CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

# Orthotics and Prosthetics Outcomes Research Program

Outcomes Research to Improve Quality of Life

For more information, please visit
cdmrp.health.mil/oporp

## 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 $19.4 billion in appropriations from its inception through fiscal year 2022 (FY22).

### 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** To attain the highest possible quality of life for individuals with limb loss and limb impairment

**MISSION** Advance orthotic and prosthetic research to optimize evidence-based care and clinical outcomes for Service Members, Veterans, and persons with limb loss and limb impairment

## BACKGROUND AND OVERVIEW

The Orthotics and Prosthetics Outcomes Research Program (OPORP) was established by Congress in FY14 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 loss and limb impairment. The OPORP supports research on outcomes-based best practices through analysis of prosthetic and/or orthotic device options that are clinically available. Congressional language for the OPORP specifies that research on the development of new devices or improvement of existing orthotic or prosthetic technology cannot be supported by the OPORP. The development and employment of new approaches and tools for measuring outcomes, however, is allowable and encouraged by the program.

Since its inception, the OPORP has received congressional appropriations totaling $125 million (M) to facilitate research within the scope of its program framework.


## OPORP FY14-FY23 Funding

| FY14 – FY19 | FY20 & FY21 | FY22 | FY23 |
|---|---|---|---|
| $10M | $15M | $20M | $15M |
| *per fiscal year* | *per fiscal year* | | |

## STRATEGIC PLAN

In 2023, the OPORP developed a strategic plan that identifies the high-impact research goals most important to the program and its stakeholders while providing a framework that is adaptable to changes in the medical research and clinical care environments to address those goals. The strategic plan can be found on the CDMRP website at https://cdmrp.health.mil/oporp/default. This plan has been formulated to provide greater clarity of the program's goals over time.

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 and all persons affected by limb loss or limb impairment, including optimization of both function and performance, as well as community integration.

## STRATEGIC GOALS

- Optimize patient-specific technology prescription: This goal focuses on identifying optimal (1) devices and device characteristics, (2) human interface with the devices, and (3) intuitive control systems, all grounded in an understanding of the requirements of patient-specific needs and the capabilities and limitation of available devices.
- Optimize patient-specific rehabilitation regimens: This goal addresses the cause and effect of an orthotic or prosthetic device on the optimal type, timing, and dosing (duration, frequency, intensity) of rehabilitation for each individual, again in the context of each person's unique requirements and preferences.
- Support standardized assessment of patient outcomes related to prosthetics and orthotics: Through this third goal, the OPORP seeks to validate function and performance, community integration, and user satisfaction outcomes associated with various device properties and functional abilities. An important objective of the OPORP is to enhance understanding of the outcomes that matter most for individuals living with orthotic and prosthetic devices.

