CDMRP
Department of Defense

Defense Health Program

Orthotics and Prosthetics Outcomes Research Program





U.S. Army Medical Research and Materiel Command

Congressionally Directed Medical Research Programs (CDMRP)

HISTORY

The CDMRP was established in 1992 from a powerful grassroots effort led by the breast cancer advocacy community that resulted in a Congressional appropriation of funds for breast cancer research. This initiated a unique partnership among the public, Congress, and the military. Since then, the CDMRP has grown to encompass multiple targeted programs and has received over $12.6 billion in appropriations from its inception through fiscal year 2018 (FY18).

APPLICATION REVIEW PROCESS

The CDMRP uses a two-tier review process for proposal evaluation, with both tiers involving dynamic interaction among scientists and consumers. The first tier of evaluation is a scientific peer review of proposals, measuring them against established criteria for determining their scientific merit. The second tier is a programmatic review, conducted by a Programmatic Panel composed of leading scientists, clinicians, and consumers. The Programmatic Panel compares proposals to each other and makes recommendations for funding based on scientific merit, portfolio balance, and relevance to overall program goals.

Orthotics and Prosthetics Outcomes Research Program

VISION

The highest possible quality of life for our injured Warfighters through the advancement of knowledge in orthotics and prosthetics related research

MISSION

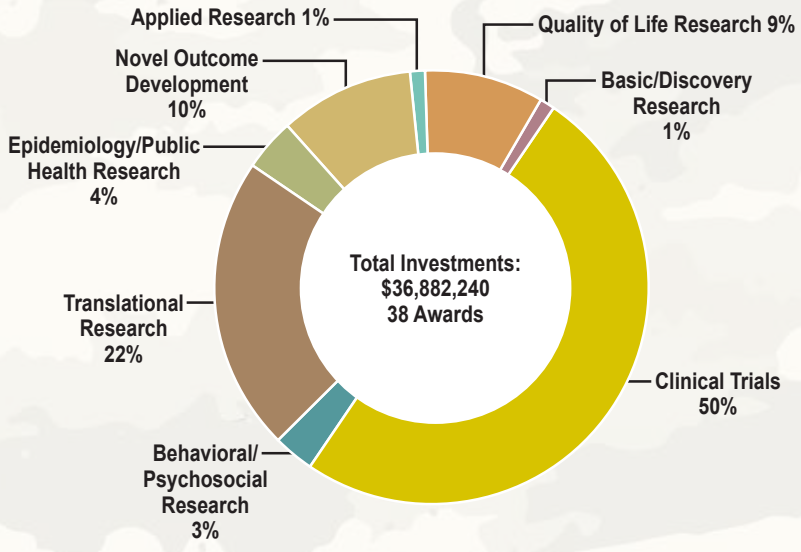
Advance orthotic and prosthetic research to optimize evidence-based care and clinical outcomes for military-related neuromusculoskeletal injury

OPORP BACKGROUND AND OVERVIEW

The Orthotics and Prosthetics Outcomes Research Program (OPORP) was established by Congress in 2014 to support research of exceptional scientific merit with the potential to make a significant impact on improving the health and well-being of Service members, Veterans, and other individuals living with limb deficit. OPORP supports research to evaluate the comparative effectiveness and functional outcomes associated with prosthetic and orthotic clinical interventions. The purpose of the supported research is to ultimately advance implementation of the most effective prosthetic and orthotic device prescription, treatment, rehabilitation, and secondary health effect prevention options for patients, clinicians, other caregivers, and policymakers.

Since its inception, the OPORP has received Congressional appropriations of $10 million (M) per year, for a total of $50M, including $10M in FY18, to facilitate research within the scope of its program framework. Current investments are summarized in the figure below.

Awards Summary by Investment Type for FY14–FY17



STRATEGIC PLAN

In 2018, the OPORP developed a strategic plan that identifies the high-impact research goals most important to its stakeholders while providing a framework that is adaptable to changes in the medical research environment to address those goals. This plan has been formulated to provide greater clarity of the program's goals over time to the public and other stakeholders.

The OPORP has identified three overarching strategic goals to guide its efforts over the next 3-5 years. Both individually and collectively, these goals are focused on enhancing outcomes for Service members and Veterans affected by limb salvage or limb amputation, including optimization of both function and performance, as well as community integration.

