhumeral level amputations.

Expanding on the field of upper extremity prosthetics, CRSR is also proud of its partnership with the Defense Advanced Projects Agency (DARPA) to evaluate the performance of the DEKA arm (http://www.dekaresearch.com/deka_arm.shtml). This revolutionary multiple degrees-of-freedom prosthetic arm has received FDA approval and is the first of its kind to help pioneer the intersection between robotics and improving human performance for individuals with disabilities. CRSR also works with DARPA and other academic and industry groups to utilize novel neuroprosthetics to help restore sensory/haptic feedback for prosthetic users. Our research portfolio is bolstered by strong partnerships with teams, such as the Human Engineering Research Laboratories (www.herlpitt.edu), which have helped collectively develop a specialized patient-controlled analgesia device adapter to improve postsurgical pain, autonomy, and independence for patients who have lost the use of their limbs, enabling them to participate in rehabilitation.

**CONCLUSION** The clinical research community has an obligation to address the needs of these service members and veterans with complex orthopedic and neurological injuries stemming from recent conflicts. Injuries to young military service members, particularly those caused by blasts, pose unique challenges to rehabilitation that require research programs and consortia to help advance science and care. CRSR is dedicated to not only identifying gaps in the research but also to aligning resources in a synergized fashion to define and validate the most effective rehabilitation strategies for this patient population. CRSR engages a broad group of interdisciplinary investigators from medicine, biology, engineering, anthropology, and physiology and connects them directly with clinicians, patients, and families to help solve clinically relevant problems for our service members, veterans, and their families.

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Improving Outcomes Following Extremity Trauma: The Need for a Multidisciplinary Approach

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ABSTRACT
Extremity injuries contribute a significant amount to the overall disability of combat-injured soldiers. Tracking patient outcomes allows military health care providers to gain a better understanding of the disability associated with various injury patterns. Only recently have orthopedic surgeons begun to collect functional outcome measures, and perhaps even more importantly, have begun to collect patient-reported outcomes. There is a growing body of evidence demonstrating the importance of a multidisciplinary approach to optimize outcomes in patients following severe extremity trauma. Tracking the outcomes of these interventions longitudinally will ultimately provide the military surgeon with an evidence-based plan to treat severe combat-related extremity injuries, leading to optimal care for future combat injured patients.

However beautiful the strategy, you should occasionally look at the results.”—Winston Churchill

INTRODUCTION
Extremity injuries contribute a significant amount to the overall disability of combat-injured soldiers. For soldiers undergoing a physical evaluation board for unfitting conditions caused by a battlefield injury, 3 out of the top 5 and 6 out of the top 10 are orthopedic/extremity conditions. Furthermore, 57% of combat-injured soldiers had unfitting conditions that were only orthopedic. Of soldiers medically evacuated with a head, thorax, or abdominal injury with a concomitant orthopedic injury, the orthopedic injury was the primary unfitting condition in over 75% of the patients. In a follow-up study consisting of a cohort of these patients whose primary unfitting condition was osteoarthritis, it was directly attributable to combat injury in 92% of cases and occurred in as little as 19 ± 10 months following the injury. This necessitates direct attention to examining lessons learned related to orthopedic injury so that every effort is made to optimize the functional recovery of soldiers injured in future conflicts. As the nation transitions to an interwar period, it provides an ideal time to reflect on the advances in the treatment of severe extremity injuries to identify “lessons learned” that will ultimately result in improving the military health care capability for the next conflict.

IMPORTANCE OF TRACKING OUTCOMES
Patient outcomes help military health care providers understand disability. Although the desired outcome is to return a patient to his or her maximal level of function, historically, orthopedic outcomes focus on factors such as radiographic union, alignment, development of arthritis, and the presence of postoperative complications such as infection. Only recently have orthopedic surgeons begun to collect functional outcome measures, and perhaps even more importantly, have begun to collect patient-reported outcomes.

The extreme value of collecting relevant outcomes assessments was identified early during the conflicts and at the same time, the inherent difficulties with doing so were realized to include additional time and infrastructure requirements. However, there is still a significant need for more relevant surgical outcome assessments to assist in guiding difficult decision-making, such as the decision to amputate or attempt limb salvage in the severe extremity injury. However, as we have entered a low volume combat casualty flow era, it can provide an opportunity to evaluate the outcomes achieved from the conflicts more thoroughly in an attempt for us, as providers, to continue to learn and improve.

When examined closely, patients do not do as well as initially perceived by their physicians. For example, Lebrun et al recently reported long-term outcomes of patients with a relatively simple fracture (patella) treated operatively. Even at 6.5 years following surgery, patients still had significant functional deficits despite the fracture being healed. Extension power and Biodex dynamometric testing revealed deficits of a quarter to one-third of the uninjured contralateral extremity. In addition, over half of the patients required an additional surgery due to symptomatic hardware. This study highlights the fact that even with a simple fracture pattern that goes on to radiographic union following surgery, patients can still have significant long-term functional deficits as a result of their injury.

Now, consider the effects seen with more severe extremity trauma, such as those resulting from combat. In a large prospective observational study, the Lower Extremity Assessment Project (LEAP) Study Group showed the long-term consequences of severe lower extremity trauma in a civilian population. At 7 years following injury, just over one-third...
(34.5%) of patients had a physical Sickness Impact Profile (SIP) subscore typical of the general population of similar age and gender.\(^5\) Furthermore, out of those who worked before their injury, only 58% returned to work 7 years later. Even worse, of those who return to work, patients are limited in their performance 20 to 25% of the time.\(^7\) These data are similar to what has been seen in the military population following severe combat extremity injuries. In a retrospective cohort study of 324 Service Members who underwent amputation or limb salvage following a combat-related extremity injury, Doukas et al reported that at an average follow-up of 38.6 months only 43.7% had returned to work and 19.9% had pain interfering with daily activities.\(^7\) These data demonstrate that similar challenges are seen long-term in patients, whether civilian or military, with severe lower extremity injuries.

THE NEED FOR A MULTIDISCIPLINARY APPROACH

In assessing outcomes of patients that sustained high-energy lower extremity trauma, O’Toole et al showed that surgeons and patients rarely agree on outcomes, as infrequently as \(\leq 25\%\), which highlights the complexity of synthesizing outcomes based research.\(^8\) Perhaps, surgeons should not just focus on treating the injury, but treating the individual patient as well. As Cannada and Jones highlighted in their review of the LEAP Study Group’s findings, a patient’s personality is not significantly influenced by changes in the patient’s life circumstances, i.e., the significant trauma they just experienced.\(^9\) However, as eluded to by Levin et al, failure to recognize the difference between treating an illness and a disease may be one explanation for the vast differences in outcomes seen following injury.\(^10\) Knowing this, could it be possible to predict which patients are going to do worse and intervene early to optimize their outcome?\(^\text{11–13}\)

A vitally important lesson learned is establishing realistic expectations for pain management, specifically noting that patients with severe lower extremity injuries may heal their bone and soft tissue injuries, but pain will frequently persist.\(^\text{11–13}\) In most cases, the bone heals, and, in some cases, there are complications. However, there remains a large degree of uncertainty as to why some patients do so much better than others, when the bone healed in good alignment and there were no postoperative complications. It has been shown that “negative mood,” specifically anxiety, plays an important role in the persistence of acute pain and both pain and depression correlates with patient satisfaction in those who have sustained severe lower extremity trauma.\(^\text{14,15}\) When evaluating predictors of disability and pain following musculoskeletal injuries, Vranceanu et al found that catastrophic thinking at 1 to 2 months postinjury was the sole significant predictor of pain at rest, pain with activity, and disability at 5 to 8 months.\(^\text{16}\) The physician must understand and recognize the impact that these factors can play in a patient’s rehabilitation process to optimize their outcome.

However, one of the most important advances in pain management during the recent conflicts can easily be summed up in the phrase “multimodal pain management.” In addition to the use of various intravenous and oral pain medications, the benefits of advanced regional anesthetics, delivered through continuous peripheral nerve catheters, were quickly realized. In many patients with severe extremity injuries or amputations, these were placed before transport back to the United States. These peripheral nerve catheters can provide the analgesia needed to make smooth transitions between the often, frequent, interval debridement and irrigations until the definitive surgery can be safely performed, while minimizing the need for intravenous or oral narcotic pain medication.\(^\text{12}\) As mentioned by Pasquina and Shero, rehabilitation needs to start in the acute care setting. The Amputee Patient Care Program, which encourages collaboration among various services, to include pain management, encouraged this to happen.\(^\text{13}\)

These studies highlight the fact that some patients may need more than just an orthopedic surgeon, following their fracture to union, to maximize their outcome. Archer et al found that 85% of patients reported a need for at least one vocational, behavioral health, or other support service following severe lower extremity trauma, and 32% had an unmet need over the course of the first year.\(^\text{17}\) The highest need unmet was for behavioral health and vocational services. Patients with a perceived unmet need have worse outcomes.\(^\text{17}\) The military has done well in meeting patients’ needs based on holistic care models, e.g., the Armed Forces Amputee Patient Care Program and newer interdisciplinary programs for combat injured undergoing limb salvage.\(^\text{11,13,18–22}\)

Quality data come from the LEAP Study Group, specifically informing orthopedic surgeons on outcomes related to high-energy musculoskeletal trauma.\(^\text{5,23}\) When comparing amputation to limb salvage, the authors found no difference in SIP scores at 2 and 7 years. The SIP assesses patients’ dysfunction through everyday behavior capturing the physical, mental, and social aspects of health-related function. Another important finding from the LEAP Study Group’s research was the identification of several predictors of poor outcome, regardless of group (amputation vs. limb salvage) to include a poor social support network and low self-efficacy.\(^\text{5,23}\) This reinforces the importance of an individualized interdisciplinary approach to treating patients with severe extremity injuries. This is especially important when counseling patients on possible courses of action as surgeons cannot rely on current lower-extremity injury severity scoring systems because they have been shown not to be predictive of functional recovery of patients who undergo reconstruction.\(^\text{24}\)

The best available data from the military are from the Military Extremity Trauma Amputation/Limb Salvage study, which found better functional outcomes in patients with amputation compared to limb salvage.\(^\text{7}\) However, when interpreting these results it is important to look more closely
at the data before concluding that amputation is superior. Patients were included in the Military Extremity Trauma Amputation/Limb Salvage study if their injury occurred between 2003 and 2007. During this period, there was a patient-centric rehabilitation program for amputees [The Armed Forces Amputee Patient Care Program], but, until late 2008, there was no such program for patients with limb salvage. In another retrospective comparison, service members with early amputation improved in several areas to include psychiatric diagnoses, but it is also important to note that they had more outpatient visits for psychiatry, occupational therapy) and physical therapy. Before acceptance of these results as definitive evidence the following question must be answered, “Did amputees do better compared to those service members who underwent limb salvage because they received more attention and more support?”

In answering this question, it is helpful to further define the clinical problem and answer the questions, “How many patients fail limb salvage and why?” Stinner et al initially reported that 15% of amputations occurred more than 90 days following injury, with many of those occurring more than a year after injury. A comprehensive analysis by Krueger et al determined that during the first 10 years of conflicts in Afghanistan and Iraq, approximately 10% of all amputations were performed more than 90 days following injury. The 90-day time period was chosen to take into account time to attempt limb salvage. When evaluating outcomes of combat-related type III open tibia fractures, Huh et al found that those undergoing late amputation had several common characteristics: (a) more flaps, (b) higher rates of infection (both deep soft tissue and osteomyelitis), and (c) more reoperations. This is similar to data reported by the LEAP Study Group, who noted that patients undergoing limb salvage for a mangled foot and ankle were likely to have a longer time to full weight bearing and more rehospitalizations. In addition, those that went on to an ankle arthrodesis (fusion) or required a free flap for soft tissue coverage were likely to have worse outcomes. Optimizing the management of these severe injuries to minimize the postoperative complications that more commonly lead to poor outcomes should be a focus of future research efforts.

**SUMMARY**

Ultimately, the surgeon should be armed with an evidence-based plan to treat severe combat-related extremity injuries and patients must be given the individualized tools to succeed. For some, the tools to succeed may simply be following their fracture to union with periodic clinic visits to be reassured that they are on the right path. For others, it may consist of custom orthotics and/or intense physical therapy. And, yet, for others, it may be a wide range of vocational, behavioral health, and other social support services to optimize their individual outcome. Military treatment facilities have recognized the importance of this and have established well rounded integrated rehabilitation programs that are pushing beyond the boundaries of traditional rehabilitation, which is resulting in improved outcomes for injured service-men and women.

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The Prevalence of Gait Deviations in Individuals With Transtibial Amputation

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ABSTRACT  Individuals with a transtibial amputation (TTA) are at increased risk for developing secondary musculoskeletal disorders as a result of multiple gait deviations. These deviations are primarily characterized using group mean comparisons, which do not establish if deviations are prevalent, of large magnitude, or both. In contrast, use of normative reference ranges and prevalence specifically identifies the percentage of individuals outside of a predefined acceptable range. The purpose of this study was to identify and characterize gait deviations in service members with unilateral TTA using group mean comparisons and normative reference ranges (able-bodied mean ± 2 SD). Temporal spatial, kinematic, and kinetic data were collected during biomechanical gait assessments of 40 able-bodied males and 16 males with a TTA. Highly prevalent and statistically significant deviations were observed at the ankle and knee of the prosthetic limb and hip of the intact limb in the TTA group. Approximately 20% of measures that were significantly different between groups demonstrated 0% deviation prevalence. Deviations in the prosthetic limb were in agreement with literature, although most intact limb deviations were not. Further study is needed to determine the exact etiology of these deviations, and their association with the development of secondary musculoskeletal conditions.

INTRODUCTION

Individuals with lower extremity amputations are at increased risk for developing secondary musculoskeletal disorders as a result of persistent gait deviations associated with prosthetic use. Compared to age-matched peers without amputation, World War II veterans with transtibial amputation (TTA) showed an increased incidence of knee and hip osteoarthritis later in life (mean age = 71.8 years); 30 to 35 years after their amputation. Individuals with a unilateral TTA were also 88% more likely to develop osteoporosis in the amputated limb compared to the general population. In addition, 60% of individuals with a TTA reported the onset of back pain within 2 years of amputation and 63% categorized pain as moderate to severe. Gait deviations and compensations such as asymmetric single limb stance time and increased vertical ground reaction forces at the intact limb are thought to exacerbate these musculoskeletal degenerative processes. Early identification of gait deviations and formal training of gait mechanics, especially in young individuals with a TTA, could help prevent a lifetime of poor gait mechanics and reduce the risk of developing secondary musculoskeletal conditions. Few studies have systematically determined the effect of a TTA on temporal spatial, kinematic, and kinetic measures on a per person basis. Gait deviations are often characterized using group mean comparisons of individuals with a TTA to able-bodied (AB) participants. However, individuals with a TTA in these studies often vary considerably in age (20–77 years) and prosthetic experience (1–59 years), which may reduce statistical power because of increased intersubject variability. A reduction in statistical power lessens the probability that significant differences (i.e., deviations) will be detected. Further, many of these studies have fewer than 10 participants, which limits rigorous statistical analysis. To achieve statistical significance using group mean comparisons, a high proportion of values from the TTA group must be consistently greater or less than the AB group mean; or a few individuals with a TTA must have sufficiently large deviations to bias their group mean. As a result, the reader is often unable to determine if a given deviation is prevalent, of large magnitude, or both.

An alternate approach for identifying gait deviations in individuals with a TTA is to compare their data against normative reference ranges (NRR), which are calculated using mean and variability data from an AB group. A value from an individual with a TTA that falls outside the NRR is considered a deviation in that specific measure. Prevalence of deviations in each measure can then be determined as the percentage of a population that functions outside the established NRR. Deviations identified using a NRR approach are indicative of abnormal mechanics in each individual, which may be missed when comparing the mean performance of a patient population to mean performance of an AB group. Further, prevalence provides an easy-to-understand metric, which indicates the frequency of deviations, not described using traditional group mean comparisons.

The prevalence of gait deviations, as identified using a NRR approach, has yet to be determined for a group of individuals with TTA. The combination of both group mean comparisons and prevalence data could be used to identify gait deviations most likely encountered when treating individuals with a TTA. Therefore, the purpose of this study...
was to determine the presence of gait deviations and their prevalence in a group of service members with a TTA.

METHODS

Subjects

Data from 40 AB males and 16 male individuals with a TTA are presented in this study. The AB group included service members between the ages of 18 and 45 years with no pain at time of data collection and no history of lower extremity injury requiring surgery. The TTA group included service members between the ages of 18 and 45 years who used an energy-storing-and-returning ankle-foot prosthesis, were able to ambulate without an assistive device, and had been ambulating for approximately 4 months. In order to detect deviations not associated with acute pain, the TTA group could not have pain of greater than 4 out of 10 anywhere on their body at the time of data collection. The TTA group was a convenience sample of patients within a military treatment facility who met the inclusion criteria without bias toward their mechanism of injury or level of physical fitness. All participants provided written informed consent before participating in this institutional review board–approved study.

Procedures

Participants underwent a biomechanical gait assessment on level ground at a predefined walking speed scaled to leg length using a Froude number of 0.16. A full-body, six-degree-of-freedom marker set comprised of 57 retroreflective markers was placed on 13 body segments. A 26 camera motion capture system (Motion Analysis Corp., Santa Rosa, California) recorded marker trajectories as participants walked across a 10-m walkway embedded with eight AMTI force plates (AMTI, Inc., Watertown, Massachusetts) operating at 1,200 Hz. Temporal spatial, kinematic, and kinetic data were normalized to 100% step cycle using Visual 3D (C-Motion Inc., Rockville, Maryland). Five representative strides from each participant were exported into MATLAB (Mathworks, Natick, Massachusetts). Key kinematic and kinetic measures for the ankle, knee, hip, pelvis, and trunk were defined as previously described. Joint range of motion (ROM) was defined as the difference between the maximum and minimum joint angle values during one gait cycle. On the prosthetic side, ankle sagittal ROM was defined as the difference between the maximum and minimum joint angle values during stance.

Temporal spatial measures were determined using kinetic gait events and foot kinematics. Step length was defined as the distance between the foot centers in the anterior-posterior direction at heel strike. Step width was calculated as the medial-lateral distance between the heel markers on each foot during double-limb stance. Step time was quantified as the duration between heel strike of the ipsilateral limb and heel strike of the contralateral limb. Stance time was determined as the duration between heel strike and toe off of the same limb. Swing time was quantified as the duration between toe off and heel strike of the same limb. Stride length was defined as the distance between the foot centers in the anterior-posterior direction on successive heel strikes of the same limb. Stride time was quantified as the duration between successive heel strikes of the same limb.

Statistical Analysis

SPSS v.19 (SPSS Inc., Chicago, Illinois) was used for all statistical analyses. AB and TTA group means and standard deviations were calculated for demographic, anthropometric, temporal spatial, kinematic, and kinetic measures. Due to differences in sample size, and a desire to retain all available data, Mann–Whitney non parametric tests were used to identify differences between AB and TTA groups for demographic-anthropometric, temporal spatial, and kinematic-kinetic measures. The AB group’s right lower limb was used in comparisons made to the TTA group’s lower limbs (e.g., AB vs. prosthetic limb and AB vs. intact limb). Bonferroni–Holm corrections were performed to correct for multiple comparisons across all measures. The Bonferroni–Holm method uses a step-down approach to account for multiple comparisons by arranging $p$ values from the smallest to the largest and comparing them to sequential significance cutoffs. Significance was set at a $p$ value of 0.05. Thus, correction factors accounting for 6, 6, and 53 comparisons yielded minimum $p$-value cutoffs of 0.0083, 0.0083, and 0.0009 for demographic-anthropometric, temporal spatial, and kinematic-kinetic measures, respectively.

Similar to the work of O’Sullivan, the NRR for each measure was defined as two standard deviations greater than and less than the AB group mean. Microsoft Excel 2007 (Microsoft Corp., Redmond, Washington) was used to determine the upper and lower bounds of the NRR for the AB group and the prevalence of deviations in the TTA group. The deviation prevalence for each measure was calculated as the percentage of participants from the TTA group with individual mean values outside the NRR. To facilitate visualization of the data and ease of presentation, prevalence values were categorized into three groups; high (>50%), moderate (25–49%), and low (<25%).

RESULTS

Participant demographics and anthropometrics including age, height, weight, body mass index, leg length, walking speed, and time since independent ambulation (TTA group only) are listed in Table I. Only age demonstrated a significant difference between groups with the TTA group being an average of 4 years older than the AB group ($p = 0.006$). Figure 1A provides an example of a measure that demonstrates high deviation prevalence in the TTA group with significant between group difference; 5.4% of all measures presented here were in this category. In addition, 7.1% of measures showed moderate deviation prevalence in the TTA group with significant between group differences (Fig. 1B).
and 12.5% showed moderate deviation prevalence in the TTA group without significant between group differences (Fig. 1C). Lastly, 17.9% of measures had low deviation prevalence in the TTA group with significant between group differences (Fig. 1D) and 57.1% had low deviation prevalence in the TTA group without significant between group differences (Fig. 1E). Kinematic, kinetic, and temporal spatial measurement means and SDs for the AB and TTA groups are shown in Table II. The direction of significant differences between the AB and TTA groups and prevalence of deviations in the TTA group is detailed in Table III.

**Temporal Spatial**

In the TTA group, swing time was significantly decreased in the intact limb and moderately prevalent. Intact limb step time and step length measures had the greatest prevalence of deviations among temporal spatial measures (37.5–43.8% respectively), but were not significantly different from the AB group. In addition, 7 of the 16 individuals demonstrated deviations of both step length and step time in the prosthetic or intact limb. However, step length and step time did not systematically increase or decrease relative to the AB group.

**Ankle**

Prosthetic ankle plantarflexion during initial swing, sagittal ROM, and power generation at terminal stance were significantly decreased (p ≤ 0.001) in the TTA group compared to the AB group with 100, 81.3, and 50% prevalence, respectively. With the exception of initial contact power absorption (43.8% deviation prevalence, p ≤ 0.001), all intact ankle measures had less than 13% deviation prevalence in the TTA group. Bilateral dorsiflexion moments were significantly different (p ≤ 0.001) than the AB group, but only with a 12.5% prevalent in the TTA group.