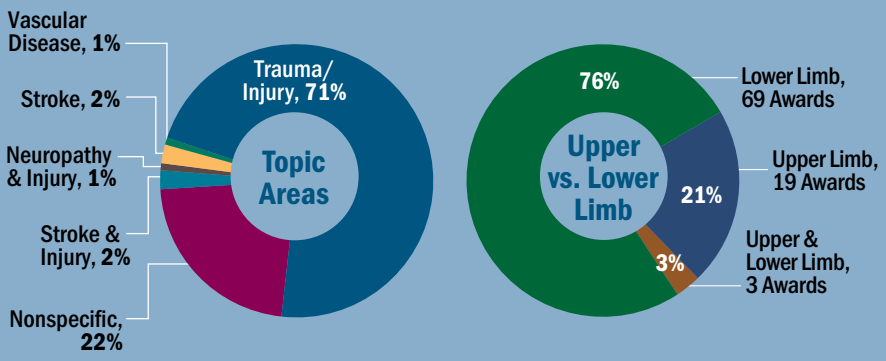
# Program Expansion

Recent advancements in commercially available orthotic and prosthetic devices have dramatically improved device capability, regardless of the underlying condition which resulted in the limb loss or limb impairment. There remains a need for evaluation of devices and treatments to identify those that provide the most improvement in user functionality and quality of life for our Service Members, Veterans, and all persons living with limb loss or limb impairment. Since its inception in FY14, the OPORP has invested heavily in addressing orthotic and prosthetic outcomes topics in trauma and injury areas. The program is expanding its inclusion to other causes of limb loss or limb impairment to potentially widen the scope of impact from these research dollars. The OPORP continues to prioritize and support research to evaluate the comparative effectiveness and functional outcomes associated with prosthetic and orthotic clinical interventions for the purpose of ultimately advancing implementation of the most effective prescriptions for prosthetic and orthotic devices, treatment, rehabilitation, and secondary health effect prevention options for patients, clinicians, and other caregivers.

# New Topic Areas

**Recent increases to the OPORP appropriation have allowed the program to expand its potential impact by supporting research in areas beyond trauma and injury (including, but not limited to, vascular disease, stroke, diabetes, neuropathy, and infection) that have resulted in limb loss or limb impairment that benefit from the use of prosthetic or orthotic devices.**

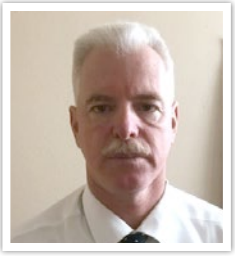
## FY14-FY21 OPORP Investment by Research Area




*A significant portion of the OPORP research portfolio addresses trauma/injury populations. The OPORP anticipates increasing future investments in non-injury topics to maximize impact for other limb loss and limb impairment populations in the near and long term.*

# 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 panel participation for those with limb loss or limb impairment.



"Participation on the OPORP panel has given me a greater appreciation of the tremendous value that research has had on advancing the care of our wounded Service Members, beneficiaries, and Veterans. The dedicated team of consumers, clinicians, and scientific professionals ensure that innovative and impactful research continues to push towards optimal orthotic and prosthetic treatment of Service Members, beneficiaries, and Veterans."

**Stuart Campbell, MPT.,**
*Extremity Trauma and Amputation Center of Excellence; OPORP Programmatic Panel Chair*

# Scientific Peer Review Panel

The OPORP scientific peer review panels are composed of respected scientists, clinicians, and specialists, as well as dedicated consumer advocates who are individuals living with limb loss or limb impairment. The CDMRP does not use standing panels; reviewers are selected based on the subject matter expertise needed to review submitted applications. Both scientists and consumers work together to provide an unbiased, expert review of the scientific and technical merit of the research proposals. All reviewers, including consumer reviewers, work together to provide a fair and unbiased assessment of the scientific and technical merit of the submitted research applications. The OPORP peer reviewers also evaluate the potential impact of outcomes from the proposed research projects on the care of patients and potential to inform clinical practice guidelines, patients, care providers, policymakers, and insurance payers.

# Programmatic Panel

The OPORP Programmatic Panel makes funding recommendations based on several factors as stated in the funding opportunity announcements. The panel also engages in discussions with the OPORP to help assess the needs of the patient, clinical, and research communities, identify the current technology and clinical care gaps, identify near- and long-term program goals, and create investment strategies consistent with these goals. The OPORP Programmatic Panel includes stakeholders from academia, clinical care, government organizations (the Department of Veterans Affairs [VA], the Department of Defense [DOD], the National Institutes of Health), and consumer organizations. The Programmatic Panel is a multidisciplinary panel with representation from physical and occupational therapy, orthotists, prosthetists, active-duty Service Members, Veterans, scientists, engineers, and prosthetic users, all of whom are dedicated to improving the outcomes of orthotic and prosthetic device users. Synergistic discussions ensure the OPORP is best utilizing congressional appropriations to meet the goals of the program.

"Those of us who are regularly immersed in the orthotics and prosthetics community can easily speak to the value that care provides to patients' quality of life, because we witness it every day."