STRATEGIC GOALS

- **Optimize patient-specific technology prescription for the Warfighter**
- **Optimize patient-specific rehabilitation regimens for the Warfighter**
- **Support standardized assessment of patient outcomes related to prosthetics and orthotics**

Scientific Peer Review Panel

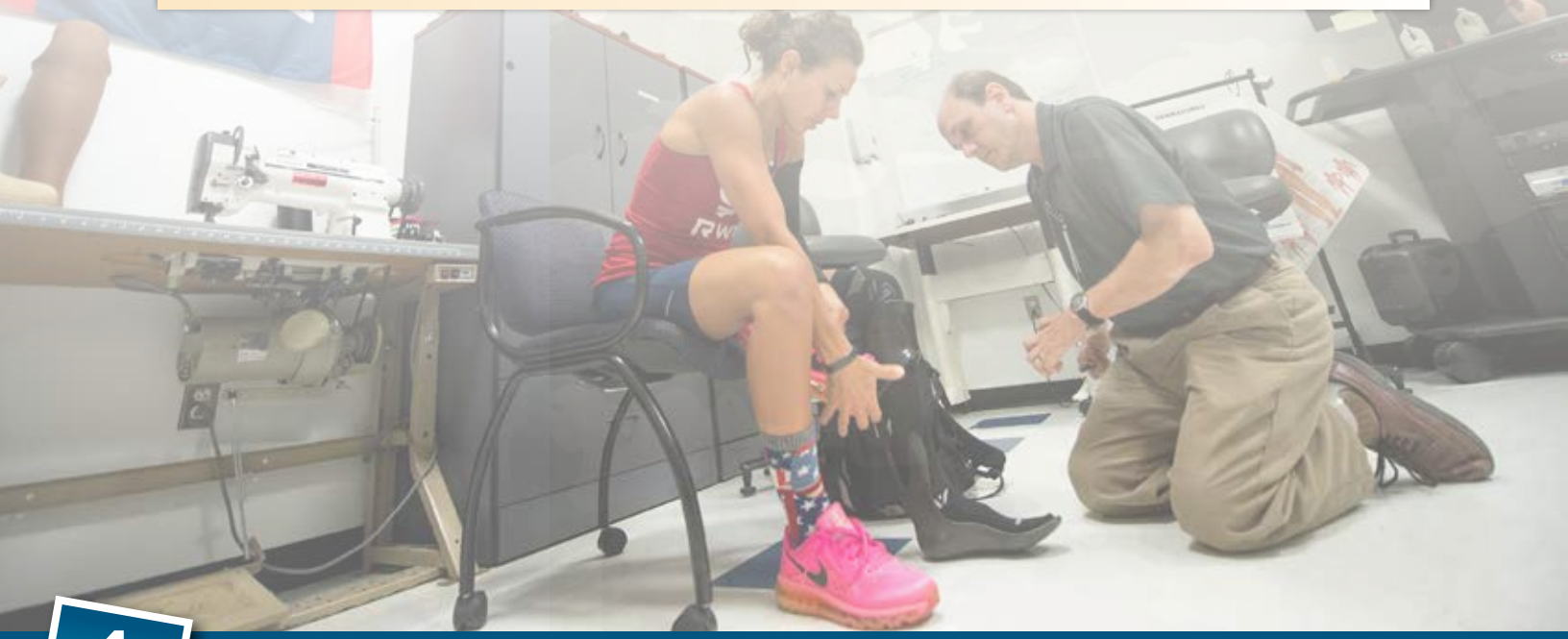
The OPORP scientific peer review panels are composed of respected scientists and clinicians, as well as dedicated consumer advocates who are individuals living with limb deficit or loss. Scientific reviewers are selected for their subject matter expertise. Both scientists and consumers work together to provide an unbiased, expert review of the scientific and technical merit of the research proposals. This panel evaluates the potential impact of research projects on the care of patients and their families to inform project selection by the Programmatic Panel.

Consumer Participation

A unique aspect of the CDMRP is the active participation of consumer advocates throughout the program. Consumers are a vital part of all CDMRP programs, as they represent the collective views of survivors, patients, family members, and those affected by or at risk for a disease. The OPORP is particularly honored to provide opportunities for engagement and aid for those who have lost limbs during active duty service and who seek to regain normal function in civilian life.