**Knee**

Midstance power generation at the intact knee of the prosthetic limb was significantly decreased (p ≤ 0.001) with a high prevalence of deviations in the TTA group. Deviations of knee kinematic measures at the prosthetic limb ranged in

| TABLE I. Demographic and Anthropometric Measures for AB and TTA Groups |
|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Mean (SD)                | Age (years)             | Height (m)               | Weight (kg)              | BMI (kg/m²)              | Leg Length (cm)          | Walking Speed (m/s)      | Ambulation (weeks)       |
| AB                       | 24.1 (6.5)*             | 1.7 (0.1)                | 77.2 (10.8)              | 25.4 (3.1)               | 91.8 (5.9)               | 1.20 (0.04)              | N/A                     |
| TTA                      | 28.5 (5.4)*             | 1.8 (0.1)                | 86.6 (12.4)              | 27.4 (3.0)               | 93.3 (6.1)               | 1.21 (0.04)              | 16.6 (3.3)              |

BMI, body mass index; Ambulation, time since independent ambulation. *Significant between group difference after Bonferroni–Holm correction with smallest p-value cutoff of 0.0083.
**TABLE II.** Peak Joint Angles, Moments, and Powers for the Lower Extremities and Trunk. Sagittal ROM and Temporal Spatial Measures are also presented. Values are Shown for the Right Limb of the AB Group and the Prosthetic and Intact Limbs of the TTA Group. Significant Group Differences between the Prosthetic and Intact Limbs and the Right Limb of the AB Group are Highlighted in Bold.

For Each Peak Measure, the Timing of the Peak in the Gait Cycle is identified.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Mean (SD)</th>
<th>AB</th>
<th>Prosthetic</th>
<th>Intact</th>
<th>Mean (SD)</th>
<th>AB</th>
<th>Prosthetic</th>
<th>Intact</th>
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<td>Ankle Moment (Nm/kg)</td>
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<td></td>
<td>0.23 (0.07)</td>
<td>0.31 (0.08)</td>
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<tr>
<td>Dorsiflexion: TSt</td>
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<td>16.3 (2.9)</td>
<td>14.1 (3.3)</td>
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<td>1.38 (0.15)</td>
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<td>-4.7 (2.7)</td>
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<td>Ankle Powers (BW/kg)</td>
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<td>Sagittal ROM</td>
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<td>18.4 (3.2)</td>
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<tr>
<td>Knee Moment (Nm/kg)</td>
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<td></td>
<td>Flexion: LR</td>
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<td>0.30 (0.07)</td>
<td>0.51 (0.07)</td>
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<td>0.41 (0.10)</td>
<td>0.30 (0.07)</td>
<td>0.51 (0.07)</td>
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<td>0.22 (0.18)</td>
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<td>Extension: TSf</td>
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<td>0.20 (0.14)</td>
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<td>Sagittal ROM</td>
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<tr>
<td>Hip Moment (Nm/kg)</td>
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<td>26.5 (6.7)</td>
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<td>Extension: Sw</td>
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<td>Flexion: TSw</td>
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<td>27.9 (5.6)</td>
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<td>Adductor</td>
<td>0.30 (0.07)</td>
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<td>Anterior Tilt</td>
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<tr>
<td>Transverse ROM</td>
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<td>Stance Time</td>
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<td>Step Time</td>
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<td>Stride Length</td>
<td>1.41 (0.09)</td>
<td>1.38 (0.11)</td>
<td>1.39 (0.09)</td>
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</tbody>
</table>

BW, body weight; ROM, range of motion; IC, initial contact; LR, loading response; MSt, midstance; TSt, terminal stance, St, stance; PSw, preswing; ISw, initial swing; MSw, midswing; TSw, terminal swing; Sw, swing. N/A: Trunk motion is tracked as 1 segment; therefore, duplicate measures in the intact limb are not reported. Kinematic and kinetic measures in bold exhibit a significant between group differences after Bonferroni–Holm correction with the smallest p-value cutoff of 0.0009. Temporal spatial measures in bold exhibit a significant between group differences after Bonferroni–Holm correction with the smallest p-value cutoff of 0.0083.

Prevalence from 18.8 to 31.3% and were not significantly different from the AB group; with the exception of sagittal ROM (68.8% deviation prevalence, \( p \leq 0.001 \)). Each of the knee kinematic measures in the prosthetic limb, except initial contact flexion, had values that were both greater and less than the NRR, resulting in statistically similar means between groups. Six of 14 knee kinetic measures in the intact and prosthetic limbs were significantly different from...
the AB group ($p \leq 0.001$), but showed low deviation prevalence in the TTA group.

### Hip

The greatest prevalence of deviations at the hip of the intact limb was with abduction (56.3%). All sagittal plane hip kinematic measures of the prosthetic limb had low deviation prevalence (12.5–18.8%), but unlike the knee of the prosthetic limb, the measures are skewed in a single direction relative to the NRR. Moderate deviation prevalence was observed for intact limb hip extension during preswing and flexion during terminal swing, however, only the latter

<table>
<thead>
<tr>
<th>Deviation Prevalence (%)</th>
<th>Prosthetic</th>
<th>Intact</th>
<th>Deviation Prevalence (%)</th>
<th>Prosthetic</th>
<th>Intact</th>
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<td>Ankle Angle</td>
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<td></td>
<td>Ankle Moment</td>
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<tr>
<td>Plantarflexion: LR</td>
<td>18.8%</td>
<td>6.3%</td>
<td>Dorsiflexion: LR</td>
<td>↑ 12.5%</td>
<td>↑ 12.5%</td>
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<td>Dorsiflexion: TSt</td>
<td>6.3%</td>
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<td>Plantarflexion: TSt</td>
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<td>Plantarflexion: ISw</td>
<td>↓ 100.0%</td>
<td>12.5%</td>
<td>Ankle Powers</td>
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<td>Sagittal ROM</td>
<td>↓ 81.3%</td>
<td>6.3%</td>
<td>Absorption: LR</td>
<td>6.3%</td>
<td>↑ 43.8%</td>
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<td>Absorption: TSt</td>
<td>12.5%</td>
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<td>Generation: TSt</td>
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<td>Knee Angle</td>
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<tr>
<td>Flexion: IC</td>
<td>18.8%</td>
<td>6.3%</td>
<td>Flexion: LR</td>
<td>↓ 6.3%</td>
<td>↑ 6.3%</td>
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<td>Flexion: LR</td>
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<td>6.3%</td>
<td>Extension: MSw</td>
<td>↓ 0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Extension: TSt</td>
<td>18.8%</td>
<td>0.0%</td>
<td>Flexion: TSt</td>
<td>6.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Flexion: MSw</td>
<td>31.3%</td>
<td>↓ 12.5%</td>
<td>Extension: TSt</td>
<td>6.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Sagittal ROM</td>
<td>↓ 68.8%</td>
<td>↓ 18.8%</td>
<td>Varus: LR</td>
<td>↓ 18.8%</td>
<td>6.3%</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Valgus: LR</td>
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<td>12.5%</td>
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<tr>
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<td></td>
<td>Hip Powers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexion: LC</td>
<td>12.5%</td>
<td>18.8%</td>
<td>Extension: LC</td>
<td>↓ 0.0%</td>
<td>↑ 6.3%</td>
</tr>
<tr>
<td>Extension: LSw</td>
<td>18.8%</td>
<td>31.3%</td>
<td>Flexion: TSw</td>
<td>6.3%</td>
<td>↓ 6.3%</td>
</tr>
<tr>
<td>Flexion: TSw</td>
<td>12.5%</td>
<td>↓ 31.3%</td>
<td>Extension: Sw</td>
<td>31.3%</td>
<td>↑ 18.8%</td>
</tr>
<tr>
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<td>Abductor</td>
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</tr>
<tr>
<td>Adduction</td>
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<td>0.0%</td>
</tr>
<tr>
<td>Abduction</td>
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<td>Pelvic Angle</td>
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<td>Trunk-Pelvic Angle</td>
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<td>Anterior Tilt</td>
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<td>↓ 31.3%</td>
<td>Sagittal ROM</td>
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<tr>
<td>Posterior Tilt</td>
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<tr>
<td>Sagittal ROM</td>
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<td>↑ 25.0%</td>
<td>Transverse ROM</td>
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<tr>
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<tr>
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<td>Transverse ROM</td>
<td></td>
<td></td>
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<td>6.3%</td>
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<td>Spatial</td>
<td></td>
<td></td>
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<tr>
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<td></td>
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<td>6.3%</td>
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<td>0.0%</td>
</tr>
<tr>
<td>Step Time</td>
<td>31.3%</td>
<td>↓ 37.5%</td>
<td>Stride Length</td>
<td>18.8%</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

Significant between group differences of kinematic and kinetic measures are after Bonferroni–Holm correction with the smallest $p$-value cutoff of 0.0009. Significant between group differences of temporal spatial measures are after Bonferroni–Holm correction with the smallest $p$-value cutoff of 0.0083.
works,10,19 individuals with a TTA on average exhibited power generation at terminal stance. Similar to earlier contributed to the significant decrease in prosthetic ankle ROM was limited, 50% of the TTA group were capable of achieving push-off powers within the NRR. This demonstrates that performance within normative ranges is possible, and interventions which allow individuals with a TTA to more effectively load and store energy in the foot are warranted.

Individuals with a TTA in the present study walked with a significant decrease in prosthetic limb sagittal knee ROM, which was highly prevalent and may be related to an extended knee posture observed in the prosthetic limb throughout gait. In agreement with previous reports, the effects of the extended knee posture were greatest at initial contact when individuals with a TTA displayed a significantly decreased knee flexor moment15,16 and a significant and highly prevalent reduction in knee power generation.15 Significant decreases in sagittal knee moments and powers measured later in stance were consistent with earlier works,11,15,16,19,27 however, demonstrated 0% deviation prevalence meaning all values were within the NRR. These kinetic differences may be related to a compensatory extended knee posture, which prevents the knee from collapsing16 during stance.

Similar to previous literature,12,16 individuals with a TTA demonstrated a trend toward greater hip extension during prosthetic limb stance. This was associated with a significant increase in hip power generation during stance16,12,19 and used to control knee flexion in the prosthetic limb and aid forward progression.19 Despite significant kinetic group mean differences, the TTA group exhibited little to no prevalence of hip deviations. Longitudinal analysis of our participants would provide insight into when and if compensations at the hip develop.

Intact Limb

Individuals with a TTA in the present study exhibited no significant differences in intact ankle kinematics compared to the AB group. However, a significant increase in intact ankle power absorption at initial contact was observed with 43.8% prevalence. We speculate this was in response to an abrupt transition off the prosthetic ankle at terminal stance and onto the intact limb at initial contact.28 Individuals with a TTA must transition off the prosthetic foot more quickly due to a shortened roll-over arc of the prosthetic foot28 and lack of active plantarflexion. This is consistent with the significant reduction in intact limb swing times observed in the TTA group. The increase in intact ankle power absorption during loading response may be associated with reports of increased intact limb loading1,3,5,29 thought to contribute to secondary musculoskeletal disorders.

The results from the intact limb knee are in contrast to previous works, which reported increases in swing knee flexion,11 maximum extension moments,11,16 and stance knee flexion...
power generation.\textsuperscript{11,14} The few significant kinematic and kinetic differences observed demonstrated prevalence less than 18.8%. Thus, it appears that knee deviations of the intact limb noted in older populations with a TTA\textsuperscript{11,14,16} may not frequently occur in our young population with a TTA this early following independent ambulation.

In contrast to Bateni et al\textsuperscript{10} who reported an increase in hip flexion of the intact limb during stance, we observed a trend toward increased extension throughout the gait cycle compared to the AB group. During swing, individuals with a TTA demonstrated significant decreases in hip flexion and abduction of the intact limb not previously reported in the literature. These deviations were 31.3% and 56.3% prevalent, respectively, and may be associated with the significant decrease in swing hip extension moments at the intact limb, likely in preparation for initial contact with a shortened step length. However, most intact limb hip kinetic values were within the NRR with less than 32% prevalence. Similar to the intact limb ankle and knee, individuals with a TTA in this study did not frequently exhibit hip deviations reported in populations with a longer history of prosthetic ambulation.\textsuperscript{10,12,14}

\textbf{Pelvis/Trunk}

To the best of our knowledge, no study has reported pelvis and trunk biomechanical data for individuals with a TTA in all three planes of motion. Consistent with a previous report of asymmetry in pelvic obliquity,\textsuperscript{13} our participants exhibited a significant decrease in pelvic drop on the intact side with 37.5% prevalence. Although we found significantly decreased frontal plane pelvic ROM using group comparisons, all individual values were within the NRR. The 0% deviation prevalence is consistent with the work of Rueda et al\textsuperscript{30} suggesting no difference between TTA and AB groups. In addition to the frontal plane deviations, individuals with a TTA demonstrated a significant increase in swing hip extension moments at the intact limb, likely in preparation for initial contact with a shortened step length. However, most intact limb hip kinetic values were within the NRR with less than 32% prevalence. Similar to the intact limb ankle and knee, individuals with a TTA in this study did not frequently exhibit hip deviations reported in populations with a longer history of prosthetic ambulation.\textsuperscript{10,12,14}

\textbf{CONCLUSION}

Prosthetic limb deviations identified and characterized using group mean and prevalence approaches are in general agreement with, and add to, those reported in the literature. Specifically, knee and hip deviations observed in the prosthetic limb are indicative of known compensations used to control the knee during stance. Decreased prosthetic ankle power generation during push off did not, however, appear to elicit compensations in the intact limb, knee, and hip. Further, individuals with a TTA in this study exhibited few of the intact limb deviations that have been previously reported. Inconsistencies between our data and previous literature may be associated with differences in age, activity level, or prosthetic gait experience. Prior data demonstrating recovery of normative metabolic cost of walking and greater function in the injured service member as compared to civilian cohorts are consistent with the reduced deviations observed here.\textsuperscript{32}

Finally, pelvic and trunk deviations in all three planes of motion are reported here for the first time. The use the NRR method allows clinicians and researchers to identify gait deviations in a single individual matching clinical practice. Further study is needed to determine the exact etiology of these deviations, and their association with the development of secondary musculoskeletal conditions.

\textbf{ACKNOWLEDGMENTS}

We thank our colleague, Kelly M. Rodriguez, for her efforts in data collection analysis and insight on this manuscript. We also thank Dr. Benjamin J. Darter, Linda Waetjen, and Melissa Brawner for contribution to data collection.

\textbf{REFERENCES}

12. Grumillier C, Martinet N, Paysant J, Andre JM, Beyaert C: Compensatory mechanism involving the hip joint of the intact limb during


ABSTRACT  Introduction: Young military Service Members with traumatic unilateral lower limb amputations may be at a high risk for developing knee osteoarthritis (OA). There is growing evidence for potential influence and predictive value of nonsystemic risk factors on development and progression of primary knee OA in older adults. Proposed factors include chronic knee pain, obesity, abnormal knee joint mechanics, muscle weakness, previous knee trauma, and altered physical activity level. However, there is limited information available regarding whether such nonsystemic risk factors could also be responsible for the increased risk of knee OA after traumatic, unilateral lower limb amputation in young military Service Members. The purpose of this narrative review is to compile and present evidence regarding prevalence of nonsystemic and potentially modifiable knee OA risk factors in Service Members with traumatic, unilateral lower limb amputation, and to identify potential strategies for intervention. Materials and Methods: A comprehensive literature search was performed in July 2015 using structured search terms related to nonsystemic risk factors for knee OA. Results: Current collective evidence does suggest an elevated prevalence of the nonsystemic knee OA risk factors in young military Service Members with unilateral lower limb amputation. In conclusion, the present state of the literature supports that young military Service Members with traumatic unilateral lower limb amputations may be at increased risk for developing knee OA compared to nonamputees. Military Service Members injured at a young age have a long life expectancy, and thus require comprehensive rehabilitation programs to prevent or delay progression of knee OA. Given the lack of strong evidence, further clinical research is needed to determine whether early identification and modification of nonsystemic risk factors for knee OA could optimize long-term function and quality of life in young Service Members after traumatic, unilateral, limb amputations.

BACKGROUND  Young military Service Members who have sustained an amputation have unique long-term health care and rehabilitation needs. Traumatic limb amputations, in particular, represent an important source of chronic impairments and functional limitations that could significantly impact returning to active duty, employment status and long-term quality of life (QOL) in young military Service Members. Although a significant amount of resources have been focused on the immediate rehabilitation needs of young Service Members after amputation, an important consideration is the early identification and modification of potential risk factors responsible for long-term development of secondary health conditions such as knee osteoarthritis (OA).

KNEE OA AFTER TRAUMATIC UNILATERAL LOWER LIMB AMPUTATION  Individuals with traumatic, unilateral lower limb amputation are at a greater risk of developing knee OA compared to nonamputees. Melzer et al reported that the prevalence of contralateral knee OA was 66% in 32 individuals with lower limb amputation, which was significantly greater than a 38% prevalence rate detected in an age- and body weight-matched control group consisting of 24 individuals without an amputation. Similarly, Hungerford and Cockin reported knee OA prevalence rates of 63%, 41%, and 21% in transfemoral amputees, transtibial amputees, and matched controls, respectively. Conversely, Norvel et al reported that the prevalence of symptomatic knee OA was 16% among 62 older amputees with no history of previous knee trauma as compared to an 11% rate in 94 elderly nonamputees. Exclusion of previous knee trauma, which is a strong risk factor for knee OA, could be partially responsible for the reports of lower contralateral knee OA by Norvel et al. More recently, Struyf et al reported knee OA prevalence rates of 27% for the intact limbs of 78 individuals with traumatic, unilateral lower limb amputation (mean age 60 years) that were considerably higher than the age- and gender-adjusted rates in the general population. The much lower knee OA prevalence rates after traumatic, unilateral limb amputation in this study compared to previous publications may be associated with advancements in prosthetic design and rehabilitation of individuals with lower limb amputation over the past decade. Nevertheless, the current evidence suggests that the intact limbs of individuals with traumatic, unilateral lower limb amputation are at great risk for developing knee OA. Given...
the importance of the intact limb for preservation of mobility and functional independence in individuals with unilateral lower limb amputation, risk factor identification, and early disease detection appear to be of high importance for effective prevention and rehabilitation of knee OA in this patient population.

**KNEE OA PATHOMECHANICS AND RISK FACTORS**

The knee is one of the joints most commonly affected by OA with a 50% lifetime risk of developing symptomatic disease in the general population. As there is no cure, conservative management of knee OA has traditionally focused on pain management and improving overall mobility. However, due to the degenerative nature of the disease, knee OA commonly progresses to a stage where joint replacement surgery may be the only viable option for alleviating symptoms and improving function and QOL. However, joint replacement surgery may not be a feasible option for some patients such as those with lower limb amputation or other concomitant comorbidities. Therefore, attempts are currently underway to identify potentially modifiable risk factors and implement joint protective strategies that can result in favorable long-term outcomes.

Although knee OA has long been viewed as a non-inflammatory “wear and tear” of the articular cartilage in older adults, this disease paradigm is rapidly changing. There is now mounting evidence that although OA is a mechanically driven condition, the disease process is chemically mediated through a complex interplay between systemic and nonsystemic factors. Normal articular cartilage has a unique load-bearing mechanism capable of tolerating customary loads without sustaining injury that is determined through contributions from genetics, as well as mechanical and age-related factors. However, long-term exposure to excessive loads and other changes in joint mechanics, similar to those observed after lower limb amputation, can lead to adaptive cellular responses and altered gene expressions that facilitate the onset and progression of the disease.

Although systemic risk factors such as genetic predisposition may increase the risk of knee OA development after traumatic limb amputation through gene-specific and time-dependent alterations in gene expression, e.g., these factors are permanent and nonmodifiable, which makes them unlikely as direct preventative or therapeutic targets. Conversely, previously identified nonsystemic and potentially modifiable risk factors such as chronic knee pain, obesity, abnormal knee joint mechanics, lower limb muscle weakness, previous joint trauma, and altered physical activity levels are all modifiable through preventative and rehabilitative strategies that could be applied to individuals with lower limb amputation. Therefore, the purpose of this narrative review is to organize the pertinent literature in an effort to identify nonsystemic, potentially modifiable risk factors related to the development and progression of knee OA in the sound limbs of Service Members with traumatic amputations and identify possible prevention and treatment solutions.

**REVIEW CRITERIA**

Electronic searches of PubMed and EMBASE databases were performed in July 2015. MeSH terms for the initial search included “knee,” “OA,” “amputation,” and “trauma.” A comprehensive search was performed for each nonsystemic, OA-related risk factor by combining the initial search strategy with the combination of the following keyword search terms: “pain,” “obesity or body mass index or BMI,” “bio-mechanics or load or force or moment or rate,” “muscle and (weakness or strength or symmetry),” “acute joint injury or trauma,” and “physical activity or sports participation.” All titles and abstracts were screened for content and pertinence to the purpose of the review. In cases where direct evidence was lacking, additional supplemental manual searches were performed for relevant articles based on reference lists of the retrieved articles or relevant published literature related to knee OA and its risk factors in the general population.

**CHRONIC KNEE PAIN**

Presence of chronic knee pain has been deemed as an early indicator of degenerative joint changes that may appear before evidence of radiographic knee OA in nonamputees. The commonly used conventional radiographs are known to be insensitive to detecting early OA structural changes and are often only useful in measuring late-stage disease. More recently it has been suggested that symptoms often precede the appearance of radiographic abnormalities, implying the existence of a potentially detectable “prodromal phase” in the transition from preradiographic to radiographic stages of OA. As such, knee pain with activities associated with higher dynamic knee loading such as climbing stairs has been suggested to help identify individuals with preclinical knee OA suitable for early intervention strategies. Furthermore, presence of chronic knee pain has been identified as an early sign of future OA-related risk of functional decline.