**Susannah Engdahl, Ph.D.,**
*American Orthotic and Prosthetic Association; OPORP Programmatic Panel Member*

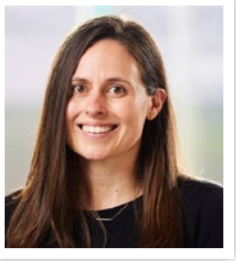
# Sample OPORP-Funded Research

## Enhanced Autodiagnostic Adaptive Trainer for Myoelectric Prosthesis Users (eADAPT-MP)

**Brent Winslow, Ph.D., Design Interactive, Inc.**

Nearly two million people live with limb loss in the United States. Restoration of lost function to complete daily activities is a constant challenge, particularly for upper limb loss patients. The loss of an upper limb has devastating impacts to motor and sensory function and can result in reduction of individual independence, quality of life, and employment opportunities.

With the help of an **FY17 OPORP Prosthetics Outcomes Research Award**, Dr. Brent Winslow evaluated the Auto-Diagnostic Adaptive Precision Trainer for Myoelectric Prosthesis Users (ADAPT-MP) ability to improve myoelectric prosthesis control training for upper limb amputees. The initial system was developed with Phase I and Phase II Small Business Innovation Research (SBIR) Program funding. Advantages of the eADAPT-MP system include increasing access to engaging tele-rehabilitation tools that mimic the activities of daily life on a system that is fun and engaging. Enhanced data availability and increased efficiency for the provider is achieved by logging into the system's web portal, which allows them to provide feedback to patients as they see fit. Furthermore, the system allows patients to better control their myoelectric prostheses, as well as better uptake of the devices for improved function and quality of life. A commercialization partner has provided strong support of the eADAPT-MP system.



## Hip Muscle Quality and Osseointegration Outcomes

**Jeanne Bailey, Ph.D., University of California, San Francisco**

Osseointegration is a newer technology available in the United States to help individuals with lower limb and upper limb amputation. Traditionally, a socket-interface is created to physically attach a prosthesis to the residual limb, for example, via a prosthetic liner suspension system. Osseointegration provides advantages over the traditional prosthetic socket as it eliminates the need for the socket, which often causes skin breakdown, pain, and discomfort. Due to altered gait mechanics and joint loading patterns, transfemoral amputees are at risk for developing hip joint degradation conditions, which can increase the likelihood of needing a future hip replacement. Dr. Bailey and her team are investigating how the hip muscles support the residual limb in the traditional prosthetic socket technology compared with the osseointegration technology to better understand outcomes associated with available treatment options. With funding from an **FY19 OPORP Clinical Research Award**, the researchers are assessing biomechanical function and hip-stabilizing muscle quality associated with transfemoral osseointegration. Preliminary data demonstrates that osseointegrated patients appear to be losing muscle quality after surgery. Additional work under this award will investigate the association between hip muscle quality and biomechanical function affecting gait, which may help inform targeted rehabilitation for improving hip muscle quality and long-term outcomes in this population.