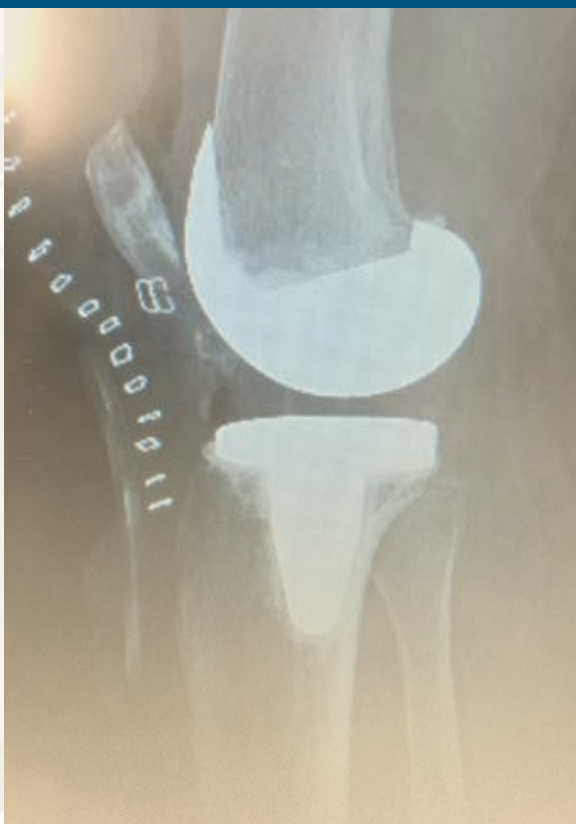
"As a consumer reviewer, I am honored and humbled to give my opinion on whether a program or innovation would benefit DoD personnel. Having been the recipient of groundbreaking technology that once had to go through the CDMRP process, it is truly rewarding to be involved in the decision-making process for medical advancement in future medical treatment of our wounded, ill, and injured Warfighters."

Andrew Lourake, Operation Second Chance, Consumer Peer Reviewer



Programmatic Panel

All of the programs in the CDMRP try to involve stakeholders from academia, clinical services, government service (the Department of Veterans Affairs [VA], the Department of Defense (DoD), the National Institutes of Health), and civilian life; the OPORP Programmatic Panel in particular is highly multidisciplinary. The panel has representation from physical and occupational therapists, prosthetists/orthotists, injured Service members, clinicians, and scientists, all of whom are striving to improve the outcomes of patients with orthotic and prosthetic devices. The potential for the funded projects to have immediate and direct impact leads to involved and synergistic discussion as the panel works to determine the best use of limited resources to optimize outcomes, while realizing that no orthosis or prosthesis yet replaces the human limb, and the "right device" may be different for each individual based on their activity level, individual needs, and lifestyle.



"It has been my privilege to work with the amazing group of military and civilian professionals on the OPORP panel. These subject matter experts are dedicated to the advancement of orthotic and prosthetic treatment and technologies and to transforming healthcare for Service members and Veterans through innovative and impactful research. The integrated partnership of consumer, scientific, professional, and military experts has made this organization one of the most impactful and influential efforts in optimizing the recovery of our Warfighters who have suffered major limb loss and impairment in combat-related operations."

Lanny L. Boswell (CAPT, ret.), PT, Ph.D., OCS,
Civilian Consultant, Programmatic Panel Chair

"As I often say to students, 'Patients are waiting.' It is clear that OPORP's mission is to translate promising technologies to implementation as expeditiously as possible."

Brian Davis, Ph.D., University of Akron,
Scientific Peer Reviewer

Orthotics Outcomes Studies

An Objective Method for Prescribing Orthosis for Patients with "Drop Foot"

Geza Kogler, Ph.D., Georgia Tech Research Corporation, Atlanta, GA

Many individuals of different ages, backgrounds, and medical histories have lower leg issues that make walking difficult. One of the most commonly diagnosed issues that requires intervention and rehabilitation is a condition nicknamed "drop foot," which is when one has difficulty voluntarily lifting his or her foot towards their shin. The causes for this condition range from strokes and multiple sclerosis to wounds, such as gunshots or blasts. To overcome tripping tendencies, orthotists prescribe a device called an ankle foot orthosis (AFO). AFOs are rigid shells or frames that attach to the ankle or foot in such a way that they assist the user in maintaining alignment of the ankle and foot. Tens of thousands of patients per year are fitted for an AFO, but the current procedure for fitting and customization is subjective. With an FY14 OPORP Orthotic and Prosthetics Outcomes Research – Funding Level 1 Award, Dr. Geza Kogler wishes to improve AFO design and patient customization through a quantitative process, where the devices are "tuned" to the exact needs of each patient rather than estimated through observation. Patients will receive a "dosage" of ankle stiffness, and device parameters will be adjusted so the mechanics of their movement will be as natural and efficient as possible. This new approach by Dr. Kogler will allow patients with drop foot to walk faster, for longer distances, for longer time periods, and be better equipped for stairs and hills.