After lower limb amputation, high knee pain prevalence rates of 50 to 55% and 36 to 38% have been reported in the intact limbs of individuals with unilateral transfemoral and transtibial amputations, respectively, compared to only a 20% prevalence rate among nonamputees. Conversely, the residual knee on the side of a transtibial amputation has been reported to be five times less likely to be painful compared to matched knees in nonamputees. Furthermore, Burke et al reported a knee pain prevalence rate of 52% in the intact limbs of individuals with unilateral transtibial amputations as compared to no reports of pain in the residual side knee. The higher prevalence of knee pain on the side of the intact lower limb in individuals with unilateral amputation is consistent with the patterns of knee OA reported in this patient population and may be a sign of development.
underlying disease that could be used for initiation of early prevention and intervention strategies.

**OBESITY**

Obesity is a well-documented individual risk factor for primary knee OA in older adults. To this end, a three-fold increase in risk of future knee OA development has been previously reported for young men between the ages of 20 and 29 years with BMI values between 24.7 and 37.6 kg/m² compared to their leaner counterparts with BMI values between 15.6 and 22.8 kg/m². Epidemiologic studies have previously demonstrated that obesity is linked to both the development and progression of knee OA; however, there is considerable debate about how obesity contributes to the onset and progression of the disease. Potential mechanisms for the contribution of obesity to knee OA include (1) a generalized negative metabolic environment reflecting a systemic inflammatory response to the products secreted by the adipose tissues; (2) increased cumulative compressive loads experienced by the joint due to a greater body mass; or (3) a combination of both metabolic and biomechanical factors. Currently, evidence in support of the metabolic explanation of the link between obesity and knee OA are mixed. Although some authors have suggested that metabolic factors associated with obesity contribute to the pathogenesis of knee OA, others have not supported this premise. On the other hand, the biomechanical theory explaining the potential link between knee OA and obesity is well supported by the contention that excessive body mass increases the loads placed on the knee joint. For example, it has been reported that a weight increase of 1 kg can result in a four-fold (4 kg) increase in compressive knee joint loads per step during activities of daily living. However, the potentially deleterious effects of greater joint loads due to an increase in body mass may be countered by the lower activity level, slower preferred walking speed, and less number of steps taken per day by individuals with higher body mass, therefore reducing the total knee joint loading exposure.

Clinical observations suggest that individuals with traumatic lower limb amputation are at increased risk for weight gain and obesity. Kurdibaylo reported higher fat content in body mass for individuals with transtibial (21%) and transfemoral amputations (23%) compared to age-matched controls (13%). Norvell et al also reported significantly higher average body weight and BMI for individuals with unilateral transtibial and transfemoral amputations compared to control subjects greater than 40 years of age. Younger individuals with amputations, in particular, are at high risk of obesity progression within their first year status post amputation, mostly as a result of a sedentary lifestyle immediately after amputation but before prosthesis fitting. Given that military standards for recruitment commonly exclude overweight volunteers, increased risk of obesity after lower limb amputation is most likely a consequence of the limb loss, which provides a great opportunity for initiation of early weight management strategies.

**ABNORMAL KNEE JOINT MECHANICS**

Knee joint mechanics experienced over time create a customary joint loading history that helps to precondition the tissue to withstand repeated mechanical demands without sustaining injury. However, joint damage may occur when the mechanical environment is significantly altered, such that new patterns of cartilage stresses/stains outside a habituated envelope result. This may be a concern after a traumatic, unilateral lower limb amputation, where the intact limb is challenged by increased demands for body support and forward progression. Several key reviews within the past decade have summarized the specific mechanical factors which influence the onset and progression of compartment knee OA in the general population and after lower limb amputations. In both populations, the external knee adduction moment (KAM) has been the most frequently used surrogate measure for medial knee joint loading related to knee OA. The KAM may be roughly estimated by multiplying the magnitude of the ground reaction force (GRF) in the frontal plane with the lever arm distance between the line of action of the GRF and the knee joint axis of rotation (Fig. 1). Individuals with knee OA characteristically demonstrate elevated peak KAM during walking that are strongly associated with severity of medial compartment knee OA, which is 10 times more prevalent in the general nonamputee population than lateral compartment knee OA. Furthermore, for patients with existing medial knee OA, KAM magnitude at baseline has strong associations with baseline knee pain severity, and was shown to be longitudinally

![Schematic representation of intact limb knee adduction moment (KAM) during initial limb loading. Ground reaction force (GRF) magnitude, along with the perpendicular distance (white dotted line) between the GRF line of action and the frontal plane knee center of rotation approximates KAM magnitude, which is highly determinate of compressive load within the medial knee compartment.](image-url)
Development of Knee Osteoarthritis After Unilateral Lower Limb Amputation

predictive of OA radiographic progression. However, measures useful in predicting progression of existing OA may differ from those associated with initiation of OA.

Previous investigations of walking in individuals with transtibial amputations (mean age ranging 41.2–56.3 years old) have reported 33 to 56% greater peak KAM on the intact limb than on the prosthetic limb, depending on walking speed and the type of prosthetic foot used in the study. While this is greater relative to an asymmetry of ~10% in non-amputees, the intact limb may not necessarily be overloaded in direct comparison to the limb of a speed-matched non-amputee. For example, Royer et al found a 56% greater peak KAM on the intact limb relative to the prosthetic side in individuals with unilateral transtibial amputations, associated with a 45% greater tibial plateau bone mineral density on the intact limb, relative to the prosthetic side. However, neither peak KAM magnitude nor the bone mineral density for the intact limb were significantly different from speed- and age-matched nonamputees. In contrast, a number of other studies have instead found mechanical differences in the sagittal plane, reporting 48% greater peak external knee extension moments on the intact limb, relative to the prosthetic side.

Higher-level analysis of net GRFs can also lend insight into pathomechanics of knee OA in individuals with limb amputation. In general, findings from collected literature support net overloading of the intact side relative to the prosthetic side, as well as relative to speed-matched nonamputees. For example, persons with unilateral transtibial amputation have a greater intact-limb peak vertical GRF during loading response relative to nonamputees, by as much as 4 to 10% during walking and 35 to 45% during running. Knee flexion angle and external knee extension moments, which are associated with GRF overloading and elevated axial knee joint compression, have also been found greater in the intact limb of individuals with unilateral lower limb amputations compared to nonamputees. Such net GRF differences may or may not lead to differences at each of the proximal joints, depending on concurrent kinematics and muscle activity. One study accounting for the latter factors found 23% greater peaks in axial knee joint total compression force on the intact limb relative to the prosthetic side, and 9% greater relative to nonamputee limbs.

Prosthetic device mechanical properties have also proven to have a significant effect on mechanics of the proximal intact limb. Briefly, findings indicate that prosthetic foot stiffness and energy return properties can effect intact limb early stance GRFs, with as much as a 7% of body weight increase in peak vertical GRF when using a solid ankle cushion heel foot versus an energy storage and return foot. Energy storage and return feet can also reduce intact limb peak KAM by as much as 13% versus a solid ankle cushion heel foot, while an active prosthetic foot that provides timed, active propulsion near prosthetic limb push-off can decrease the magnitude of intact limb peak KAM by as much as 30%. Currently, there is a clear need to ascertain whether such prosthetic advancements are associated with a reduced incidence of knee joint pain and early OA in the intact limb of patients with unilateral amputation.

MUSCLE WEAKNESS

Lower limb muscle weakness is a hallmark impairment for primary knee OA in older adults. In general, muscular strength is critical for maintaining proper dynamic joint function as muscles aid in shock absorption and proper force transfer across the joint. To this end, quadriceps muscle weakness has been suggested as a strong risk factor for primary knee OA. Several mechanical theories have been previously suggested for the potential relationship between quadriceps muscle weakness and structural knee OA development and progression. For instance, it has been suggested that quadriceps muscles plays a joint protective role as a shock absorber to dampen the rate of knee loading such as decreasing the heel strike transient during the loading response phase of gait. In individuals with lower limb amputation, prior studies have shown a significant decrease in quadriceps strength for the prosthetic limb when compared to the intact limb. Quadriceps atrophy has also been noted on the prosthetic side in comparison to the intact limb. Comparisons of individuals with unilateral transfemoral amputations to a control group have also demonstrated that those with amputations have weaker quadriceps bilaterally compared to nonamputees, which were highly correlated with increased rates of vertical impact loading of the lower limb during gait.

While the quadriceps remain the major focus of research efforts examining the role of muscle weakness in pathogenesis of primary knee OA, a new body of evidence is emerging to suggest that hip muscle weakness may also be a risk factor for knee OA. As the hip shares a common segment (i.e., the femur) with the knee, adequate hip muscle performance is necessary to provide dynamic proximal stability for maintaining appropriate knee joint mechanics during weight bearing. For example, Chang et al reported that a greater hip abductor strength is associated with a reduced likelihood of medial compartment knee OA progression. Other studies, however, have shown that strengthening of the hip musculature can lead to significant improvements in pain and function despite virtually no change in KAM in older adults with primary knee OA. Strength testing in individuals with unilateral transfemoral amputations, traumatic and nontraumatic, has shown that isometric hip abduction strength of the amputated limb is 47 to 54% lower compared to the intact limb and 35 to 65% lower compared to nonamputees. Conversely, Nadolke et al found no difference in elderly individuals with unilateral transfemoral amputations between the prosthetic and intact limbs; however, comparisons to hip strength in a control group were not made. Additional research is needed to provide a clearer picture of the prevalence and extent of lower limb muscle weakness and its potential relationship with development and progression of knee OA after traumatic lower limb amputation.
PREVIOUS KNEE INJURY OR TRAUMA

High-impact loading knee injuries such as tears of the meniscus, ligaments, or capsule; joint dislocations; and intra-articular fractures in young individuals has been previously linked with a 5.2-fold increased relative risk of developing subsequent knee OA.22 The energy initially absorbed by the joint surfaces at the time of injury has been suggested as an important predictor of development of knee post-traumatic OA (PTOA).64 This PTOA has fundamentally different etiology than the primary degenerative OA discussed previously in this review. The emerging hypothesis related to PTOA is that the severity of the initial trauma and the subsequent cascade of pathophysiological events such as inflammation and chondrocyte senescence, along with any residual joint instability, incongruity, or alteration in biomechanics, contribute substantially to the onset and progression of knee OA.65

The risk of knee PTOA is most likely even higher in young military Service Members due to the high-energy nature of most battlefield injuries. In fact, in a recent report in combat-injured warriors who could not return to duty, injuries to the knee resulted in post-traumatic knee OA in every case at an average of 19±10 months after injury.56 This trajectory of knee PTOA development after combat injuries appears to be much steeper than the 10 to 15 year rate previously reported after anterior cruciate ligament ruptures or meniscal damage in the general population.67-69 Given that most combat-related injuries resulting from high-energy explosions involve multiple limbs and joints,56 it is likely that the concurrent injury to the knee of the intact limb along with altered joint biomechanics after amputation could lead to a greater risk of developing PTOA in individuals with traumatic unilateral lower limb amputation. Additional research to better understand the involvement of multiple joint tissues and the critical cellular and molecular events after trauma and injury is needed to develop strategies (e.g., surgical, pharmaceutical, rehabilitative, etc.) to slow or halt the onset or progression of knee PTOA after lower limb amputation.

PHYSICAL ACTIVITY LEVEL

Previous findings concerning the association between exercise, sports participation, and risk of knee OA have been somewhat perplexing. For instance, regular exercise has been suggested as a favorable option for maintaining articular cartilage health.35 Experimental studies in animals have also shown that loading of healthy joints through moderate bouts of running is associated with increased articular cartilage thickness, proteoglycan content, and mechanical stiffness of the tissue.23,24 In addition, recreational- or even elite-athlete level long-distance running have shown to be unrelated to accelerated incidence or severity of radiographic knee OA in the absence of underlying joint disease.30,71 In contrast, other studies have associated participation in specific sports that involve running, jumping, and heavy lifting with higher incidents of knee OA and an increased rate of disease progression.72,73

In general, individuals with unilateral transtibial amputation, regardless of traumatic or nontraumatic origin of the initial injury, demonstrate decreased activity levels when compared to nonamputees.74 In previous literature, it has been reported that individuals with lower limb amputation on average take 1,540 to 3,163 steps per day.75,76 as compared to healthy adults who ambulate anywhere between 4,000 and 18,000 steps per day.77 Given that mechanical loading of the knee joint is inherently linked to maintenance of the articular cartilage, adequate levels of mechanical stimulation are essential for maintaining articular cartilage tissue homeostasis through balancing solid matrix synthesis and degeneration.78 Therefore, lower frequency of knee joint loading due to diminished activity levels can lead to the reduction in cartilage tissue resiliency35 needed to meet the requirements of higher demanding activities, such as sports participation or returning to active duty that may be desired by young Service Members with lower limb amputations.

It has been suggested that individuals with amputations who participate in sports and/or regular physical activity report significant benefits both physically and psychologically, such as improved strength, endurance, balance, and improved self-esteem and QOL.79 Previous studies have shown that 32 to 60% of individuals with lower limb amputation participate in some form of sports, whether recreationally or competitively.80 Currently, whether sports participation in individuals with lower limb amputation could be a risk factor for onset and progression of knee OA remains unknown. In a small study, Melzer et al1 found no differences in the intact limb knee OA incidence between individuals with amputations who did and did not play volleyball. Additional longitudinal data are needed to better understand how early return to high-demanding sports activities may contribute to the onset and progression of knee OA. Additionally, Service Members are anticipated to perform physical activities beyond level walking and running, which warrants further investigation of such activities.

CONCLUSIONS

Available scientific evidence to date supports that young military Service Members with traumatic, unilateral lower limb amputations may be at increased risk for developing knee OA compared to nonamputees. Given the high life expectancy of young injured military Service Members, development of effective rehabilitative programs to prevent or delay knee OA through early risk factor identification and modification is a crucial step in optimizing long-term function and QOL after traumatic, unilateral limb amputations. Future development of such programs should span a comprehensive range. Components should include screening of the intact limb for prior high-energy trauma and joint pain, managing body weight, further study of intact side knee joint mechanics, and
addressing lower limb muscle weakness. In retraining undesirable biomechanics, technological advancements to guide real-time feedback and adjustments in movement strategies may be useful. Continued future research and clinical programs that address nonsystemic knee OA risk factors are anticipated to increase long-term preservation of intact limb function and overall QOL in young Service Members after unilateral lower limb amputation.

REFERENCES

41. Underwood HA, Tokuno CD, Eng JJ: A comparison of two prosthetic feet on the multi-joint and multi-plane kinetic Gait compensations in


Differences in Military Obstacle Course Performance Between Three Energy-Storing and Shock-Adapting Prosthetic Feet in High-Functioning Transtibial Amputees: A Double-Blind, Randomized Control Trial

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ABSTRACT  Background: Approximately 683 persons engaged in military service experienced transtibial amputation (TTA) related to recent war in Iraq and Afghanistan. Military TTAs function at a level beyond basic ambulation. No empirical data demonstrate which higher functioning prosthetic feet maximize injured service personnel’s ability to continue performing at a level commensurate with return to duty. This study’s purpose was to determine which of three high-functioning, energy-storing prosthetic feet maximize performance and preference in a field obstacle course (OC) and to quantify physical performance differences between TTAs and high-functioning nonamputees. Procedures: A randomized, double-blind, repeated measures experimental design compared three prosthetic feet (Ossur Variflex, Endolite Elite Blade, and Ossur Re-Flex Rotate) during performance on a field OC. TTAs accommodated with study feet and the OC before assessment. 14 TTAs and 14 nonamputee controls completed the course. Subjective and objective performance differences were compared across feet conditions and between groups. Results: Total OC completion times were similar between prosthetic feet: Elite-Blade (419 seconds ± 130), Variflex (425 seconds ± 144), and Re-Flex Rotate (444 seconds ± 220). Controls’ OC completion time (287.2 seconds ± 58) was less (p ≤ 0.05) than TTA times. In total, controls had faster completion times (p ≤ 0.05) compared to all prosthetic feet conditions in 13/17 obstacles. Re-Flex Rotate had 2 additional obstacles different (p ≤ 0.05) than controls and required more time to complete. Median RPE values were lower (p ≤ 0.05) for controls than TTA regardless of foot. Regarding foot preference for OC completion, 7/14 (50%) preferred Elite Blade, 5/14 (36%) preferred Re-Flex Rotate, and the remaining 2/14 (14%) preferred Variflex. Conclusion: Controls completed the OC faster and with less effort than TTAs regardless of prosthetic foot. No clear differences in prosthetic feet emerged during OC completion; however, individual task performance, perceived effort, and preference resulted in trends of slight performance improvement with and preference for Elite Blade, a dual function energy-storing and return foot combined with vertical shock absorption. Understanding how to maximally improve performance in such functional tasks may allow service members to best sustain physical fitness, return to their military occupational specialty and possibly in-theater duty.

INTRODUCTION

Traumatic amputation represents more than 2% of all battlefield injuries and greater than 7% of major extremity injury associated with military service.1,2 Speciﬁc to the wars in Iraq and Afghanistan, there have been 1,221 persons engaged in military service who have experienced 1,631 amputations from 2001 to 2011.3 Of these, 683 amputations (or 41.8%) were at the transtibial level and 366 people suffered multiple amputations.1–4 Military transtibial amputation (TTAs) likely function at a level beyond basic ambulation and will require a longer duration of care over their remaining lifespan compared to dysvascular amputees in the civilian sector. Today’s younger military TTA will challenge the health care system that is best suited for management of lower functioning patients.5,6

Rehabilitation following TTA routinely involves use of a prosthesis. Optimizing the TTA prosthesis requires selecting componentry, including a prosthetic foot best suited for the patient’s particular functional demands. Problematically, little empirical data are available to guide selection of the optimal foot for a high-functioning member of the armed forces who may be interested in extreme recreational pursuits as a Veteran or in staying on active military duty. Available comparative effectiveness research for prosthetic feet in the TTA population has included perceptive, biomechanical, and
bioenergetic measures in a limited selection of prosthetic feet including solid ankle cushioned heel (SACH), energy-storing, and vertical shock–absorbing feet.7 Briefly, compared to alternatives such as SACH feet, TTA’s studied preferred energy-storing feet and reported enhanced performance, comfort and less effort in association with their use.7–12 In some cases, additional functions have resulted in improved performance of specific functional needs. Examples include specialty running feet improving bioenergetic efficiency during ambulation above comfortable walking speeds and vertical shock absorption improving stair-climbing kinetics.13,14 Despite the available, however limited evidence, there is no empirical data to demonstrate which higher functioning prosthetic feet can maximize an injured service member’s ability to continue performing at a level commensurate with return to duty.

Obstacle courses (OCs) are a familiar element of military and law enforcement culture and qualification. They are used in preparatory training and skill maintenance in physically demanding work environments. OCs are further used for assessment to demonstrate continued preparedness in terms of skill proficiency and fitness. Use of OCs have become even more widespread to include recreation and to determine disease severity. In the health care literature for instance, OCs have been used with the elderly, those using assistive mobility aids, visually impaired, community ambulatory transfemoral amputees, those recovering from cardiac events, firefighters, and the military.15–24 Use of OCs in these examples have provided determinations of fitness and situational preparedness for physically rigorous work environments. Given that OCs are familiar to military personnel to assess physical preparedness and because there are no field-based physical performance assessments of high-functioning TTA using high-functioning prosthetic feet, use of an OC is a logical assessment choice in this population. Therefore, the purpose of this study was to determine which of three high-functioning, energy-storing prosthetic feet maximize performance and preference in a rigorous field OC. A second purpose was to quantify the differences in physical performance between persons with TTA and a high-functioning nonamputee control group.

METHODS

The protocol was approved by Institutional Review Boards for the University of South Florida and the U.S. Army. The study was also listed in a federal clinical trials registry (www.clinicaltrials.gov; no. NCT01404559).

Study Design

A randomized, double-blind (subjects and data collectors), repeated measures experimental design was used to compare three prosthetic feet conditions in physical performance. The study statistician (also blinded to the interventions) used an electronically generated, randomized, and balanced block allocation to sequence independent variable (prosthetic foot) assignment to subjects (off-site and concealed) via the study prosthetists. The study prosthetists fabricated prosthetic blinding covers that concealed the identity of prosthetic feet during testing to mask participants and investigators.

Subject Recruitment and Eligibility

TTA subjects were recruited in collaboration with case managers through a military treatment facility specializing in amputee rehabilitation as well as advertisement with local prosthetic and rehabilitative clinics. Nonamputee control subjects were recruited through the local County Sherriff Department’s Special Weapons and Tactics Team (SWAT). All subjects had to be aged ≤45 years and provide evidence of medical clearance to be able to participate in vigorous physical activity. Nonamputee control subjects had to be a SWAT team member. Additional eligibility criteria specific to TTAs included that candidates had to be determined by study prosthetists to be at the K4 functional level and currently active duty military or other uniformed service, a recently separated Veteran or have a strong high-performance athletic history as an amputee (e.g., ranked triathlete, paralympian).

Experimental Procedures

Study Fees (Independent Variables)

All amputee subjects (experimental group) were tested in random order with each of the following three energy-storing prosthetic feet (blinded) (Fig. 1).

1. Variflex (Ossur, Reykjavik, Iceland. Energy-storing and return [ESR]).

These feet were selected as they represent differing types of energy-storing feet including a basic energy-storing foot, a light weight ESR foot with vertical shock absorption and a heavier ESR foot with vertical shock and torsion absorption. A cross-section of nonamputees were also assessed to provide a comparison to unimpaired physical performance (control group).

Prosthetic Fitting and Accommodation Periods

Board-certified and state-licensed study prosthetists duplicated TTA participants’ prosthetic sockets and suspension. The duplicate socket was then fit and aligned (to manufacturer specifications using a LASAR posture tool [Ottobock Healthcare, Duderstadt, Germany]) with the three 3 prosthetic feet using modular coupling components to control potential confounding issues related to socket fit. TTA participants accommodated with each prosthetic foot by wearing it for a minimum of 7 days (minimum of 8 hours per day). Participants recorded their foot accommodation use in a written journal provided to them during fitting and training. Usage
and minimal accommodation were confirmed by study staff verbally and via journal entries before scheduling testing. This assured a minimum accommodation period between fitting and testing of at least 21 days total for the duplicate socket and 7 days per foot condition in subjects’ home environment (Fig. 2).