# Sample OPORP-Funded Research

## Patient-Centered Measurement of Mobility Outcomes in Lower Limb Orthosis Users

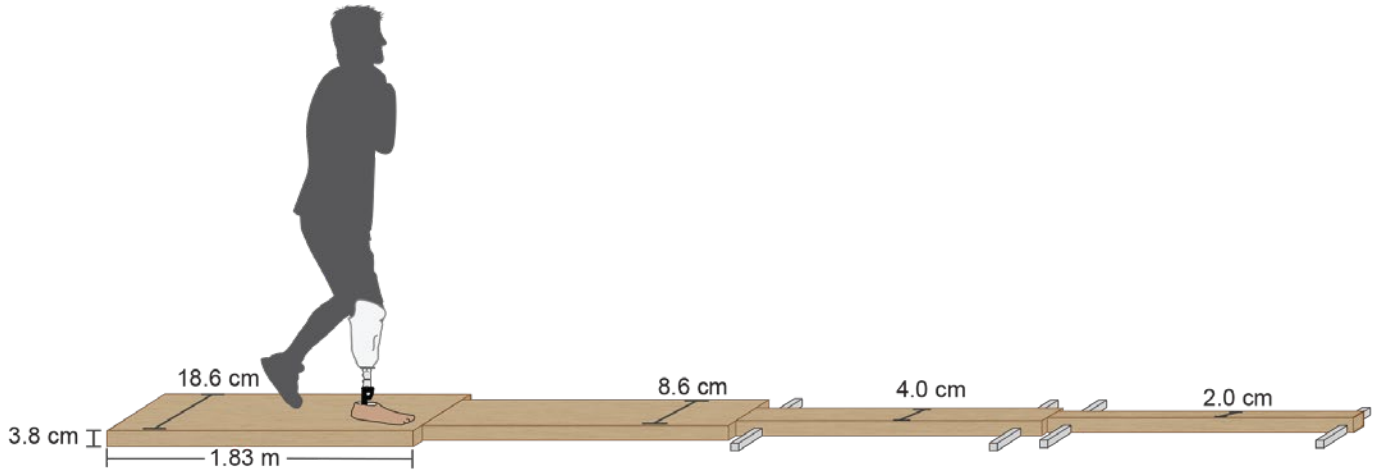
**Brian J. Hafner, Ph.D., University of Washington**

The decision of what orthotic device is best for a patient can be difficult and is limited by a lack of long-term data on how the devices affect a patient's function, health, and quality of life. Patient-reported outcomes (PRO) assessments can be helpful in making these decisions; however, there is limited information on how to interpret the information gained from these tools. With an **FY19 OPORP Clinical Research Award**, Dr. Brian Hafner sought to finalize the Orthotic Patient-Reported Outcomes – Mobility (OPRO-M), an instrument that he and his team developed specifically for lower limb orthosis users. Under this award, Dr. Hafner and his team conducted a large-scale study of 1,000 orthosis users, comparing four different types of PRO instruments, including the OPRO-M. Data collected in the study allowed the research team to not only assess the relative merits of each instrument, but also to establish reference values for each test based on a large national sample of orthosis users. The reference values obtained can assist in the interpretation of PRO scores in clinical care and research. Study results also allowed the team to calibrate the OPRO-M item bank and to create user-friendly short forms and a computerized adaptive test. Future steps will include performing studies to assess the validity, sensitivity, and responsiveness of the tested instruments. Dr. Hafner's research will ultimately help clinicians better understand the impact different orthotic devices have on their patients, allowing them to be better equipped to identify problems and improve their patients' outcomes.

## The Narrow Beam Walking Test: An Improved Clinical Balance Test for Assessing Fall Risk in Unilateral Lower Limb Prosthesis

**Andrew Sawers, Ph.D., C.P.O., University of Illinois at Chicago**

Over half of lower limb prosthesis users report falling, an event that can lead to additional injury and loss of mobility. With funding from an **FY16 OPORP Prosthetics Outcomes Research Award**, Dr. Sawers and his co-investigator, Dr. Brian Hafner, evaluated the psychometric properties of a novel Narrow Beam Walking Test (NBWT) for assessing fall risk in lower limb prosthesis users. Dr. Sawers hypothesized that existing clinical balance tests were not sufficiently challenging to accurately discriminate between fallers and non-fallers. To test this hypothesis, his team designed the Narrowing Beam Walking Test (NBWT), which consists of four low beams, each narrower than the previous, in order to provide a progressively increasing challenge to balance control. In addition, Dr. Sawers' team developed and tested a fall-type classification framework. The team used the framework to classify fall patterns reported by 66 lower limb prosthesis users to better understand the circumstances surrounding falls. Drs. Sawers' and Hafner's research to-date demonstrates that the NBWT discriminates fallers and non-fallers with greater accuracy than existing clinical balance tests. They also worked to improve the NBWT design to increase portability and durability, and developed a detailed fabrication guide to make the NBWT more accessible. As a result, clinical, industry, and academic centers across the U.S., including several VA Health Care Systems, are now using the NBWT.



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