An Initiative to Advance Care for Individuals Following Injury of the Lower Limb

M. Jason Highsmith, Ph.D., P.T., D.P.T., CP, FAAOP, University of South Florida, Tampa, FL

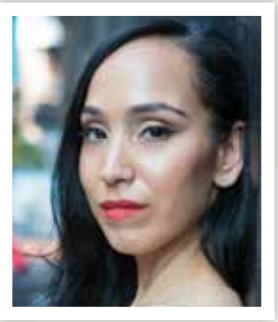
During the recent Iraqi and Afghanistan wars, the annual estimate of Service members experiencing limb trauma is 20,000. For non-military persons, the annual average is 30,000. The orthotics market has expanded due to these figures, but the cost of newer braces and the time to fabricate them has increased. This paradox has raised multiple issues and questions. For one, insurance companies or other reimbursement entities do not necessarily reimburse patients for these more expensive braces. In addition, while these devices are newer and/or more advanced, it is unclear whether they improve comfort and function or how much of the improved function is due to the physical abilities of the user. Dr. Jason Highsmith, recipient of an FY15 OPORP Orthotics Outcome Research – Funding Level 2 Award, seeks to determine whether different types of leg/foot braces will improve comfort and function in persons who have sustained lower limb injury. This study will capitalize on the established bracing infrastructure within the VA and Hanger Clinics systems and recruit participants from the Veteran and civilian sectors. During the 3-year study, Dr. Highsmith and his team plan to collect evidence to inform clinical decision-making about which brace, advanced or conventional, maximizes patient comfort and function. This study may provide information that can improve conditions for Service members to maintain active status in their military career or reintegrate into society as a Veteran.

Prosthetics Outcomes Studies

A Prosthetic Foot Emulator to Optimize Prescription of Prosthetic Feet in Veterans and Service Members with Leg Amputations

David Morgenroth, M.D., VA Puget Sound Health Care System and Seattle Institute for Biomedical and Clinical Research, Seattle, WA

As the recipient of an FY15 OPORP Prosthetics Outcomes Research – Funding Level 2 Award, Dr. David Morgenroth and his team at the VA Puget Sound Health Care System and Seattle Institute for Biomedical and Clinical Research are seeking to improve the mobility of individuals with lower limb amputation by optimizing the process of prescribing prosthetic feet. They are studying a patient-centered "test-drive" strategy to improve prosthetic foot prescription using a customizable, robotic prosthetic foot that mimics the mechanical properties of commercially available prosthetic feet through software control. This "prosthetic foot emulator" can provide individuals with leg amputations the opportunity to "test-drive" many prosthetic foot designs within a single test session. After laboratory testing with the prosthetic foot emulator under different terrain conditions, participants wear each of the actual prosthetics for 2 weeks and then return to the laboratory for re-evaluation. The study will compare users' preference for emulated feet to their preference for corresponding actual feet. Allowing patients to participate and offer feedback during the prosthetic foot prescription process, using either the emulator or a brief trial of commercial prosthetic feet, has great potential to enable increased patient satisfaction, walking ability, and achievement of functional goals.



The Unique Needs of Women with Amputation

Roxanne Disla, O.T.D., OTR/L, VA New York Harbor Health Care System and Narrows Institute for Biomedical Research, New York, NY

Thirty-five percent of the current population living with amputation is female, yet women with limb loss are studied less than their male counterparts. Furthermore, male structure and biomechanics are the basis for the vast majority of prosthetic devices that are commercially available. As a result, women living with limb loss face challenges such as ill-fitting prostheses, skin issues, and an increased risk of other health problems, such as osteoarthritis. Dr. Roxanne Disla hopes to determine the unique physical and psychosocial needs of females living with amputation with an FY16 OPORP Prosthetic Outcomes Research – Funding Level 2 Award. Veterans, Service members, and civilians living with amputation will be enrolled. Each participant will be asked to complete an online survey, developed in collaboration with the Army Public Health Center, that addresses physical health, quality of life, prosthetic use and needs, and psychosocial experiences. There is a growing population of women living with amputations, specifically in the VA and DoD Healthcare systems, yet little research has been performed to understand the unique needs of this population. Providers for women with amputation must evolve healthcare delivery and research practices, as well as work jointly with manufacturers who create prosthetic devices to meet these needs. Through a joint VA and DoD collaboration, Dr. Disla and her team hope to bridge the knowledge gap to meet the needs of the women living with limb loss.

For more information, please visit
https://cdmrp.army.mil
or contact us at:
usarmy.detrick.medcom-cdmrp.mbx.cdmrp-public-affairs@mail.mil
(301) 619-7071

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