**OC and Familiarization**

The local law enforcement and military OC were selected and approved as the test facility. It is routinely used to train police officers, SWAT team members, and various branches of military service members. SWAT operators and trainers were onsite at all times to familiarize and supervise participants during study training and assessment.

As recommended, OC familiarization included three preparatory performance trials to eliminate confounding learning effects. The study familiarization and accommodation plan also included provision of an OC map (Fig. 3) to participants in advance of a physical familiarization and training trip to the OC (Fig. 2). This included a 5-day prosthetic fitting and familiarization visit. Using their prestudy, preferred prosthesis, subjects visited the OC for instruction by SWAT operators on OC safety and completion technique. After instructional training and supervised practice, subjects performed three supervised OC trials independently, for a practice time.

The OC included the following obstacle tasks:

1. Jacob’s Ladder
2. Rope Climb
3. Balance Beam
4. A-Frame
5. Culverts
6. Chain-Link Fence
7. Rope Bridge and Stumps
8. Cargo Net
9. High Step
10. Angle Wall (Fig. 4)
11. Slalom
For the individual TTA subject, the study commitment involved 5 weeks of activity (Fig. 2) as follows:

**Preparation period:** Following enrollment and consent, the preparation period commenced. This was a 5-day session. The daily itinerary was as follows:

- **Monday:** First meeting with a study prosthetist to initiate duplication of preferred socket. Preliminary fitting, adjustment, and alignment of 3 prosthetic feet began on completion of socket duplication.
- **Tuesday:** First training visit to OC. Subjects trained on OC sequence, completion technique, and safety. Visit with study prosthetist as needed.
- **Wednesday:** Finalize prosthetic fittings adjustments and alignments.
- **Thursday:** Second visit to OC. While supervised, subjects physically practiced OC. Visit with study prosthetist as needed.
- **Friday:** Final meeting with study investigators, OC personnel, and study prosthetist.

**Study Schedule**

Review accommodation period. Discuss and schedule the testing period.

**Accommodation period:** See “Prosthetic Fitting and Accommodation Period” section above.
Testing period: Following accommodation, the testing period commenced. The testing period was a 5-day session as follows:

Monday: OC test 1 of 3 (randomized foot assignment)
Tuesday: Biomechanical and bioenergetic laboratory tests (reported elsewhere)
Wednesday: OC test 2 of 3 (randomized foot assignment)
Thursday: Biomechanical and bioenergetic laboratory tests (reported elsewhere)
Friday: OC test 3 of 3 (randomized foot assignment)

Biomechanical and bioenergetic laboratory testing involved minimal walking and running at comfortable speeds sufficient to achieve steady state yet insufficient to confound recovery between field test days. For control subjects, OC testing was completed in a single session. This is because of their routine (i.e., weekly) practice, assessment, and instruction with the course.

Outcome Measures

Demographic information, anthropometric measures, fully assembled prosthetic masses, and final alignments (i.e., sagittal and coronal distances from LASAR line to manufacturer’s recommended foot reference location) were recorded during the testing period before performance data collection. Using an ad hoc rating scale, subjects were also asked to rate their activity level (i.e., sedentary, minimally, moderately, or highly active) as well as to quantify the number and type of activity bouts per week and the number of years of participation. Subjects then completed the field OC, one time per foot (three times total) to determine total time-to-completion and per-task completion times. Time data were recorded using laser timing gates (Brower TC-Gates, Brower Timing Systems, Power Systems, LLC, Knoxville, Tennessee) situated in front of and behind each obstacle on the OC. As subjects would pass between the laser gates, times were triggered and recorded into a data file for later aggregation and processing. Immediately following each individual OC completion, subjects were asked to rate their perceived exertion (RPE) using the Borg (6–20) scale for the entire course with the respective foot condition. Following the third and final OC completion, TTAs were asked to indicate which of the three feet conditions they preferred to utilize in order to complete the OC.

Statistical Analyses

Sample size and power calculations were based on effect sizes calculated from performance outcomes (i.e., walking speed, oxygen uptake, lower limb joint kinetics, and perceived exertion) previously published regarding comparable high-functioning feet (e.g., Re-Flex Shock, Variflex, Ossur, Reykjavik, Iceland) in basic mobility tasks. These estimates provided that 10 TTA subjects would adequately power the study with $\beta = 0.80$. Given the available data are from basic walking and running, the resulting sample estimates were regarded as conservative. Therefore, planning for attrition and accounting for the conservative estimates provided from basic mobility data, recruitment was set at 14 TTA participants. Following all assessments, data were entered into a database and verified before analysis. Subjects’ performance data within a given condition (i.e., Variflex) were averaged (and variance calculated) to represent that condition for further analysis and comparison across conditions and between groups. Descriptive statistics were calculated (i.e., means, standard deviations) where possible. Continuous data (i.e., OC time to completion) were examined for normalcy and outliers using NCSS/PASS’s omnibus calculation of skewness and kurtosis (2004 edition, Kaysville, Utah). A within subjects’ repeated measures analysis of variance model was used to reveal statistical differences in performance between prosthetic feet conditions (dependent comparisons). Differences between control and experimental subjects were independent comparisons and thus ineligible for comparison using the repeated measures analysis of variance model. Therefore, depending on their distribution, either independent samples $t$ tests (normally distributed data eligible for parametric analyses) or the Mann–Whitney $U$ test was used to identify statistically significant differences between TTA and non-amputee controls (as independent comparisons per foot condition). The protocol’s a priori level of significance was 0.05. All comparative statistical analyses were performed using SPSS 2012 v.20 (Armonk, New York). Finally, effect size was calculated using Cohen’s $d$ and interpreted as $d \geq 0.20$ represents a small effect, $d \geq 0.50$ represents a medium effect, and $d \geq 0.80$ represents a large effect.
provided the related finding was statistically significant. Results were unmasked following all statistical analyses.

RESULTS

Subjects
A total of 28 participants provided informed consent and completed the protocol (i.e., no missing data). Of these, 14 were TTAs and the other 14 were members of the local Sheriff’s SWAT team who served as nonamputee control subjects. The 14 TTAs included 5 Army Veterans, 3 Marine Corps Veterans, 3 accomplished civilian athletes, 2 active duty Army soldiers, and 1 active duty Air Force airman. TTAs lost their limbs 8.9 ± 10.5 (mean ± SD) years before enrollment primarily because of exposure to blasts from improvised explosive devices. Two of the civilian TTAs lost their limbs because of trauma and one was a congenital amputee. TTA subjects’ mean age (31.4 years ± 5.9) was significantly (p ≤ 0.05) younger than controls (38.5 years ± 5.1). The TTA’s body mass index was 28.4 ± 6.7 kg/m² compared to controls’ 26.3 ± 2.9 kg/m² (p > 0.05). Although 66.7% of TTAs rated themselves as highly active, only 35.7% of controls rated themselves as highly active (p > 0.05). Self-reported activity (years and no. of bouts/week) was not significantly different between TTAs and controls, however, duration/bout was (p ≤ 0.05). Control subjects reported physical training of 2 to 5 bouts per week (3.1 ± 1.1) related to their work, whereas TTAs reported 3.5 ± 1.2 (range: 1.0–5.0) bouts per week. TTAs reported training duration of 62.7 ± 24.3 minutes compared to 42.5 ± 16.3 reported by controls.

Prosthetic Characteristics
TTAs reported using 0.9 ± 0.9 (range: 0–3) additional recreational prostheses for the following activities; cycling, jogging/running, skiing, snowboarding, rock climbing, swimming, kayaking, soccer, and cross-fit exercise, which constituted much of the aforementioned physical training. Sagittal and coronal alignment of prosthetic feet setup for the study was to manufacturer specification and were not significantly different between conditions (p > 0.05). In terms of prosthetic suspension, 9 subjects used a sleeve and 5 used a pin lock. Two of the subjects using pin suspension also used auxiliary suspension (one suction pin and one sleeve). All subjects used a total surface bearing socket design. Re-Flex Rotate (1.92 kg ± 1.10) made prostheses significantly heavier (p < 0.05; without socks/shoes) than the Variflex (1.67 kg ± 0.96) and the Elite Blade (1.52 kg ± 0.96).

OC Timing Data
The OC includes 18 tasks. During the preparation period, the fitting and accommodation week, it became clear during OC practice that TTAs were greatly challenged by obstacle no. 2, the rope climb (Fig. 2, OC map). There were numerous potential reasons including an inability to move the prosthetic ankle-foot system sufficient to use the feet to elevate the body and assist the upper limbs during climbing. Thus, SWAT operators determined the rope climb obstacle required elimination from further practice and evaluation for safety reasons. Removing the rope climb obstacle reduced the total number of tasks from 18 to 17 for both the TTAs and the control group. Following removal of the rope climb obstacle, total OC completion times (mean ± SD) were similar (p > 0.05) between prosthetic feet: Elite-Blade (419 seconds ± 130), Variflex (425 seconds ± 144), and Re-Flex Rotate (444 seconds ± 220). Controls’ total OC completion time was 287.2 seconds ± 58 which was less (p ≤ 0.05) than TTA times. In total, controls had significantly faster completion times (p ≤ 0.05) compared to all 3 prosthetic feet conditions in 13 of 17 obstacles (Table I).

The Re-Flex Rotate had two additional obstacles that were significantly different (p ≤ 0.05) than controls. The Elite Blade had one additional obstacle that required more time to complete. In terms of per-obstacle completion time differences between prosthetic feet, only two obstacles yielded differences: (1) climbing the chain-link fence and (2) the sprint finish. Climbing the chain-link fence required greater time with the Variflex than it did with the Elite Blade (14.0 seconds ± 4.9 vs. 12.4 seconds ± 4.6; p ≤ 0.05). The sprint finish took significantly longer (p ≤ 0.05) to complete with the Re-Flex Rotate (6.6 seconds ± 1.7) than it did with either the Variflex (5.9 seconds ± 1.1) or the Elite Blade (5.9 seconds ± 1.4).

Perceptive Measures
Median RPE values were significantly lower (p ≤ 0.05) for controls (17; range: 14–17) than TTA regardless of foot condition (Variflex 18.5[15–20], Elite Blade 18.5[13–20], and Re-Flex Rotate 18[15–20]). Finally, when asked to rate their preference of foot for completing the OC, 7/14 subjects (50%) preferred the Elite Blade, 5/14 (36%) preferred the Re-Flex Rotate, and the remaining 2/14 (14%) preferred the Variflex.

DISCUSSION
We hypothesized that the lightest weight foot would outperform other prosthetic foot alternatives and be the most preferred. We further hypothesized that nonamputees would outperform TTAs in all physical performance measures. The Elite Blade was the foot with the lowest mass, but it was not significantly different than the Variflex.

TTA subjects in this study are representative of combat injured military personnel and similar to TTAs from other studies of persons who have lost limbs in military service, in terms of demographic and anthropometric characteristics.1,2,4,6,20 Among the more obvious results from this study were the differences in performance between TTA and control. TTAs were younger than controls by approximately...
7 years; however, controls had the advantage of familiarity and routine training on the OC facility. This familiarity controls had with the OC may account for some of the difference in performance; however, large performance differences between amputees and nonamputees are observed in multiple other reports.\textsuperscript{13,30}

In 1995, approximately 2% of soldiers with major limb amputation returned to duty. With regard to OEF/OIF, there was an eight-fold increase (16%) of soldiers with amputation returning to duty.\textsuperscript{6,31} One means for a soldier with amputation to demonstrate function beyond basic ambulation may be completing a military equivalent OC with performance comparable to nonamputees. For military applications, OCs are used to simulate impediments to tactical soldier movement that might be found in urban or rural settings.\textsuperscript{25,32} OC completion speed may relate to fitness components such as upper and lower body aerobic and anaerobic power, muscular strength and endurance, and less quantifiable skill attributes such as agility and technique.\textsuperscript{23,25} In military training, OCs have many intended functions including improving fitness, agility, confidence, and camaraderie.\textsuperscript{23,25} Utilization of timed OCs for military performance assessment is important as multiple physiologic attributes contribute to overall performance in these tests and a tactical unit can only move as fast as it is slowest member.\textsuperscript{17,21,25,32} Therefore, removing the rope climb obstacle was a salient point in this study. SWAT operators’ safety decision to eliminate the obstacle raised concern over the ability of TTAs, as a group, to complete the course. During training and accommodation, a small number of the TTA group were able to complete the task largely as an exclusively upper limb activity. This was not advised by the trainers because many of the remaining obstacles require vigorous, reliable use of the upper limbs or a combination of upper and lower limbs. Therefore, completing the rope climb exclusively with the upper limbs created notable fatigue and compromised performance during the remainder of the course while participants were training and practicing. Hence, use of the feet to assist with the rope climb was advised. Unfortunately, TTAs were unable to oppose their prosthetic feet and ankles to create sufficient friction to enable the lower extremities to assist the upper limbs in lifting during the climb. This presented an obvious limitation of existing feet and ankle systems for TTAs in this task. It also prevented the TTAs, as a group to be able to complete the course as originally designed. This, in addition to the 31% to 35% difference in overall performance, further highlights some of the impairment created by TTA. However, a few individuals in the TTA group were able to complete the course as designed. Although group analyses were necessary in order to meet study objectives, individual analyses may reveal considerable differences between TTAs. This observation that some individuals could complete the course, supports individual assessment for making return to duty determinations following injury related to combat or other facets of military service.

The mean number of additional artificial limbs used by subjects in this study was lower than that reported elsewhere.\textsuperscript{33} In this study, TTAs reportedly used approximately 1 additional recreational prosthesis, thus having 2 prostheses in service, whereas others have reported an average of 3 prostheses. Although these two studies disagree over one additional prosthesis, the present study demonstrates an

### TABLE I. Time to Completion Data

<table>
<thead>
<tr>
<th>Obstacle</th>
<th>Variflex Mean (SD)</th>
<th>Variflex Mean (SD)</th>
<th>Re-Flex Rotate Mean (SD)</th>
<th>Control Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jacob’s Ladder</td>
<td>32.9 (12.8)</td>
<td>31.8 (15.6)</td>
<td>29.6 (10.2)</td>
<td>22.0 (8.2)</td>
</tr>
<tr>
<td>Balance Beam</td>
<td>11.6 (3.7)</td>
<td>11.3 (3.3)</td>
<td>10.9 (2.7)</td>
<td>8.4 (1.7)</td>
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<tr>
<td>A-Frame</td>
<td>39.6 (14.4)</td>
<td>37.0 (11.6)</td>
<td>36.6 (13.9)</td>
<td>23.4 (5.7)</td>
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<tr>
<td>Culverts</td>
<td>14.0 (3.8)</td>
<td>14.4 (3.9)</td>
<td>14.4 (3.3)</td>
<td>12.0 (1.8)</td>
</tr>
<tr>
<td>Fence</td>
<td>14.0 (4.9)</td>
<td>12.4 (4.6)</td>
<td>13.2 (4.0)</td>
<td>8.6 (2.6)</td>
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<tr>
<td>Rope Bridge</td>
<td>29.7 (11.3)</td>
<td>26.9 (8.0)</td>
<td>27.6 (7.9)</td>
<td>19.5 (5.2)</td>
</tr>
<tr>
<td>Cargo Net</td>
<td>57.1 (20.0)</td>
<td>62.4 (27.1)</td>
<td>57.9 (23.7)</td>
<td>37.1 (6.9)</td>
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<td>High Step</td>
<td>13.9 (5.5)</td>
<td>12.4 (2.9)</td>
<td>12.1 (2.4)</td>
<td>9.8 (1.6)</td>
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<tr>
<td>Angle Wall</td>
<td>11.7 (4.8)</td>
<td>11.1 (3.5)</td>
<td>14.9 (17.0)</td>
<td>7.0 (2.4)</td>
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<td>Slalom</td>
<td>14.2 (3.5)</td>
<td>13.6 (3.0)</td>
<td>14.5 (3.2)</td>
<td>13.8 (1.6)</td>
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<tr>
<td>Pete’s Dragon</td>
<td>58.7 (28.3)</td>
<td>51.6 (17.5)</td>
<td>69.9 (73.2)</td>
<td>38.5 (7.6)</td>
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<td>Monkey Bars</td>
<td>20.7 (8.4)</td>
<td>20.9 (7.2)</td>
<td>21.7 (8.4)</td>
<td>14.5 (4.7)</td>
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<tr>
<td>Over/Under Walls</td>
<td>20.9 (11.4)</td>
<td>19.5 (6.6)</td>
<td>19.4 (8.3)</td>
<td>14.3 (3.1)</td>
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<tr>
<td>Angle Tube</td>
<td>17.1 (9.9)</td>
<td>16.6 (7.4)</td>
<td>21.3 (23.5)</td>
<td>11.5 (3.2)</td>
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<td>Rope Traverse</td>
<td>36.8 (15.0)</td>
<td>41.4 (22.0)</td>
<td>44.5 (26.6)</td>
<td>26.3 (9.6)</td>
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<td>SWAT Ladder</td>
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<td>25.1 (9.4)</td>
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<td>15.5 (4.7)</td>
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<td>Sprint Finish</td>
<td>5.9 (1.1)</td>
<td>5.9 (1.4)</td>
<td>6.6 (1.7)</td>
<td>5.1 (0.8)</td>
</tr>
<tr>
<td>Total Time</td>
<td>424.7 (143.9)</td>
<td>418.9 (130.2)</td>
<td>443.9 (219.9)</td>
<td>287.2 (58.4)</td>
</tr>
</tbody>
</table>

Time data are in seconds. Effect sizes (Cohen’s $d$) was large ($d \geq 0.80$) for all statistically significant comparisons between prosthetic feet conditions and controls; small ($d = 0.34$) for significant comparisons between Variflex and Elite Blade; and medium ($d = 0.53$) for significant comparisons of Elite Blade with Re-Flex Rotate. \textsuperscript{$*$}$p \leq 0.05$ compared to all prosthetic feet conditions. \textsuperscript{$\dagger$}$p \leq 0.05$ compared to controls. \textsuperscript{$\ddagger$}$p \leq 0.05$ compared to Elite Blade. \textsuperscript{$§$}$p \leq 0.05$ compared to Variflex.
objective level of utilization of these additional recreational/exercise prostheses and that their prescription appears to have the benefit of permitting the maintenance of high functional performance. That is, subjects in this study reported use of exercise prostheses, as opposed to their daily function limb, is what was used to maintain their fitness such that they were able to complete this rigorous OC with minimal modification.

Prosthetic socket design (total surface bearing) was consistent across all subjects, whereas suspension was not. That is, 64% of study prostheses were suspended via sleeve and the remaining 35% were suspended with a pin mechanism. There were no skin issues or subjective complaints at any point during the study to suggest suspension was a factor; however, it may bear consideration in future studies. Accommodation with study feet was 7 days per component in this study and 21 days with the duplicate socket. Socket accommodation was consistent with other transtibial studies who also reported 21 days. In terms of feet components, the 7-day accommodation utilized here was substantially longer than the 30-minute accommodation used in some foot studies, but notably shorter than the 4 weeks used in others. There is no agreed on accommodation time for prosthetic componentry. Thus, confounding related to a lack of full accommodation can never be completely ruled out; however, we were confident subjects were proficient in the use of all study feet at the point of assessment.

Unlike other prosthetic considerations discussed thus far, the prosthetic foot design was the independent variable. One of the study’s hypotheses was that foot mass would have been a key variable to impact function. The Variflex is an ESR foot shown to improve stride length and bioenergetic efficiency during ambulation, stair ascent kinetics, and to reduce fatigue. The other two feet studied incorporated both ESR and additional functions. The Elite Blade also incorporates vertical shock absorption and the Re-Flex Rotate incorporates vertical shock and torsional force absorption. These two additional features engineered into the Re-Flex Rotate increase component mass by 13% to 21% compared with the Variflex and Elite Blade, respectively. The Re-Flex Rotate stood out in individual tasks compared with controls. Although control subjects completed the OC faster (31–35%; p ≤ 0.05), and completed 13/17 tasks faster (p ≤ 0.05) than TTA regardless of foot condition, controls were significantly faster than TTA when using Re-Flex Rotate for completing the culvert and angle tube obstacles (16.7% and 46.0%, respectively; p ≤ 0.05). These two tasks were not significantly different than controls when TTA used Elite Blade and Variflex feet. The culvert obstacle requires ducking to crawl through a concrete culvert (3 ft or 0.9 m diameter × 8 ft or 2.4 m length), standing up out of the first culvert, turning 180°, ducking and crawling through a second culvert (identical size). The angle tube is a plastic pipe (comparable size to the culvert obstacle) that must be crawled through after climbing upward into the pipe (3.8 ft or 1.2 m from the ground). The pipe is angled on a 4° incline so the subject exits the pipe 0.2 m higher than the start (4.7 ft or 1.4 m elevation). It is not clear how the Re-Flex Rotate may challenge function while crawling through the culverts unless perhaps the user is attempting to accept body weight through a transversely rigid foot that is rotating and thus requiring additional effort and time to control. In addition, on the culvert obstacle, the stand and turn maneuver may require added time and effort to control as does the climb into and landing from the angle tube obstacle. Nevertheless, use of the Elite Blade and Variflex did not result in significant time delays compared to controls as the Re-Flex Rotate foot condition did.

Perceptively, there were no significant differences between prosthetic feet. Variflex and Elite Blade yielded RPE (median) of 18.5/20, whereas Re-Flex Rotate yielded 18/20 immediately following OC completion. Although the Re-Flex Rotate’s median RPE was lower, it yielded the same RPE range as Variflex (15–20), whereas Elite Blade yielded the lowest
RPE range at 13 to 20. Although no foot condition emerged as a clear overall advantage in this test battery, the Elite Blade yielded multiple trends of improvement which were given confirmation by being selected by half of study subjects while blinded to condition. Interestingly, more than twice as many participants preferred the Re-Flex Rotate relative to Variflex despite trends of performance advantages favoring Variflex. Considering other potential benefits of the Re-Flex Rotate, perhaps TTA are willing to trade nonsignificant differences in performance for greater comfort with this component. This finding is consistent with evidence-based practice, which places as much emphasis on patient preference as it does empirical evidence.

LIMITATIONS
Although there were no skin-related or performance complaints to suggest suspension issues, suspension was not controlled and could be a factor related to performance. Study feet were not blinded during training and accommodation as study personnel felt it was important to train subjects on individual attributes of the feet. This could have led to some level of kinesthetic or other familiarity with the components that cued subjects to identification even while masked during testing. This could potentially be confirmed in future studies, however, the success of masking was not assessed. Also impacting results may have been the choice to acclimate subjects with study feet in a singular, extended time block as opposed to individually acclimating and then assessing with each foot. Finally, there are multiple statistical modeling approaches available to analyze these data. For instance, the OC used in this study could be viewed as a single task or as individual obstacle tasks. The primary hypothesis for this study sought to address overall performance. Thus, multistest correction was not incorporated into the analysis. Incorporation of multistest correction may have resulted in minor differences between prosthetic feet in individual obstacle outcomes, but would have been unlikely to impact overall outcomes.

CONCLUSIONS
This study has quantified performance differences between highly mobile TTAs with optimized prosthetic componentry and able-bodied controls in a never before studied field OC environment. This could assist in determining the potential for retention of already trained soldiers following TTA. Ultimately, nonamputee SWAT team members completed a military equivalent OC significantly faster and with less effort than a group of high-functioning transtibial amputees regardless of prosthetic foot condition. There were no clear differences in prosthetic feet when completing the OC; however, individual task performance, perceptive measures, and preference resulted in trends showing a slight improvement in performance with and preference for the Elite Blade, which is a dual function ESR foot combined with vertical shock absorption. Ultimately, patient preference should be regarded highly during foot selection and prescription. Understanding how to maximally improve performance in such functional tasks may allow soldiers to best sustain physical fitness, return to their military occupational specialty and possibly in-theater duty. Data from this study have identified trends in the tested prosthetic feet to assist in optimizing performance in these activities, which can reduce wasteful costs associated with the current practice of trial-and-error foot selection based on anecdotal evidence.

ACKNOWLEDGMENTS
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REFERENCES
Functional Outcomes of Service Members With Bilateral Transfemoral and Knee Disarticulation Amputations Resulting From Trauma

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Erik J. Wolf, PhD*‡; Jason M. Wilken, PT, PhD†‡

ABSTRACT As longitudinal studies for those with bilateral transfemoral amputation (BTFA) or knee disarticulation (KD) are lacking, it is important to quantify performance measures during rehabilitation in an effort to determine reasonable expectations and trends that may influence the rehabilitation process. At initial evaluation (date of first independent ambulation) and follow up (median 135 [range = 47–300] days later), 10 participants with BTFA/KD completed 6 minute walk testing and Activity Specific Balance Confidence and Lower Extremity Functional Scale questionnaires. Of these, six participants also completed stair ambulation; ascent time and stair assessment index (SAI) scores were calculated. Patients utilized their prescribed prostheses at each visit. Participants were able to cover a significantly greater distance (135.3 [70.1] m) in 6 minutes at the follow-up visit (*p = 0.005). The change in SAI scores for stair ascent and descent was not statistically significant (p = 0.247). Stair ambulation confidence scores were significantly greater at the final visit (*p = 0.034). Stair negotiation appears to plateau early; however, confidence builds despite absence of functional gains over time. Service members with BTFAs/KDs are able to achieve functional community ambulation skills. Thus, this investigation suggests that clinicians can realign rehabilitation paradigms to shift focus towards community distance ambulation once safe stair ascent and descent is achieved.

INTRODUCTION

Recent conflicts in Iraq and Afghanistan have resulted in a cohort of individuals who have survived multiple limb amputation. The total percent of troops with multiple limb injury increased steadily throughout Operation Iraqi Freedom (OIF), Operation Enduring Freedom (OEF), and Operation New Dawn (OND).1 Of those with extremity injuries, the estimated prevalence of multiple limb amputation is 30%, of which bilateral transfemoral amputation (BTFA) were most common (27%).1–3 Transfemoral-level injuries are often among the most severe and require complex surgical and rehabilitative care.4–7 Despite the increased prevalence of BTFAs compared to prior conflicts, the body of literature characterizing this injury group is minimal compared to that of persons with unilateral lower extremity limb loss.

One of first long-term follow up studies of military service members (SMs) with BTFA was published by Dougherty in 1999, and the results were encouraging in terms of their adaptability to amputation, employment, and general well-being.7 The presence of BTFA severely affects function but may not affect other quality of life metrics. Of the 30 veterans from the Vietnam War that were evaluated, 22% of respondents used prostheses for ambulation, and used them for an average of 7.7 hours per day, at mean time from injury of 27.5 years. Seventy percent were employed outside of their homes. The study group had lower physical functioning score on the Short Form-36 (SF-36) compared to a matched control group, but there was no significant difference between the groups in terms of pain, social functioning, general, emotional, and mental health.

SMs with BTFA from recent conflicts appear to have better health status, prosthesis adaptation, and mobility compared to SMs from prior conflicts. In a follow-up to their previous study, Dougherty et al (2012)8 compared outcomes between 23 individuals with BTFA injured during the Vietnam War and 10 SMs who sustained BTFA during OEF, OIF, and OND. The OEF, OIF, OND group reported better health status, more frequent prosthesis usage, a greater number of prosthetic devices used, and mobility compared to the Vietnam group. However, the two groups reported similar quality of life. The greater number of prosthetic devices used is likely an indication of both the frequency of prosthetic care provided to the younger SMs and the provision of prostheses to allow participation in multiple specific training and recreational activities.

In the same year, Paul et al9 reported on a retrospective analysis of outcomes from 25 Indian civilians with multiple limb amputation. In 12 patients with BTFA, 8 with bilateral transtibial amputation and 5 with mixed combination of the two levels of amputations, the authors found that there was no significant difference in the activities of daily living scores across groups. However, function was significantly greater for prosthesis users than nonusers, and this difference was greater for the BTFA group than other groups. The authors concluded that successful prosthetic rehabilitation appeared...
achievable independent of amputation level, although the small sample size limits the strength of their conclusion.

The largest study of war-related bilateral lower extremity amputations, published by Ebrahimzadeh et al., found that SMs with BTFA have similar well-being and functioning as individuals with other amputations. The study included 291 Iran–Iraq War (1980–1988) veterans, and the Persian version of the SF-36 questionnaire was used to assess impact of amputation on health-related quality of life. The authors devised an ordinal grouping system based on the number of major joints impaired, grouping individuals with BTFA and hip disarticulation into a single group (Group V). This group comprised 25% of the study population, and the authors did not find the Type V groups to have different SF-36 scores than other groups; it is unclear if their finding is applicable specifically to the BTFA cohort due to their grouping system.

The lack of literature on gait and function of young, otherwise healthy SMs with BTFA is notable. Furthermore, all mentioned studies compare the rehabilitation outcomes between prosthetic and nonprosthetic groups. There is no literature describing benchmarks of rehabilitation or outcomes in the prosthetic BTFA group. As the literature has established the general favorable rehabilitation outcome in BTFA group, it is of vital interest for rehabilitation specialists to understand reasonable expectations and deficits of those who had achieved prosthetic ambulation in this group. The purpose of this study was to characterize physical recovery in SMs with BTFA, using objective and self-reported measures collected at two functional evaluations within the first year of independent ambulation with prostheses.

### METHODS

Ten SMs with combat-related bilateral transfemoral and/or knee disarticulation amputations, secondary to blast injury, participated in a large cross-sectional, longitudinal study of SMs with amputation. Institutional approval was provided by the local institutional review board and written informed consent was obtained before data collection. SMs were enrolled at the time they achieved the ability to independently ambulate without using assistive devices (all participated at zero-month time point) and then at follow-up evaluation within the next year. Inclusion criteria: age 18 to 45 years old; presence of BTFA; ability to walk independently without the use of an assistive device for at least 30 feet; ability to walk continuously for a minimum of 5 minutes; and visual analog scale pain score less than 4 out of 10. Exclusion criteria: moderate or severe traumatic brain injury; cardiac or pulmonary problems that limited physical activity; and post-traumatic stress disorder or other psychological condition that would be worsened by participation in the study. As a result of blast injuries, there were numerous comorbidities that did not preclude participation. SMs sustained any combination of additional injuries including trauma to one of both upper extremities (including amputation at transhumeral and/or transradial and/or multiple digits), abdominal and groin injuries (some requiring colostomies), tympanic membrane injury, as well as mild head trauma.

SMs completed all testing with their daily-use prostheses, consisting of microprocessor-controlled or mechanical prosthetic knee units and energy storing and return feet (Table I).

Data are reported on the following tests and questionnaires: 6-Minute Walk Test (6MWT), Stair Assessment Index (SAI),

### TABLE I Demographics

<table>
<thead>
<tr>
<th>Participants</th>
<th>Age (Years)</th>
<th>Time of Initial and Follow-Up Visit (Days From Injury)</th>
<th>Knee Type at Initial and Follow-Up Visit</th>
<th>Height at Initial and Follow-Up Visit (cm)</th>
<th>Weight at Initial and Follow-Up Visit (kg)</th>
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<tr>
<td>1</td>
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<td>Cleg</td>
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<td>410</td>
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<td>4</td>
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<td>CLeg</td>
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<td>87.5</td>
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<td>672</td>
<td>Genium</td>
<td>168.5</td>
<td>88.2</td>
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<tr>
<td>Average (SD)</td>
<td>25.8 (3.4)</td>
<td>357.1 (121.7)</td>
<td>495.5 (147.9)</td>
<td>175.1 (4.4)</td>
<td>78.4 (9.2)</td>
</tr>
</tbody>
</table>
Timed Stair Ascent (TSA), Lower Extremity Functional Scale (LEFS), and Activity-Specific Balance Confidence (ABC) Scale. Scripted instructions were read to each SM for respective tasks.

The 6MWT is frequently used to assess aerobic fitness, endurance, and mobility.11,12 Age-based normative times have been established in military and civilian personnel,11,13,14 and the 6MWT is suggested as a reproducible measure of exercise tolerance.15,16 The SMs were instructed to walk as far as possible in 6 minutes and the total distance walked was recorded.

The SAI assesses functional ability while ascending or descending one flight of stairs. Scores range from 0 to 13 based on ability to perform the task, how the task is executed, and level of upper extremity support required.17 Zero signifies inability to negotiate stairs and 13 represents reciprocal gait without use of a rail or assistive device. Ascent and descent are scored independently.

For the TSA, SMs were timed while safely ascending 11 stairs. They were required to touch each stair on ascent and completed 5 trials (with 1-minute rest in between). Time began when their foot hit the first stair and stopped when both feet were on the top platform. Timed stair climbing is often used as an objective measure of mobility and power, and has established test-retest reliability in older adults.18,19 SMs were instructed to touch every step to the top of the staircase as quickly and as safely possible, turn around, and come back to the bottom. It was documented if the SMs needed to use the handrail, if needed, for safety. Every subject performed 5 trials with 1 minute of rest between trials.

The LEFS questionnaire, completed by SMs, involves a list of 20 activities that are rated on a scale from 0 (unable or difficult to perform) to 4 (able to perform without difficulty). This tool has been used in various patient populations to assess and track a person’s ability to perform everyday tasks. It is often used as a baseline measure, and throughout the course of rehabilitation, to monitor progress and set functional goals.20

The ABC Scale is a self-report instrument used to evaluate an individual’s balance confidence and fear of falling during functional activities.21 It has demonstrated reliability and validity in older adults who have sustained an amputation; however, the psychometric properties of this instrument have not been specifically examined in younger adults following a traumatic amputation.22 The ABC Scale has 16 items representing balance/functional activities, and the participant is asked to rate his/her confidence level in performing these tasks (using a scale of 0–100, with 0 = no confidence and 100 = complete confidence). The response to the following pertinent question is reported: “Do you or would you have any difficulty at all with going up or down 10 steps (about one flight of stairs)?”

Normality was determined using the Shapiro–Wilk test with a threshold value of \( p \leq 0.05 \). Between-session differences were evaluated using paired \( t \) tests for normally distributed data (participant height, participant weight, 6MWT, stair ascent time, and ABC score) whereas nonparametric data were assessed using the Wilcoxon signed-rank test. Significance was again set at \( p \leq 0.05 \). Effect sizes (Cohen’s \( d \)) were determined for performance measures.

RESULTS

The SMs had an average (SD) age of 25.5 (3.4) and time from injury of 352.4 (119.6) days at enrollment. It is important to note that the time to independent ambulation, as defined in the inclusion criteria of the study, was variable for the subject group (range = 203–580 days). The follow-up...
evaluation was completed on average 135 (47–300) days after initial evaluation. Although leg length can be readily modified for individuals with bilateral amputation, height did not significantly differ between sessions \((p = 0.386)\); all but one participant was either the same height or slightly shorter at the final visit. Weight did not change between sessions \((p = 0.452)\) with all but two SMs staying within 2.0 kg of initial weight. All SMs completed LEFS and 6MWT testing.

At the follow-up visit, all SMs were able to cover significantly more distance within 6 minutes \((p = 0.005, d = 0.76)\).

DISCUSSION

Longitudinal outcomes data are lacking for individuals who have experienced BTFA. Functional outcomes data can play a valuable role in clinical treatment planning as data can be used to objectively track recovery over time and identify factors that may influence the rehabilitation process. Many SMs with BTFA are able to return to functional community ambulation but require more time than uninjured individuals to complete gait-related tasks. Therefore, the data presented provide insight into the functional abilities of SMs with BTFA at the point of independent ambulation and progress during the first year of rehabilitation.

As a group, initially these SMs with BTFA demonstrated large deficits in the 6MWT compared to uninjured controls. However, mobility did improve over the course of rehabilitation as seen in the increase in distance traveled during the 6MWT. In fact, the average distance traveled increased from 327.8 (75.0) to 388.5 (93.8), which was much closer to the 452 (141) m previously reported for those with unilateral TFA. \(^{23}\) Remaining differences could be because our SMs were tested earlier in the rehabilitation process, relative to those with unilateral TFA who were on average 2.3 years’ postamputation. \(^{23}\) The average distance of SMs with BTFA at follow-up was still much less than the distance traveled by uninjured controls: 761 (87) m. \(^{23}\) These results provide a 6MWT milestone for those with BTFA.

Many aspects of mobility did not improve beyond the point of independent ambulation. Although subjective ABC score significantly improved, objective improvement was not observed in the SAI during ascent or decent, the LEFS, or the TSA. Ascending stairs requires greater strength and motion than level-ground walking, \(^{24}\) and not surprisingly, several SMs were unable to complete the task at initial assessment. The lack of statistically significant changes in the SAI score, the ABC score, and the LEFS score shows the difficulty of completing important functional tasks in
individuals with BTFA. Difficulty with stairs is well documented in those with lower extremity amputations. De Laat et al\textsuperscript{25} reported that in unilateral TFA and knee disarticulation group, the success rate of achieving independent stair ambulation after outpatient rehabilitation is 60% without rail and 16% without handrail. Hobara et al\textsuperscript{24} demonstrated that time from injury has a positive correlation with the SAI in unilateral TFA, but published literature relies on patient report rather than direct observation with patients that were more than 17 years postamputation. We see a trend in decreasing time required to ascend stairs in SAI, but not in the time required to descend stairs. The ABC and LEFS questions combine stair ascent and descent within the same questions, so we cannot determine if these instruments also reflect different trends between ascending and descending stairs observed in SAI. There are several possible explanations for our findings. The improvement of stair ascent time may be indicative of gains in strength, balance, coordination, and motor control sufficient to achieve the task more rapidly. Descending stairs poses greater risk of injurious falls,\textsuperscript{26} and individuals with BTFA must rely on resistance in the prosthetic knee to control the lowering from 1 step to the next. Therefore, the lack of SAI improvement during descent of stairs may be influenced by comorbidities, e.g., muscular deficits, or inherent prosthetic limitations contributing to mistrust of the prosthesis. In addition, the lack of statistically significant improvement in these assessments over time indicates that the ability to navigate stairs in individuals with BTFA may plateau early without any significant improvement overtime.

These findings have practical impact in guiding rehabilitative therapies and prosthetic design. During the first year of independent ambulation, although efforts may have been made to improve safety or quality of movement, there were no systematic improvements over time during stair ambulation. Clearly, individuals with BTFA demonstrate deficits in physical performance relative to their able-bodied counterparts.\textsuperscript{7} However, in the 6MWT, these SMs performed close to civilians with unilateral transfemoral amputations. These findings, combined with the fact that this generation of SMs report confidence in stair negotiation and are wearing and walking in their prostheses more than the previous generations of SMs,\textsuperscript{8} might suggest that clinicians should realign rehabilitation paradigms for those with BTFA. Training emphasis may be better placed on other movements required for daily living. Although stairs negotiation is limited, expectations can be increased in the area of community distance ambulation. Prosthetic development should focus on incorporating these seen restrictions into new devices. Progress remains hopeful as the prosthetic industry is incorporating new materials and advanced prosthetic technology into current designs.\textsuperscript{27,28} These advances will likely further increase expectations in terms of rapid recovery rates, quality of life measures, and ability to return to occupation and leisure activities despite high-level injuries such as BTFA.

Several limitations should be considered when interpreting the results of this study. First, there are inherent differences between the study population and the general population. Military SMs are generally in better physical condition than their civilian counterparts. In addition, the heterogeneity and complexity of injuries sustained by SMs differ from amputations incurred by civilians. Injuries sustained from improvised explosive device blasts are rarely confined to the severed extremity and result in injury of varying severity to adjacent body parts. Any comorbidities can impact the rehabilitation process, likely adding variability to study results thereby influencing the ability to detect changes over time. Also, the SMs were treated in a military treatment facility that is highly specialized in the rehabilitation of traumatic war injuries. They underwent intensive rehabilitation managed by multidisciplinary teams with years of experience in surgical management of war-related traumatic amputation and soft tissue injuries, pain management, and prosthesis prescription, fabrication, fitting, and troubleshooting. Furthermore, military treatment facilities provide a dedicated environment where SMs can focus on returning to premorbid level of function, with minimal distraction from family needs and financial pressure. These inherent differences limit the generalizability of the finding in this study into non-military population. Other limitations include the time period between initial and follow-up evaluations being variable from patient to patient. Lastly, though we detected generally favorable changes in the tested instruments, only improvements in 6MWT and ABC reached statistical significance, and we found no significant changes in the stair ambulation.

In summary, we showed that through intensive rehabilitation, the recovery of SMs with BTFA is generally favorable, with statically significant improvement in walking distance over the first year of independent ambulation, while the improvement of their stairs ambulation function remained static. These findings can be used to help set outcome expectation as well as rehabilitation guidelines.

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REFERENCES

Core Temperature in Service Members With and Without Traumatic Amputations During a Prolonged Endurance Event

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ABSTRACT

Introduction: Service members with traumatic amputations may be at an increased risk of elevated core body temperature, since their ability to dissipate heat may decrease with the reduction in body surface area (BSA) after injury. Elevated core temperature can impair physical performance during combat operations potentially putting the service members and their teams at risk. The purpose of this study was to compare core temperature between individuals with and without amputations during a prolonged endurance event. Materials and Methods: Twenty healthy male military service members (10 with amputations, 10 without) participated in the Bataan Memorial Death March 26.2-mile event on March 27, 2011. Data collected include BSA, body mass index, body composition, body weight before and after the event, core temperature during the event, and postevent hydration status. Body composition was measured by dual-energy X-ray absorptiometry. Body weight was measured by digital scale. Core temperature was measured by ingestible sensor. Hydration was measured by urine specific gravity. The Walter Reed Army Medical Center Institutional Review Board approved this study and participants provided written informed consent. Results: Three participants’ data were not included in the analyses. No significant differences in core temperature were found between participants in both groups, and no correlation was found between core temperature and either BSA or hydration status. There was no significant difference in maximal core temperature between the groups \( (p = 0.27) \) Nearly all participants (8 control, 6 amputation) reached 38.3°C, the threshold for increased risk of heat exhaustion. No subjects reached 40.0°C, the threshold for increased risk of heat stroke. Time spent above the 38.3°C threshold was not significantly different between groups, but varied widely by participant in relation to the duration of the event. Participants without amputations finished the event faster than participants with amputations \( (7.9 \pm 1.4 \text{ vs. } 9.6 \pm 0.96, p < 0.01) \), possibly indicating that participants with amputations self-selected a slower pace to attenuate increased core temperature. Conclusion: Until conclusive evidence is accumulated, it is prudent for military leaders, trainers, and military service members to closely monitor this population during physical activity to prevent heat injuries.

INTRODUCTION

Heat illness and injury continue to be a concern for the military with 2,027 documented incidences of heat stroke/injury in active duty service members in 2014.\(^1\) Elevated core temperature has harmful effects on the brain, liver, muscles, and kidneys, and can significantly impair a military service member’s physical performance.\(^2\) When service members develop heat illness and injury during combat, their team’s capabilities degrade placing all team members at risk. Determining who is more likely to suffer heat illness, and developing strategies to mitigate the risk, may increase the safety of the entire combat team.\(^3\)

From September 2001 to 2014, 1,573 military service members suffered traumatic major limb amputations as a result of combat operations.\(^4\) The proportion of U.S. service members remaining on active duty after undergoing amputations has increased from 2.3% in the 1980s to about 16.5% in 2010.\(^5\) Many of these active duty service members return to combat operations conducted in harsh environmental conditions. Anecdotal information suggests that service members with amputations report feeling hotter than before their amputation, and experience more profuse sweating during activity.

Individuals with amputations may be at higher risk for experiencing elevated core temperature during exercise than their uninjured counterparts, potentially due to increased heat production and/or decreased dissipation ability. Exercise intensity significantly impacts the amount of heat produced during exercise\(^6\) and persons with amputations have higher levels of energy expenditure when performing the same task, such as walking, as persons without amputation.\(^7\) Body surface area (BSA) plays a significant role in the body’s ability to regulate core temperature and dissipate heat.\(^2,8\) Individuals with amputations have decreased BSA and frequently their...
residual limbs are covered with a prosthesis, both of which may decrease the ability to dissipate heat. Hindrance to any thermoregulatory mechanisms may increase the risk of heat injuries.\textsuperscript{5}

To date, there is only one published pilot study comparing the core temperatures of service members with and without amputations leaving open to discussion whether service members with amputations are more susceptible to heat injuries than their counterparts without amputations.\textsuperscript{6} The primary objective of this study was to determine if individuals with amputations were more predisposed to heat illnesses than individuals without amputations by comparing core temperature during a prolonged endurance event. We hypothesized that individuals with amputations would have higher core temperatures than individuals without amputations. Secondary objectives included determining how BSA and hydration status affected core temperature in individuals with and without amputations during a prolonged exercise event. We hypothesized that decreased BSA would be directly correlated with higher core temperature while hydration status would be inversely correlated.

\textbf{METHODS}

The current study is a case–control investigation to test whether individuals with amputation are at increased risk of heat injury while performing duties typical to military service, this study was conducted during the Bataan Memorial Death March (BMDM), a 26.2-mile road march in New Mexico, on March 27, 2011. The event mimics extended marching frequently performed by many operational military forces.

Twenty participants from a convenience sample of service members planning to participate in the event volunteered for this study: 10 with amputations and 10 without amputations served as a control group. The participants with limb loss included 7 participants with a unilateral transfemoral (below the knee) limb loss, 1 participant with a unilateral transfibial (below the knee) limb loss, 1 participant with a unilateral transfemoral (above the knee) limb loss, 1 participant with unilateral transradial limb loss, and 1 participant with unilateral transhumeral limb loss. The range in time since amputation was 6.97 to 39.87 months (mean 15.10 months). All participants were recruited from teams at Walter Reed Army Medical Center, Washington, DC, and Joint Base San Antonio, Texas who were trained and had already registered for the event. Participants were contacted by the study team during training sessions for the event or by word of mouth upon referral from the medical staff. The Walter Reed Army Medical Center Institutional Review Board approved the protocol and all participants provided written, informed consent. Research team members met with participants at their respective sites before the pre-event data collection session in order to explain the study and study-related risks.

All participants were active duty or retired service members. Participants with amputations were required to have had at least 6 months of prosthesis usage before the event and a physician cleared all participants who were still undergoing medical treatment. Participants were excluded from the study if they had previous heat injuries, nontraumatic amputations, neurological, cardiovascular, pulmonary, orthopedic, or other conditions or medications that would contraindicate completion of a 26.2-mile march or swallowing an ingestible sensor.

Data collected before the event included height, weight, body composition, body mass index (BMI), and BSA. Pre-event weight was collected just before the start. During the event, core temperature was monitored using ingestible core temperature sensors. Following completion of the event, event duration was recorded and postevent weight and urine specimen were collected. All participants wore comfortable attire and shoes or boots during the event.

Body composition and background information were collected within 4 weeks of the event. Background information included age, gender, and the date and level of any amputation. Body weight was measured on a calibrated digital scale to the nearest 0.1 kg. Participants reported their height from their last preinjury physical fitness test. This is an official military measurement conducted according to precise standards.\textsuperscript{10}

BMI was calculated using standard calculations (kg/m\textsuperscript{2}). Adjusted weight was used for participants with amputations. Adjusted body weight was calculated as current body weight/\((1 − P)\), where \(P\) is the proportion of total body weight represented by the missing limb or limbs.\textsuperscript{11}

BSA was calculated using the Mosteller (1987) formula, the preferred method in clinical medicine for determining BSA:\textsuperscript{12}

\[
\text{BSA} = (H/\text{cm}) \times W/\text{kg}/3.600^{0.5}
\]

Without amputations: \(\text{BSA} \ (\text{m}^2) = (H/\text{cm}) \times W/\text{kg}/3.600^{0.5}\)

With amputations: \(\text{BSA} \ (\text{m}^2) = \text{BSA} - ([\text{BSA}] \times [% \text{BSA part}])\)

Percent (%) BSA part reflects the level of amputation of the missing limb or limbs.\textsuperscript{13} Calculated BSA for participants with amputations used adjusted weight and excluded the area covered by the prosthesis liner.

Body composition was measured by dual-energy X-ray absorptiometry (DXA Windows XP version QDR software, Hologic, Discovery-Wi, Bedford, Massachusetts). Data collected include lean mass, fat mass, and body fat percentage. Participants were scanned in minimal clothing with prostheses, jewelry, and metal objects removed.

Participants were weighed on site using a calibrated digital scale before and after the event to account for fluid loss. Participants consumed food and beverages ad libitum during the race. Urine samples were taken immediately after participants completed the BMDM to assess hydration status. Urine-specific gravity (USG) was assessed using a calibrated handheld refractometer (model HR-200 ATC, AFAB Enterprises, Eustis, Florida).

Calibrated temperature sensors (CoreTemp, HQ Inc, Palmetto, Florida) were distributed to the participants the night before the event and ingested by participants the
Core Temperature in Service Members With and Without Traumatic Amputations

Statistical Analysis

Data are presented as mean ± SD. Core temperature data were processed to provide 5-minute averages for the duration of the event. The primary outcome variables of interest were maximal core temperature, time to reach maximal core temperature, time to 38.3°C, time above 38.3°C, time to 40°C, and time above 40°C. These core temperature levels were chosen based on risk of heat exhaustion and heat stroke, respectively.17 Group temperature means and demographic data were compared using an independent t test. Levene’s test for equality of variance was used to ensure assumptions of normality were met for the two groups. Pearson’s correlations were used to assess the relationship of maximal core temperature and time above 38.3°C to event duration, hydration status (USG), BSA, and BMI. Statistical analyses were conducted using the PASW Statistics 18 (SPSS Inc, Chicago, Illinois). A priori power calculation suggested that with group sample sizes of 10 each, there was 80% power to detect a difference of 0.59°C between groups with significance level of \( p < 0.05 \).

RESULTS

All participants started the BMDM. Two participants (1 transfemoral, 1 transfemoral) with amputations did not finish the event: one due to prosthesis malfunction and a second opted to complete the 15.2-mile honorary march due to pain. Data for these participants were not included in the analysis. One control group participant’s temperature reader malfunctioned rendering the data unusable. As a result, data from 17 participants (9 control, 8 amputation) were used in the analyses. The groups were well matched in anthropometrics, with the exceptions that the control group was older (\( p = 0.029 \)) and the amputation group was taller (\( p = 0.038 \)) (Table I).

There was no significant difference in maximal core temperature between the groups (\( p = 0.27 \)) (Table II). Nearly all participants (8 control, 6 amputation) reached the threshold of 38.3°C (Fig. 1). Maximal core temperature for the amputation group ranged from 38.2 to 38.8°C. For the control group, maximal core temperature ranged from 38.1 to 39.0°C. No subjects reached 40.0°C. Time spent above the 38.3°C threshold was not significantly different between groups (Table II) but varied widely by participant in relation to the duration of the event.

The control group finished the event faster than the amputation group (\( p = 0.01 \)). There was no significant correlation between event duration and time above 38.3°C or max core temp (Fig. 1). There were no significant correlations between hydration, BSA, and BMI with either maximal core temperature or time above 38.3°C.

DISCUSSION

The primary objective of this study was to compare changes in core body temperature in individuals with and without amputations during a prolonged endurance event. Although we hypothesized that participants with amputations would have higher core temperatures than participants without amputations during the 26.2-mile BMDM, the data collected did not support this hypothesis. Specifically, all metrics were similar between the two groups, except time to completion.

When walking at similar speeds individuals with amputations may expend up to 33% more energy than individuals

### TABLE I. Participant Demographics for Participants With and Without Amputation

<table>
<thead>
<tr>
<th></th>
<th>With Amputation (( n = 8 ))</th>
<th>Without Amputation (( n = 9 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Year)</td>
<td>26.1 ± 3.6*</td>
<td>33.3 ± 7.7</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>181.9 ± 5.2*</td>
<td>176.4 ± 4.8</td>
</tr>
<tr>
<td>Weight (kg)*</td>
<td>92.3 ± 19.9</td>
<td>84.4 ± 11.2</td>
</tr>
<tr>
<td>BMI (kg/m²)*</td>
<td>27.8 ± 4.5</td>
<td>27.2 ± 4.1</td>
</tr>
<tr>
<td>BSA Adjusted*</td>
<td>4.46 ± 0.98</td>
<td>4.14 ± 0.55</td>
</tr>
<tr>
<td>Body Fat %</td>
<td>18.0 ± 8.9</td>
<td>19.6 ± 5.5</td>
</tr>
<tr>
<td>Muscle Mass (g)</td>
<td>65,996 ± 10,918</td>
<td>63,685 ± 5,629</td>
</tr>
<tr>
<td>Fat Mass (g)</td>
<td>18,978 ± 8,527</td>
<td>16,773 ± 6,667</td>
</tr>
</tbody>
</table>

Data are mean ± SD. *Significantly different than control group at \( p < 0.05 \).

### TABLE II. Event Measures for Participants With and Without Amputation

<table>
<thead>
<tr>
<th></th>
<th>With Amputation (( n = 8 ))</th>
<th>Without Amputation (( n = 9 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum Core Temp (°C)</td>
<td>38.56 ± 0.23</td>
<td>38.64 ± 0.26</td>
</tr>
<tr>
<td>Time to Maximum</td>
<td>390 ± 124</td>
<td>344 ± 143</td>
</tr>
<tr>
<td>Core Temp (Minutes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to 38.3°C (Minutes)</td>
<td>293 ± 161</td>
<td>206 ± 178</td>
</tr>
<tr>
<td>Time Above 38.3°C (Minutes)</td>
<td>101 ± 83</td>
<td>128 ± 113</td>
</tr>
<tr>
<td>USG Postevent</td>
<td>1.021 ± 0.011</td>
<td>1.022 ± 0.008</td>
</tr>
<tr>
<td>Weight Loss (End kg)</td>
<td>1.55 ± 1.12</td>
<td>1.72 ± 1.01</td>
</tr>
<tr>
<td>Weight Loss %</td>
<td>1.78 ± 1.32</td>
<td>1.87 ± 1.08</td>
</tr>
<tr>
<td>Duration of Event</td>
<td>9.6 ± 0.96*</td>
<td>7.9 ± 1.4</td>
</tr>
</tbody>
</table>

Data are mean ± SD. *Significantly different than control group at \( p = 0.01 \).
without amputations. Although participants with amputations marched at a slower pace than their counterparts, they may have been working at a similar metabolic rate due to gait differences observed in previous studies. Metabolic rate during exercise is an important determinant of core temperature, which may explain the similarities in core temperature between groups in the present study.

Similarly, heavy exercise in hyperthermal conditions at a constant workload or pace is associated with limited performance time and greater oxygen uptake. In marathons where an individual is able to self-select pace, pace was slower by 2% in elite runners and 10% in less-trained runners as the ambient temperature increased. We suspect that participants in the BMDM inherently adjusted their pace to mitigate the metabolic-related increase in core temperature, thereby affecting their time to completion.

Participants without amputations were slightly older on average than the group with amputations. However, studies conducted in hot environments have shown that age does not significantly affect thermoregulatory function.

One of the most frequently reported reasons for not wearing a prosthesis is heat and consequent sweating of the residual limb. We hypothesized that the prosthesis and liner could inhibit heat dissipation, which might cause core body temperature to rise more substantially and quickly with exercise. The variables of BSA and adjusted BSA with prosthesis liner, however, did not significantly correlate with core temperature. Seven of the 9 participants with amputations had transtibial amputations, which made comparisons between levels of amputation, and therefore BSA, more challenging.

There was no correlation between hydration status and maximum core temperature \( r = 0.09, p = 0.69 \), consistent with other research conducted in an outdoor environment. Participants in this study lost less than 2% of their body weight, which is under levels previously reported to affect core temperature and within the guidelines for hydration during exercise. Previous studies have shown that adequate fluid replacement during exercise may help attenuate the rise in core temperature. Unlike this study, however, many of those studies controlled fluid intake.

It is possible that the relatively mild temperatures during the BMDM, which ranged from 12 to 23°C, were not in the hyperthermal ranges tested in other studies that showed significant differences between conditions. The low relative humidity of 10 to 25% and average wind speed during the BMDM ranged 5 to 15 miles per hour most likely assisted in heat dissipation, as well.

The main limitation in this study is the small sample size and possibility of a type 2 error. The loss of three participants degraded the ability to detect statistical differences and required the analyses to be limited in complexity. A larger sample size would allow analyses that controlled for the effect of all of the covariates on core temperature during exercise. To provide a more complete understanding of the role of hydration and sweat rate in body temperature regulation, future studies should monitor fluid intake, food intake, and urination during the event, in addition to weight before and after. The results are promising, though, in suggesting future research related to the effect of workload or pace on core temperature.

The results of this study suggest that people with amputations may not be at higher risk for heat injury when exercising at a self-selected pace in moderate conditions. Until conclusive evidence is accumulated, however, it is prudent for trainers and military service members to closely monitor this population during physical activity to prevent heat injuries. Future research that is adequately powered is needed to fully investigate the potential differences in core temperature between service members with and without amputations during prolonged exercise. Additional research should be performed in additional conditions with greater heat stress to validate the preliminary findings of this study will ensure adequate safety protocols are developed and procedures are implemented to decrease risk of heat injury for military service members and athletes with and without lower limb amputation.

REFERENCES


A Review of Unique Considerations for Female Veterans With Amputation

COL Billie J. Randolph, SP USA (Ret.)†‡; Leif M. Nelson, DPT†; CPT M. Jason Highsmith, SP USAR†‡

ABSTRACT  This article explores unique considerations that face both women living with limb loss and their health care providers. This demographic of patient has a higher rate of artificial limb rejection, thus challenging providers to address needs for cosmesis and function that varies from those of male counterparts. Health care providers for women with amputations, such as the Veterans Affairs, must evolve health care delivery, research practices, and work jointly with industry in order to meet the needs of this population.

Of the estimated 1.6 million people living with limb loss in the United States in 2005, approximately 35% were female. Among the Americans living with amputation, 45% were of traumatic etiology and 19% of this subgroup were female. Despite these numbers, females with amputation are studied less than their male counterparts in prosthetic and amputee rehabilitation research thereby limiting evidentiary support for clinical decision-making in this demographic.

Within the U.S. Department of Veterans Affairs (VA), female Veterans represent an expanding component of the overall Veteran population. Nine percent of the overall Veteran population is female, and women make up 12% of the personnel for Operation Enduring Freedom (OEF), Operation Iraqi Freedom (OIF), and Operation New Dawn (OND). Female Veterans with amputation make up approximately 2% of the Veteran amputee population. In 2013, the Veterans Health Administration served 1,805 female Veterans with amputations including 53 who served in OEF/OIF/OND. A 2012 report from the VA Office of the Inspector General cited OEF/OIF/OND Veterans with amputations are significant users of all health care services and require comprehensive interdisciplinary care to meet their needs. Within VA, female Veterans with amputation are seen more frequently for rehabilitative and prosthetic services than their male counterparts. Providers caring for female amputees should consider that one in five female Veterans screen positive for military sexual trauma and they are 22% more likely to be diagnosed with a mental health condition compared to male Veterans. Additionally, female Veterans are twice as likely to be homeless and have a higher unemployment rate for 25- to 44-year-olds compared to female non-Veterans in the same age range in the United States. Of all women with amputation that have domiciles, 57% are likely to live alone compared to 36% of males with amputations.

Women generally require smaller prosthetic components compared to men because of their smaller bone structure and muscle mass. Commercially available prosthetic components are not gender specific and may be designed more with typical male anthropometry, biomechanics, and function in mind. Therefore, dissatisfaction with prosthetic fit and appearance tends to be higher in the female population living with limb loss. Collectively, poor cosmesis, few female-specific components, heavy prosthetic weight, combined with socket fitting challenges can lead to skin integrity concerns, pistoning, and unwanted noise. Although there is no gender difference in use of upper limb prostheses by individuals with congenital limb loss, 80% of females with acquired proximal amputations reject their prosthesis compared to 15% of males.

There seem to be no differences across gender for intensity or frequency of residual limb pain or phantom limb pain. However, females with amputations tend to report greater pain, and that pain interferes with function to a greater extent than males. This pain also interferes with activities of daily living including recreational and social activities, communication, self-care, and learning new skills.

Functional outcome is not impacted by gender in the same way it is affected by etiology, level of amputation or age as measured by the 2-minute walk test. Although all individuals living with lower limb loss are at an increased risk of comorbidities such as osteoarthritis in proximal and contralateral joints, the risk of osteoarthritis among women with amputation is elevated 15% for each kg/m². This supports the need to address weight management, lower extremity strengthening, and activity modification in this specific demographic.

Another common pathology in women is osteoporosis. Of the 44 million diagnosed with or at risk for the disease, 68% are female, and 80 to 90% of all prosthetic users have a reduction of approximately 30% bone mineral density in their residual limb.

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Contents of this article are the opinions of the authors and may not represent those of the EACE or the U.S. Department of Veterans Affairs.
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to develop strategies to decrease the risk of loss of bone mineral density.

Pregnancy is another consideration for many women with amputations of traumatic etiology that are of reproductive, childbearing age. Pregnancy-related volume change weight gain may cause abnormal wear on components (e.g., prosthetic feet) that need to be monitored more frequently. Significant fluid and volume fluctuations of the residual limb are also more common in women particularly during pregnancy, and this can affect the fit of the prosthetic socket. Additionally, weight fluctuation may necessitate a category change in selected componentry if, for instance, a component’s weight limit is exceeded during gestation. Similarly, pregnancy will alter the woman’s center of mass throughout the pregnancy, which may challenge balance, prosthetic alignment, and risk of falls for the prosthetic user. Appropriate monitoring and intervention should be applied if any of these complications arise; however, prevention of such issues is always the preferred strategy.

Transdisciplinary care teams including medical professionals that work with female Veterans with amputations should consider that enhanced levels of communication may be necessary in order to maximize satisfaction and quality of care. Women Veterans may also have a greater need for privacy and security in the clinic setting. Women Veterans with amputations will frequently have different rehabilitation goals, including a greater desire to become independent in household activities and to pursue different recreational and leisure pursuits. Women who have undergone amputation also have different psychological and adjustment issues related to their amputation. Providers caring for this group will be able to optimize health and quality of life if armed with awareness of key differences in gender as well as the latest scientific developments.

VA INITIATIVES AND STRATEGIES

The VA increasingly recognizes the growing population and unique health care needs of women Veterans, including those who have limb amputations. VA implemented the Polytrauma System of Care and the Amputation System of Care (ASoC) to provide specialized expertise in rehabilitation and amputation care. The ASoC incorporates the latest practices in medical rehabilitation, therapy services, and prosthetic technology in order to enhance the environment of care and ensure consistency in the delivery of rehabilitation services for all Veterans with amputations.

VA clinicians working with Veterans with amputations evaluate each patient individually and develop unique, patient-specific treatment plans that consider the Veteran’s gender and other individual characteristics. A transdisciplinary team including specialized physicians, prosthetists, and rehabilitation therapists utilizing a team-based approach helps to assure that each Veteran’s short- and long-term goals and health care needs are addressed. To ensure that the psychosocial and emotional needs of the female Veteran with an amputation are met, enhanced supportive services, including peer support mentoring or psychological counseling are provided. Counseling or psychological support for other mental health issues such as post-traumatic stress disorder (PTSD) or military sexual trauma are also extended as needed.

Since implementing the ASoC in 2008, VA has completed and implemented numerous initiatives related to this group:

- Convening education and training conferences focused on women’s health care needs;
- Conducting panel discussions with groups of Female Veterans with amputations;
- Hosting national conference calls including education for various groups of providers and care managers on the Veteran amputee population and specific considerations;
- Publishing scientific journal articles to educate providers on the unique needs of Female Veterans with amputations;
- Providing online educational training (FY2013) on the unique needs of female Veterans with traumatic extremity injury and amputation.

This review has provided an overview of considerations unique to the female Veteran with amputation. These factors should be taken into account if treatment strategies are to be successful and gaps in commercially available products and research are going to be appropriately identified. Logical next steps might include rigorously defining the population of women Veterans with amputation, systematically reviewing the literature regarding what is known about issues facing women Veterans with amputation, and generating associated research priorities. Still, much remains unknown and ongoing clinical and academic discourse on this topic is necessary to continue advancing the science and improving care for this deserving population.

REFERENCES


Outcomes Associated With the Intrepid Dynamic Exoskeletal Orthosis (IDEO): A Systematic Review of the Literature

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ABSTRACT
High-energy lower extremity trauma is a consequence of modern war and it is unclear if limb amputation or limb salvage enables greater recovery. To improve function in the injured extremity, a passive dynamic ankle-foot orthosis, the Intrepid Dynamic Exoskeletal Orthosis (IDEO), was introduced with specialized return to run (RTR) therapy program. Recent research suggests, these interventions may improve function and return to duty rates. This systematic literature review sought to rate available evidence and formulate empirical evidence statements (EESs), regarding outcomes associated with IDEO utilization. PubMed, CINAHL, and Google Scholar were systematically searched for pertinent articles. Articles were screened and rated. EESs were formulated based upon data and conclusions from included studies. Twelve studies were identified and rated. Subjects (n = 487, 6 females, mean age 29.4 year) were studied following limb trauma and salvage. All included studies had high external validity, whereas internal validity was mixed because of reporting issues. Moderate evidence supported development of four EESs regarding IDEO use with specialized therapy. Following high-energy lower extremity trauma and limb salvage, use of IDEO with RTR therapy can enable return to duty, return to recreation and physical activity, and decrease pain in some high-functioning patients. In higher functioning patients following limb salvage or trauma, IDEO use improved agility, power and speed, compared with no-brace or conventional bracing alternatives.

INTRODUCTION
The decision to amputate or attempt salvage of injured limbs is a subject of debate. This decision often emerges in the presence of high-energy lower extremity trauma (HELET).1,2 An increase in HELET cases has resulted from conflicts related to Operations Iraqi Freedom (OIF), Enduring Freedom (OEF), and Operation New Dawn (OND) compared to previous conflicts.3,4 This is because of improvements in body armor and battlefield trauma care, as well as changes in warfare style including enemy use of improvised explosive devices (IEDs).2,5–7 Approximately 15,000 cases of extremity injury are associated with these conflicts, with 79% of all combat injuries resulting from blast exposure.2,4,7 Further, approximately 1,600 amputations have occurred as a result of injuries sustained in these conflicts.3

Both limb amputation and salvage result in neuromusculoskeletal deficit, which can lead to pain and loss of strength, power generation, range of motion, and sensation. These impairments can impact function and quality of life. Outcomes following amputation have been compared to those following limb salvage.8 A definitive advantage to either has not been identified.9–12 Common goals of many injured service personnel include returning to an active lifestyle and possibly to active duty.1 The high incidence of HELET and high functional expectations following rehabilitation has pressed the U.S. Departments of Defense (DoD) and Veteran’s Affairs (VA) to create innovative adaptive devices and rehabilitation interventions.

One such device is the Intrepid Dynamic Exoskeletal Orthosis (IDEO). This energy storing and return—ankle-foot orthosis was first reported in 2009.13 The IDEO was designed to address impairments created by HELET, such as diminished plantarflexion and propulsive force, decreased weight acceptance, and compromised joint stabilization.1,13,14 Additionally, an integrated rehabilitation program Return to Run (RTR) in concert with prescription of an IDEO has shown promise in enabling military personnel to return to duty (RTD) and reintegrate into an active lifestyles following injury.1,15 This orthosis also shows potential in managing other military- and combat-related conditions such as primary and traumatic arthritis.16 Several studies have demonstrated efficacy in military service personnel after accommodation and use of the IDEO following HELET.17 Therefore, the purpose of this systematic literature review was to rate the level of evidence and formulate empirical evidence statements (EESs) regarding outcomes associated with IDEO utilization.
PICO QUESTION
The PICO\textsuperscript{18} (population, intervention, comparison, outcome) question guiding the search for evidence for this review was: In patients exposed to high-energy lower extremity trauma and limb salvage (P), what functional outcomes can be expected (O), following use of the IDEO (I) compared to alternatives such as conventional orthoses or amputation (C).

METHODS
Search Strategy
A search strategy used in several previous prosthetic and amputee systematic reviews was implemented.\textsuperscript{19,20} The Medline and CINAHL databases were searched via the Ovid and EBSCO Host interfaces (respectively). Google Scholar was also searched. Searches were conducted on July 1, 2015, and were based on the following terms:

— Primary search terms: “ankle-foot orthosis, IDEO or Intrepid Dynamic Exoskeletal Orthosis, military, and limb salvage” (searched independently and in combination with 1 of the secondary search terms).

— Secondary search terms: “AFO, ankle brace, ground reaction, energy storing and return, running orthosis, patella tendon bearing orthosis, posterior strut orthosis, orthoses, orthotic, return to duty, return to run, lower extremity trauma, high activity, veteran, high energy lower extremity trauma, HELET, post-traumatic, lower limb impairment, integrated orthotic, integrated rehabilitation, integrated orthotic and rehabilitation, carbon fiber, limb reconstruction, and trauma.”

Searches were prelimitted using the following criteria: English language, abstract available, and peer reviewed (CINAHL and Google Scholar). In Medline, the “map term to subject heading” feature was deselected to eliminate a medical subject heading (MeSH) term search. In CINAHL, a default Boolean search was used. A publication date of 2003–2015 was chosen in all databases as the beginning of OIF was in 2003. A manual search of included articles’ reference lists was also conducted in the event of very recent publications or keywords missed important publications in the automated search.

Screening
Resulting references were exported to EndNote (vX7, Thompson, California) bibliographic citation software. Two reviewers independently screened resulting references’ titles, then abstracts, and finally, full-text articles according to inclusion/exclusion criteria (listed below). Articles were then classified as either (i) pertinent, (ii) not pertinent, or (iii) uncertain pertinence. Full-text articles were then reviewed for all manuscripts classified as pertinent or uncertain pertinence. Disagreements regarding citations of uncertain pertinence were resolved by having the 2 reviewers independently review full-text articles then discussing and agreeing on ultimate inclusion or exclusion.

Inclusion Criteria
(1) Peer-reviewed publication;
(2) Study used objective/quantifiable outcome measures;
(3) IDEO was utilized as an intervention.

Exclusion Criteria
(1) Endoprosthetic ankle joints (i.e., joint arthroplasty);
(2) Editorial, classification or taxonomy articles; and
(3) Duplicate publication.

Study Data
Data from each article including demographic, anthropometric, dependent and independent variables, quantifiable outcomes, and conclusions were entered into an Excel database (Microsoft Corporation, Redmond, Washington). These data were verified by a multidisciplinary team (i.e., physical therapists, orthotists, epidemiologists, and biomechanists) for completeness and accuracy. Data were assessed for the ability to aggregate for descriptive characteristics (i.e., anthropometrics) as well as outcomes (i.e., RTD rate, number of delayed amputations). Effect sizes (Cohen’s $d$), were calculated for all articles with available data using formulas based on independent $t$ tests.\textsuperscript{21} Controversy exists in the use of this technique compared with a calculation enabling control for data dependency. Effect sizes are commonly larger when data dependency is considered. However, limitations include requiring more information from source studies (i.e., correlation and coefficient between the data under examination).\textsuperscript{21} Because the articles reviewed provided limited information, the calculation based on independent groups was selected recognizing that this is a conservative approach. Cohen described effect sizes as small (0.2), medium (0.5), and large (0.8).\textsuperscript{21}

Quality Assessment
The study design and methodological quality of those publications that met eligibility criteria were independently assessed by 2 reviewers according to the American Academy of Orthotists and Prosthetists (AAOP) State-of-the-Science Evidence Report Guideline Protocol.\textsuperscript{22} Reviewers discussed pertinent issues until consensus on study design and methodological quality was obtained for the included publications. Each reviewer rated each study according to the AAOP Study Design Classification Scale that describes the type of study design.\textsuperscript{22} The State of the Science Conference (SSC) Quality Assessment Form\textsuperscript{22} was used to rate methodological quality of studies classified as experimental (E1–E5) or observational (O1–O6). The form identifies 18 potential threats to internal validity with the first 4 (E3–E5) or 5 (O1–O6) criteria not applicable for given study classifications and 8 potential threats to external validity. Threats were evaluated and tabulated.
The internal and external validity of each study was then subjectively rated as “high,” “moderate,” or “low” based on the quantity and importance of threats present. As a guide, for internal validity, 0 to 3 threats was rated “high,” 4 to 6 threats as “moderate,” and 7 to 13 threats as “low.” For external validity, 0 to 2 threats was rated “high,” 3 to 5 threats as “moderate,” and 6 to 8 threats as “low.” Each study was given an overall quality of evidence of “high,” “moderate,” and “low” outlined by the AAOP State-of-the-Science Evidence Report Guidelines. The overall ratings from the AAOP State-of-the-Science Evidence Report Guidelines were used in assigning confidence to the developed EESs described in the results section.

Empirical Evidence Statements

Based on results from the included publications, EESs were developed describing efficacy of the IDEO. Reviewers rated the level of confidence of each EES as “high,” “moderate,” “low,” or “insufficient,” based on the number of publications contributing to the statement, the methodological quality of those studies and whether the contributing findings were confirmatory or conflicting.

RESULTS

In total, 375 articles were identified from the search (Fig. 1). Of these, 12 met inclusion criteria. Publication dates of the 12 included articles ranged from 2011 to 2015 with 6 published in 2014. Half of the studies were observational and the other half was experimental (Table I). No systematic reviews or meta-analyses were identified. Because of heterogeneity in sample size and demography, methods, accommodation periods, outcome measures and design, and meta-analyses were not possible. Manuscripts were published predominantly in orthopedic trauma and biomechanical journals (Table II).

Subjects

A total of 487 subjects were studied within all 12 manuscripts (Table III). Only six females were reportedly studied. One subgroup of amputees (n = 57) were included. Uninjured, healthy subjects were recruited as controls in two studies to provide reference values of unimpaired gait function in which to compare against. This accounted for 25 subjects wherein both articles, reference groups’ mean age was 23 years, mean height was 1.8 m, and the mean mass was 86 kg and 87 kg respectively. Conversely, control subjects (n = 81), utilized in two other studies had experienced HELET including volumetric muscle loss below the knee, distal motor nerve injury, lower limb fracture, and other injuries. Of these 81 control subjects, 31 had a mean age of 30 years and received IDEO only as opposed to IDEO and RTR training. The remaining 50 of these subjects received limb salvage and there were no reports of IDEO provision nor anthropometry.

Of the total 487 subjects from all included studies, another subgroup of 102 participants served as their own controls in

<table>
<thead>
<tr>
<th>TABLE I. Distribution of Included by Studies by Study Design</th>
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<tbody>
<tr>
<td>Study Design</td>
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<tr>
<td>---------------</td>
</tr>
<tr>
<td>S1 Meta-Analysis</td>
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<tr>
<td>S2 Systematic Review</td>
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<tr>
<td>E1 Randomized Control Trial</td>
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<tr>
<td>E2 Controlled Trial</td>
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<tr>
<td>E3 Interrupted Time Series Trial</td>
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<tr>
<td>E4 Single Subject Trial</td>
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<tr>
<td>E5 Controlled Before and After Trial</td>
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<tr>
<td>O1 Cohort Study</td>
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<tr>
<td>O2 Case–Control Study</td>
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<tr>
<td>O3 Cross-Sectional Study</td>
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<tr>
<td>O4 Qualitative Study</td>
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<tr>
<td>O5 Case Series</td>
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<tr>
<td>O6 Case Study</td>
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<tr>
<td>X1 Group Consensus</td>
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<tr>
<td>X1 Expert Opinion</td>
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<tr>
<td>Total</td>
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</tbody>
</table>

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<th>TABLE II. Distribution of the Studies per Journal</th>
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<tbody>
<tr>
<td>Journal</td>
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<tr>
<td>-----------</td>
</tr>
<tr>
<td>Clinical Biomechanics</td>
</tr>
<tr>
<td>Clinical Orthopaedics and Related Research</td>
</tr>
<tr>
<td>Gait and Posture</td>
</tr>
<tr>
<td>Journal of Biomechanical Engineering</td>
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<tr>
<td>Journal of Bone and Joint Surgery</td>
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<tr>
<td>Journal of Orthopaedic Trauma</td>
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<tr>
<td>Journal of Surgical Orthopaedic Advances</td>
</tr>
<tr>
<td>Journal of the American Academy of Orthopaedic Surgeons</td>
</tr>
<tr>
<td>Journal of Trauma and Acute Care Surgery</td>
</tr>
<tr>
<td>Journal of Trauma, Injury, Infection and Critical Care</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>
repeated measure design protocols. They first completed preorthotic physical therapy. One group ($n = 84$) underwent baseline assessment then received IDEO plus additional therapy followed by post-assessment. 14 This group included 5 females and was described in the manuscript better from an injury perspective than from a demographic perspective. The remaining 18 randomized for repeated assessment with three different orthoses including IDEO.26

Finally, a total of 253 of the 487 subjects were studied as experimental subjects. Eleven of the 12 studies reported age, and five 24–28 reported subject height and mass or body mass index (BMI). Interquartile mean (range) for studies reporting anthropometric data yields an age of 29.4 (1.7) years, height of 1.8(0.02) m, and mass of 87.8(1.9) kg. Mean BMI was 28.5 kg/m² reportedly. 23 Diagnoses for subjects in the experimental groups of studies included; open ankle fracture, knee, or ankle ligamentous damage or instability; bone, muscle, or other tissue loss; post-traumatic osteoarthritis; fractures of the spine and upper extremity; burns; hip subluxation; lower extremity motor nerve injury; ankle muscle weakness; neuropathy; paresis; equinovarus; shrapnel presence; vascular injury; ankle arthrodesis; reconstruction of the foot or ankle and soft tissue trauma. Additionally, subjects with spinal cord injury were provided IDEOs and physically assessed. 14,15 The mechanism of injury for these diagnoses tended to include HELET and more specifically causes such as motor vehicle accidents, blast injuries, gunshot wounds, and falls.

Delayed Amputation and RTD

Seventy three patients initially requested amputation. Of these, 13 continued to request or received an amputation following provision of an IDEO and RTR training. Among these, there were no reports of RTD. 14,16,17,26 Conversely, one study 23 reported that of 57 patients who received amputation, 7 (12.3%) RTD. Of 325 patients that received limb salvage, 108(33.2%) returned to duty. Within these 325 cases, one subset of 275 (84.6%) received an IDEO and a second subset of 244 (75.1%) reportedly received an IDEO in combination with RTR therapy. From the first subset, 96 (34.9%) returned to active duty, whereas 92 (37.7%) from the second subset returned to active duty. 1,13,15–17,23

Internal Validity

The most prevalent threats to internal validity in this body of literature include a lack of blinding, a lack of reporting exclusion criteria, no reported consideration for fatigue and learning, and no reporting of effect size (Table IV). The overall assessment was blended with 5/12 of the studies being rated as having low internal validity, 5/10 having moderate-level internal validity, and 2/10 having high internal validity. Additionally, two studies had attrition greater than 20% (22–38%). 14,15

External Validity

All 12 studies had high external validity. The most common threat to external validity across studies was a lack of describing the sample adequately. For instance, 7 of 12 studies did not adequately describe the sample in terms of anthropometry and demographics.

Effect Size

Effect sizes were unable to be calculated in several of the included studies. Five studies utilized either case report methodology or descriptive outcomes, which are not conducive to these calculations. 1,13,15–17 Additionally, Harper et al

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TABLE III. Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>Study Design</th>
<th>Independent Variable(s)</th>
<th>Sample Size</th>
<th>Mean Age</th>
<th>Outcome Measures</th>
<th>Overall Quality of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patzkowski et al (2011)</td>
<td>O6</td>
<td>IDEO + RTR</td>
<td>1</td>
<td>29</td>
<td>Return to Recreation and Duty</td>
<td>Moderate</td>
</tr>
<tr>
<td>Owens et al (2011)</td>
<td>O4</td>
<td>IDEO + RTR</td>
<td>10</td>
<td>28.8</td>
<td>Return to Recreation and Duty</td>
<td>Moderate</td>
</tr>
<tr>
<td>Patzkowski et al (2012)</td>
<td>O3</td>
<td>IDEO + RTR</td>
<td>17</td>
<td>31.4</td>
<td>RTD + Clinical Endpoints</td>
<td>Moderate</td>
</tr>
<tr>
<td>Patzkowski et al (2012)</td>
<td>E1</td>
<td>IDEO + RTR vs. Other Orthoses</td>
<td>18</td>
<td>31</td>
<td>Clinical Functional Performance</td>
<td>Moderate</td>
</tr>
<tr>
<td>Blair et al (2014)</td>
<td>O1</td>
<td>IDEO + RTR</td>
<td>146</td>
<td>31.5</td>
<td>Return to Duty</td>
<td>Moderate</td>
</tr>
<tr>
<td>Bedigrew et al (2014)</td>
<td>E2</td>
<td>IDEO + RTR. Early vs. Late Rehab Entry</td>
<td>84</td>
<td>NR †</td>
<td>Functional Performance Outcomes and Perceptive Measures</td>
<td>Moderate</td>
</tr>
<tr>
<td>Esposito et al (2014)</td>
<td>E3</td>
<td>IDEO Strut Stiffness</td>
<td>26</td>
<td>29.4</td>
<td>LE Biomechanical Analyses</td>
<td>Moderate</td>
</tr>
<tr>
<td>Shean et al (2014)</td>
<td>O1</td>
<td>Hindfoot Reconstruction (w/IDEO + RTR) vs. Amputation</td>
<td>122</td>
<td>26</td>
<td>Return to Function, Recreation and Duty</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

IDEO, (Intrepid Dynamic Exoskeletal Orthosis; LE, Lower Extremity; NR, Not Reported; RTR, Return to Run. *Experimental subjects and age in years. †Eligibility was aged >18 year.
chose a graphic representation of spatiotemporal and biomechanical differences between carbon fiber and nominal stiffness IDEO braces.\(^28\) This is an acceptable method for presenting measures of central tendency and variance and even preferred at times to depict continuous phenomena. However, this form of data presentation is also not conducive to the calculation of magnitude of effect.

Bedigrew et al compared differences in physical performance and perceptual measures at 3 assessment points; immediately postinjury, post physical therapy before bracing and again following bracing with additional physical therapy.\(^14\) This group reported effect size (calculated as a difference in means) in all study measures. Effect sizes for differences in physical performance measures immediately postinjury compared to post bracing and therapy were considerable, ranging from 24 to 166% improvements. Effect sizes for pain scores were generally improved (i.e., reduced pain) following bracing and therapy by a magnitude of 23 to 35%. Patients entering into rehabilitation late experienced reduced magnitude of effect to 16 to 45% for physical performance and 27 to 38% for perceptual measures. Although these outcomes were of a relatively reduced effect compared to their early-entry peers, these were still statistically significant (\(p \leq 0.05\)) as well as clinically important.

In total, 82 comparisons were eligible for effect size analysis per this review’s protocol. Of these, 64 involved use of an IDEO. More specifically, IDEO was compared relative to either a comparator (or no brace) or IDEO configuration (i.e., strut stiffness) was modified and compared. Within the subset of IDEO involved comparisons, 37.5% were of a large magnitude of effect, 25% were of medium magnitude, and the remaining 37.5% were of a small effect size.

For instance, Haight et al studied differences in IDEO strut stiffness between sound and involved limbs and to unimpaired control limbs.\(^24\) Effect size (Cohen’s \(d\)) was 0.03 (small) regarding peak knee extension moment between control and experimental subjects’ involved limb while using a compressive IDEO brace. Oppositely, effect size was 5.9 (large) when comparing the differences in ankle range of motion between sound and involved sides when a stiff IDEO brace was utilized.

Esposito et al identified 5 statistically significant kinematic comparisons.\(^25\) Of these, comparisons between compliant and more rigid IDEO strut designs were larger than those comparing nominal with stiff strut designs. Specifically, 3/3 kinematic comparisons were of medium effect size when comparing compliant with nominal and stiff IDEO struts, whereas 2/2 significant comparisons between nominal and stiff strut designs resulted in small effects.

During functional performance tasks, IDEO use resulted in large effects in self-selected walking velocity regardless of comparator and again had large effects on speed over uneven terrain and the 40-yd dash compared to a Blue Rocker orthosis (Allard USA, Rockaway, New Jersey). Medium effects were observed during stair climbing and in the four-square step test when IDEO was used in comparison with the Blue Rocker and a no brace condition.\(^26\) When non-IDEO braces or no brace was used all significant comparisons were of a small magnitude of effect. Conversely, when IDEO was used during these tasks, 25% of significant comparisons were of a medium or large magnitude of effect.

### Empirical Evidence Statements

The following four evidence statements were formulated and supported by moderate-level evidence:

1. In service personnel under 40 years of age, injured with high-energy lower extremity trauma, potentially confounded by post-traumatic ankle osteoarthritis, fitting, and use of IDEO with RTR physical therapy following limb salvage surgery may allow return to active duty for a limited population of high-functioning patients.\(^{1,13,15–17,23}\)

2. In service personnel under 40 years of age, injured with high-energy lower extremity trauma, potentially confounded by post-traumatic ankle osteoarthritis,
Outcomes Associated With the Intrepid Dynamic Exoskeletal Orthosis

fitting, and use of IDEO with RTR physical therapy following limb salvage surgery may allow return to exercise, recreation and physical activity, and decreased pain for a limited population of high-functioning patients.1,13,14,16,17,26

(3) In service personnel under 40 years of age, injured with high-energy lower extremity trauma, fitting, and use of IDEO with RTR physical therapy following limb salvage surgery, results in improved agility, power, and speed, compared with no-brace or conventional bracing alternatives.26

(4) IDEO strut stiffness should be considered with respect to patient preference.24,27–29

Evidence statements 1 and 2 are each supported by six moderate-quality studies. Evidence statement 3 is supported by a single moderate-quality study and statement 4 is supported by two high-quality studies and two moderate-quality studies. These combinations of evidentiary support provide a “moderate” level of confidence for each of the four EESs.

DISCUSSION

With regard to study design, half of included studies were observational and half experimental. Although this is a reasonable blend of study designs, an optimal body of literature would enable meta-analysis from more prospective, randomized control trials. Internal validity could have been strengthened in these studies with minor reporting changes in accordance with standardized criteria.30,31 For instance, had the included samples been better described (i.e., more uniform reporting of anthropometry and demography), effect sizes been reported and learning/accommodation and fatigue reported, more of the studies would have likely improved their internal validity ratings from “low” to “moderate” or “moderate” to “high.” Conversely, external validity was uniformly high which provides confidence that results have clinical importance but may be biased from a methodologic perspective (i.e., internal validity). Selection and reporting bias could contribute to favorable results in the included articles. Epidemiologic studies including larger samples could clarify the potential for larger generalizability to clinical practice.

Another strength of the included studies is that a blend of outcome measures supports the evidence statements and conclusions from these studies. Perceptive, functional performance, biomechanical, RTD, and delayed amputation outcomes have been studied. Although this is a strength and provides the ability to determine how the IDEO and RTR program may effect patients like those studied, it is unlikely that some of the outcomes selected would be valuable to others who may be able to utilize these interventions. For instance, older Veterans and civilians will not have comparable endpoints such as RTD. Many others such as biomechanical, functional, and perceptive measures will likely translate across populations. The fact that the majority of the effect sizes were medium and large when IDEO and RTR therapy were provided suggests that the outcome measures selected were responsive to change and that these interventions had clinical significance in the studied populations.

As anticipated, all of the subjects studied were young (≤30-year mean) in accordance with a military population. With the exception of subjects diagnosed with post-traumatic osteoarthritis,16 the majority were recently injured with acute HELET. A small number of female patients and some with spinal cord injury were included. However, there was insufficient representation to determine efficacy of IDEO and RTR in either of the latter groups. Further, the performance results described herein are largely attributed to IDEO and RTR (independent variables). However, it must be considered that a factor contributing to the effects observed include the prior fitness level and age of the subjects. It could be that the magnitude of effect would not be as large in patients who are older, have increased BMI and have lower levels of fitness. Moreover, the confounding effects of post-traumatic stress disorder (PTSD) and traumatic brain injury (TBI) as it relates to prescription, utilization, and efficacy of IDEO and RTR remain unknown. As patients such as those studied begin to separate from military service and enroll for benefits with the Veterans Health Administration, it is unclear the extent to which these results will generalize to a larger Veteran population.

Approximately 3% of studied subjects requested or received an amputation despite provision of IDEO and RTR. None of this group returned to duty and the factors preventing their potential return were not reported.14,16,17,26 Oppositely, approximately 12% of patients who went directly to amputation, did RTD.23 It is unclear what differentiated the clinical decisions that lead each group to their respective endpoints. However, it is important to understand through future study, why limb salvage coupled with IDEO and RTR were not as successful in these cases. This further emphasizes the value of individual evaluations at the present time to determine the best clinical path for the individual patient. Approximately 33% of patients who received limb salvage, returned to duty. From these, approximately 80% received IDEO and RTR and approximately a third, returned to active duty.1,13,15–17,23 A significant barrier in understanding this patient demographic and the associated clinical pathways they will follow, is the lack of an agreed upon definition for “limb-salvage” cases. Having such a definition would clarify which injuries are determined to be “salvageable” and what are the associated functional prognoses.

Major findings of this review include the EESs supported by moderate evidence suggesting that following HELET it is reasonable for a limited, homogeneous population within the military community, to be able to RTD.1,13,15–17,23 Given the high costs and time associated with training for military service, this has obvious financial implications. Further, positive outcomes associated with post-traumatic interventions
such as IDEO and RTR may provide assurance with a decision to serve as opposed to a scenario where functional prognoses following HELET are only poor. Although the clinical endpoint of RTD is not applicable within the Veteran and civilian communities, return to high levels of function and recreation are.1,13,15–17,23 Accidents resulting in lower limb trauma are prevalent outside of the military community accounting for nearly 250,000 hospitalizations per year in the private sector.32 Therefore, adoption of IDEO and RTR interventions may likely have high clinical translation into the Veteran and private sectors. Under ideal circumstances, moderate evidence supports a return to high levels of function and recreation and decreased pain in accordance with these interventions.

Another salient finding is that IDEO outperformed the Blue Rocker and Posterior Leaf Spring designs in functional tasks requiring multidirectional stepping, walking, and running on flat and uneven ground and stair climbing. Performance was also greater with IDEO than with a no brace condition. Confidence in this statement is also supported by moderate-level evidence. It is helpful to have comparative outcomes assessments to assist with clinical prescription of a device to maximize function with consideration for a certain patient demographic. Unfortunately, this body of literature only had a single comparative efficacy study.26

With regard to perceptive measures, moderate-level evidence also supports that IDEO strut stiffness was more of a factor with regard to patient preference than for gait quality.24,25,27,28 Finally, pain is a concomitant issue following limb trauma. Use of IDEO was associated with decreased levels of pain.14 Moderate-level evidence supports both of these effects associated with use of the IDEO. Included literature did not contain reports of safety incidents (i.e., breakage) or adverse events in association with use of the IDEO or RTR therapy and the only contraindication reported related to IDEO use was a knee range of motion of less than 90°.13 The specific design elements of the IDEO that led to the reported outcomes were not clearly delineated. Therefore, it is unclear if design and construction differences will yield the same results. For instance, two specific IDEO designs are described: a modular rehabilitation device and a definitive device.13 However, performance differences between these are not reported.

**LIMITATIONS**

This body of literature only included two studies with high methodologic quality and one comparative efficacy study of multiple interventions. Additionally, the subjects studied were homogeneous. Therefore, generalizability beyond young, traumatically injured males is questionable. Methodologic quality could also be improved with standardized reporting.30,31 Examples include more thorough sample descriptions and effect sizes. Additionally, incorporating blinding (i.e. raters, statisticians) would also improve internal validity.

**CONCLUSIONS**

The IDEO was introduced to increase function and return to duty rates following lower extremity trauma and limb salvage. A return to run clinical rehabilitation pathway routinely accompanied the device. Twelve studies provide moderate evidence to support four empirical evidence statements. Briefly, following lower extremity trauma and limb salvage, use of IDEO with RTR therapy can enable return to duty, return to recreation and physical activity and decrease pain in some high functioning patients. Further, in higher functioning patients, the IDEO improved agility, power and speed, compared with no-brace or conventional non-custom bracing alternatives.

**REFERENCES**

Descriptive Characteristics and Amputation Rates With Use of Intrepid Dynamic Exoskeleton Orthosis

LTC Owen Hill, SP USA†‡; Lakmini Bulathsinhala, MPH†‡; Susan L. Eskridge, PT, PhD†‡; Kimberly Quinn, MSN, RN-BC†‡; MAJ Daniel J. Stinner, MC USA†

ABSTRACT Advancements in ankle-foot orthotic devices, such as the Intrepid Dynamic Exoskeletal Orthosis (IDEO), are designed to improve function and reduce pain of the injured lower extremity. There is a paucity of research detailing the demographics, injury patterns and amputation outcomes of patients who have been prescribed an IDEO. The purpose of this study was to describe the demographics, presenting diagnosis and patterns of amputation in patients prescribed an IDEO at the Center for the Intrepid (CFI). The study population was comprised of 624 service members who were treated at the CFI and prescribed an IDEO between 2009 and 2014. Data were extracted from the Expeditionary Medical Encounter Database, Defense Manpower Data Center, Military Health System Data Repository, and CFI patient records for demographic and injury information as well as an amputation outcome. The most common injury category that received an IDEO prescription was injuries at or surrounding the ankle joint (25.0%), followed by tibia injuries (17.5%) and nerve injuries below the knee (16.4%). Over 80% of the sample avoided amputation within a one year time period using this treatment modality. Future studies should longitudinally track IDEO users for a longer term to determine the long term viability of the device.

INTRODUCTION Improvement in U.S. military combat casualty care, coupled with advances in surgical techniques and improved body armor, has led to an increase in battlefield injury survival.¹ The “wounded-to-killed ratio,” which compares the number of wounded in action to the number who perished, currently stands at 7.4:1 for Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF).² Service members injured in these current conflicts have a survival rate that is higher than those injured in previous conflicts.³ This increase in survival has led to a substantial increase in the number of service members who now struggle with long-term disability. In addition to battle injuries, service members experience nonbattle injuries because of training activities, physical fitness training, as well as off-duty accidents which can result in long-term disability.⁴

Severe lower extremity injuries (LEI) make up the preponderance of combat-related injuries seen in service members injured within the OIF and OEF theatre of operations.⁵,⁶ Data gleaned from the Joint Theatre Trauma Registry showed that severe LEI make up 65% of all injuries in both OIF and OEF theatre and 26% of these injuries involve a fracture, with over two thirds complicated by concomitant open wounds.¹ Not surprisingly, given the severity of many of these injuries, 10 to 15% of combat-related amputations occur after attempts at limb reconstruction and are considered late amputations, defined as occurring more than 90 days following the injury.¹,⁷ In a review of severe open tibia fractures (G&A type III) sustained in combat, 16.9% underwent early amputation whereas 5.2% underwent late amputation.⁸ Those that went on to late amputation were more likely to require free or rotational flaps, had higher rates of deep soft tissue infection or osteomyelitis, and underwent more reoperations, all of which highlight the severity of these injuries and complicated post-limb reconstruction clinical course.⁹

Noncombat injuries can also result in severe and complex extremity injuries. When considering the impact of noncombat injuries, Hauret et al¹⁰ reported that in 2009, injuries of the lower extremity made up 35% of all noncombat injury problems among military personnel; the most of any anatomical region. These overuse injuries were found to have a huge impact on mission readiness and deployment eligibility. The insulation of LEI and resulting disabled service members (from both battle and nonbattle environments) have brought attention to the need for improving the rehabilitative care in the Department of Defense.

The Center for the Intrepid (CFI), along with two other Department of Defense Advanced Rehabilitation Centers, strives to recuperate injured Soldiers back to duty or civilian life. An
advanced ankle-foot orthotic (AFO) device, the Intrepid Dynamic Exoskeletal Orthosis (IDEO), was developed at the CFI. The IDEO offers an alternative treatment modality to conventional AFOs and increases function of the injured limb allowing patients to achieve relatively high levels of mobility while simultaneously reducing pain levels.\(^{10}\) When compared to traditional, commercially available AFOs to include the posterior leaf spring and Blue Rocker (Allard, Rockaway, New Jersey), patients performed significantly better in all validated physical performances measures when using the IDEO. The IDEO has been shown to improve the functional capabilities of the LEI population when accompanied with a comprehensive return to run (RTR) clinical pathway.\(^{11}\) For instance, a cohort of patients prescribed an IDEO were found to have improved outcomes in the domains of running, cycling, and self-reported decreased amounts of pain.\(^{10,11}\) The combination of the IDEO and RTR pathway has been shown to change a patient’s decision to amputate and instead continue with their salvaged limb using the IDEO.\(^{12}\)

Although the benefits of the IDEO device have been characterized in the fields of biomechanics and recreational activity\(^{11,12}\), there is a paucity of research detailing the descriptive characteristics and injury patterns of the patients who have been prescribed an IDEO. Moreover, little information exists quantifying the percentage of patients that have undergone amputation after being prescribed an IDEO and completing the RTR program. Therefore, the purpose of this descriptive epidemiologic study was to comprehensively detail demographic and occupational characteristics of those who use an IDEO, categorize the presenting injury, and quantify the proportion of patients who underwent amputation after IDEO prescription. The overarching study aims were to: (1) comprehensively describe the demographic and service characteristics of the CFI patient population who used an IDEO and (2) identify IDEO prescription patterns and rates of amputation. This research was the first step in creating an injury profile of patients who will benefit most from an IDEO and the subsequent rehabilitation. Creating such an injury profile will provide clinicians information on which patients can benefit the most from the IDEO and the RTR training program.

**MATERIALS AND METHODS**

The population under study included all injured service members who were treated at the CFI during the period 2009–2014. Data were extracted from the Expeditionary Medical Encounter Database (EMED), Defense Manpower Data Center (DMDC), Military Health System Data Repository (MDR), and the CFI patient records. An analytic dataset was constructed with variables representing the most current status on demographic and military characteristics. Injured service members who were prescribed an IDEO at the CFI were identified and corresponding administrative and medical records were merged to form the final analytical dataset. The demographic descriptions were: sex (M/F), age (<20, 20–25, 26–30, and >30 years), race (White, Black, Asian, American Indian/Alaskan Native, Hawaiian/Other Pacific Islander, and Other), and marital status (married, divorced/single/separated). Military characteristics were: service (Army, Marines, Air Force, and Navy/Coast Guard/NOAA) and length of service (1–5, 6–10, 11–20, and 20+ years).

Data elements such as initial referral diagnosis and date of first visit were collected at CFI from February 2009 to November 2014 for all patients who were referred for an IDEO. Initial referral diagnosis was the primary diagnosis that was the cause of the IDEO referral to the CFI. Because of the absence of a systematic method to record the referral diagnoses, this information was collected in a disparate manner. To categorize these data, subject-matter experts (a fellowship-trained orthopedic trauma surgeon and a senior rehabilitative clinician) assigned the primary referral diagnoses into seven injury types: (1) nerve injury below knee; (2) tibia (excluding pilon fracture); (3) ankle (pilon fracture, ankle post-traumatic osteoarthritis [PTOA], and ankle fusion); (4) hindfoot (hindfoot PTOA, fusion); (5) midfoot/forefoot; (6) soft tissue (compartment syndrome, Achilles tendon injury, and quadriceps injuries); and (7) other. For data quality assurance, a random 10% of referral diagnoses were compared with the electronic military medical record system by a qualified clinician.

An amputation of the lower extremity was identified if one of the diagnosis codes (see Appendix A) or procedure codes (see Appendix B) was found after at least 22 days from the date of initial evaluation. Procedure codes for fitting a prosthesis were taken into consideration only when found in consortium with an ICD-9 (International Classification of Diseases, 9th Edition) code.

**TABLE I.** Demographic Characteristics and Amputation Status of Service Members Prescribed IDEO (\(N = 624\), 2009–2014)

<table>
<thead>
<tr>
<th>Demographic Characteristic</th>
<th>Total(^{a})</th>
<th>Amputation(^{a})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>573 (91.8)</td>
<td>120 (99.2)</td>
</tr>
<tr>
<td>Female</td>
<td>28 (4.5)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Age (Years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;20</td>
<td>5 (1%)</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>20–25</td>
<td>121 (19.4)</td>
<td>31 (25.6)</td>
</tr>
<tr>
<td>26–30</td>
<td>119 (19.1)</td>
<td>23 (19.0)</td>
</tr>
<tr>
<td>&gt;30</td>
<td>313 (50.2)</td>
<td>52 (43.0)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>64 (10.2)</td>
<td>10 (8.3)</td>
</tr>
<tr>
<td>Black</td>
<td>32 (5.1)</td>
<td>7 (5.8)</td>
</tr>
<tr>
<td>Asian</td>
<td>4 (&lt;1)</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>American Indian/Alaskan Native Hawaiian/Other Pacific Islander</td>
<td>4 (&lt;1)</td>
<td>2 (1.6)</td>
</tr>
<tr>
<td>Marital Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>414 (66.3)</td>
<td>89 (73.5)</td>
</tr>
<tr>
<td>Divorced/Separated/Single</td>
<td>178 (28.5)</td>
<td>32 (26.4)</td>
</tr>
<tr>
<td>Service</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Army</td>
<td>423 (67.8)</td>
<td>80 (66.1)</td>
</tr>
<tr>
<td>Marines</td>
<td>97 (15.5)</td>
<td>32 (26.4)</td>
</tr>
<tr>
<td>Air Force</td>
<td>46 (7.4)</td>
<td>5 (4.1)</td>
</tr>
<tr>
<td>Navy/Coast Guard/NOAA</td>
<td>37 (5.9)</td>
<td>4 (3.3)</td>
</tr>
<tr>
<td>Length of Service (Years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–5</td>
<td>95 (15.2)</td>
<td>21 (17.3)</td>
</tr>
<tr>
<td>6–10</td>
<td>171 (27.4)</td>
<td>48 (38.0)</td>
</tr>
<tr>
<td>11–20</td>
<td>169 (27.1)</td>
<td>34 (28.1)</td>
</tr>
<tr>
<td>&gt;20</td>
<td>94 (15.1)</td>
<td>11 (9.1)</td>
</tr>
</tbody>
</table>

\(^{a}\)Subject numbers for each variable do not add to total sample due to missing data.
TABLE II. Referring Injury Diagnosis Categories, N = 533

<table>
<thead>
<tr>
<th>Injury Type</th>
<th>Description</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle</td>
<td>Pilon fractures, PTOA, fusion</td>
<td>139 (25.0)</td>
</tr>
<tr>
<td>Tibia</td>
<td>Fractures, excludes pilon fractures</td>
<td>96 (17.5)</td>
</tr>
<tr>
<td>Nerve injury; below knee</td>
<td>Functional deficit below knee</td>
<td>91 (16.4)</td>
</tr>
<tr>
<td>Hindfoot</td>
<td>PTOA, fusion</td>
<td>79 (14.2)</td>
</tr>
<tr>
<td>Soft tissue</td>
<td>Compartment syndrome, Achilles tendon injuries, quadriceps injuries</td>
<td>33 (5.9)</td>
</tr>
<tr>
<td>Midfoot/Forefoot</td>
<td>Foot pain, forefoot/midfoot PTOA, toe amputation</td>
<td>21 (3.8)</td>
</tr>
<tr>
<td>Other</td>
<td>Osteomyelitis, late effects of fracture, nerve injury above knee</td>
<td>93 (17.4)</td>
</tr>
</tbody>
</table>

PTOA, post-traumatic osteoarthritis.

Revision, Clinical Modification) or procedure code for a lower extremity amputation.

RESULTS
The study population comprised 624 service members who were treated at the CFI and prescribed an IDEO between 2009 and 2014. The demographics of the population are documented in Table I. The majority of the service members were equally divided above and below 30 years of age (50.2%), male (91.8%), married (66.3%), and white (70.3%). In comparison with the overall Armed Services, this sample is slightly older, more likely to be male and married but similar in race/ethnicity. The study cohort predominately consisted of Army (67.8%) service members, followed by the Marine Corps (15.5%). This is consistent with the U.S. military population. The majority of the population had a length of service between 6 and 10 years (27.4%), closely followed by 11 to 20 years (27.1%).

The description and distribution of the referring injury diagnoses are outlined in Table II. Of the 624 service members prescribed an IDEO, 533 (85.4%) had a clear presenting diagnosis documented in the medical record and of these, 38 (7.1%) had a bilateral diagnosis. The most common injury category that received an IDEO prescription was of injuries at or surrounding the ankle joint (25.0%), followed by tibia injuries (17.5%) and nerve injuries below the knee (16.4%).

Less than 20% (n = 121) of the study sample underwent a delayed amputation during the study period. Figure 1 displays the percentage of service members prescribed an IDEO in each injury diagnosis category who later underwent delayed amputation. Amputation rates were highest for injuries involving the ankle joint, including pilon fractures, ankle fusions, and PTOA, fusion 21 (3.8) in 2014.

DISCUSSION
After over a decade of military conflicts in Iraq and Afghanistan and improvements in combat casualty care and body armor, the focus of care of the wounded service member is shifting from acute care to improving the quality of life for those with long-term disability. To adequately care for all injured service members, a careful evaluation of current rehabilitative treatments is necessary. This study provides information on the demographics, injury profile, and delayed amputation rates of service members who have been prescribed an IDEO at the CFI after severe LEI. It is an important step toward identifying which injuries are most appropriately treated by this type of lower extremity bracing.

When examining the IDEO prescription patterns, an injury involving the ankle joint, including pilon fractures, ankle fusions, and PTOA, was the most frequently reported primary diagnosis (25%), followed by injury to the tibia (17%) and a nerve injury below the knee (16%). Considering nearly 58% of the injuries were at or could influence the functioning of the ankle joint, these groupings are consistent with the mechanism of action of the IDEO, which is designed to provide support as well as energy storage for the ankle joint during gait and other high-level activities.

Less than 20% of the study sample underwent an amputation during the study period. In a prospective observational study of IDEO users completing the RTR clinical pathway, 82% of patients who were initially considering amputation at the start of the program favored limb salvage after receiving an IDEO and completing the RTR program. When examining the individual diagnostic categories of the present study, 29% of midfoot/forefoot injuries, 27% of soft tissue injuries, and 27% of hindfoot injuries required eventual amputations, whereas the lowest rates of amputation were of nerve injuries below the knee (14%) as well as injuries of ankle (14%). These results are consistent with the categories in published disability data following combat-related injuries.

With the high prevalence of battle and nonbattle-related serious extremity injuries in our service members, it is important to examine the efficacy of treatment modalities for rehabilitative care. This descriptive study is a first step in identifying injured patients who may benefit the most from an IDEO prescription in terms of both rehabilitation and reducing the likelihood of amputation. Further research is necessary to fully understand this profile. Once an injury profile is identified, injured service members can benefit from having an IDEO prescribed earlier in the rehabilitative process and thus facilitate a more timely recovery of function. In addition, by understanding who will benefit most from an IDEO, resources that are currently allocated for the unnecessary use of the IDEO could be redirected.
for other treatment options. This injury profile should not take
the place of clinical decision-making but rather enhance the cur-
rent knowledge base and help to inform both clinicians and ser-
vice members as decisions on care are made.

One of the limitations of this study is the potential for selec-
tion bias since the study sample was one of convenience and
included only service members who were prescribed an IDEO
at the CFI. In addition, a clear presenting diagnosis was docu-
mented in only 85% of the total study sample and acute diagno-
ses, side of injury, or mechanism of injury (including combat or
noncombat) was not available for the majority of the sample.
Since the side of injury is unknown, it is possible that the lower
extremity with an amputation was opposite to the lower extrem-
ity with the IDEO prescription. The amputation rate would be
an overestimation if this occurred. Although a functional bene-
fit with the IDEO prescription. The amputation rate would be
an overestimation if this occurred. Although a functional benefit
to the use of the IDEO compared to other AFOs has been dem-
onstrated,11 the number of patients who benefited from the
IDEO from a functional rehabilitation standpoint is unknown.
This study reports IDEO prescription but cannot determine the
extent to which the treatment may have been efficacious. In addi-
tion, the current study suffers from some small sample sizes in the
diagnostic groups. Although the midfoot/forefoot had the highest
proportion of amputations, one or two individuals having an
amputation in another diagnostic group could shift that percentage
significantly. It will be beneficial for future studies to estimate
the weighted amputation probability for each diagnosis group.

Although a presenting diagnosis was not available for the
entire study sample, a qualified clinician from the armed forces
validated a random 10% of the referral diagnosis with electronic
military medical record system. The validation process provided
data quality assurance to the diagnostic category data element,
which was a key component of the analysis. A strength of the
study was that multiple datasets were able to be merged to
include primary data and secondary data. The primary dataset
identified the study sample and presenting diagnosis whereas
secondary datasets provided access to a large volume of medi-
cal data for validation and augmentation of primary data.

This is the first study to comprehensively examine the demo-
graphics, referral diagnoses, and amputation outcomes of a sam-
ple of service members prescribed the IDEO to facilitate function
of an injured lower extremity. The majority of the service mem-
bers had a presenting diagnosis at or near the ankle, and can
potentially benefit from an AFO designed to support the joint and
augment some of the lost ankle function. Twenty percent of the
sample underwent eventual amputation during the year follow-
ing initial IDEO prescription. This study is a first step in catego-
rizing primary injuries that may benefit from IDEO prescription
and determining which injuries undergo delayed amputation at
higher rates. Longitudinal tracking of IDEO users and identifi-
cation of functional outcomes will provide additional information
on the efficacy of this device for rehabilitation after an LEI.

APPENDIX A

ICD-9 Codes for Amputations

<table>
<thead>
<tr>
<th>89600</th>
<th>89620</th>
<th>89700</th>
</tr>
</thead>
<tbody>
<tr>
<td>89610</td>
<td>89630</td>
<td>89710</td>
</tr>
</tbody>
</table>

89720 89760 89750 89730 89770 89760 89740 89730 89740

APPENDIX B

Procedure Codes for Amputation

8410 8414 8417 8446
8412 8415 8440 8447
8413 8416 8445 8448

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