CDMRP
DEPARTMENT OF DEFENSE
CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

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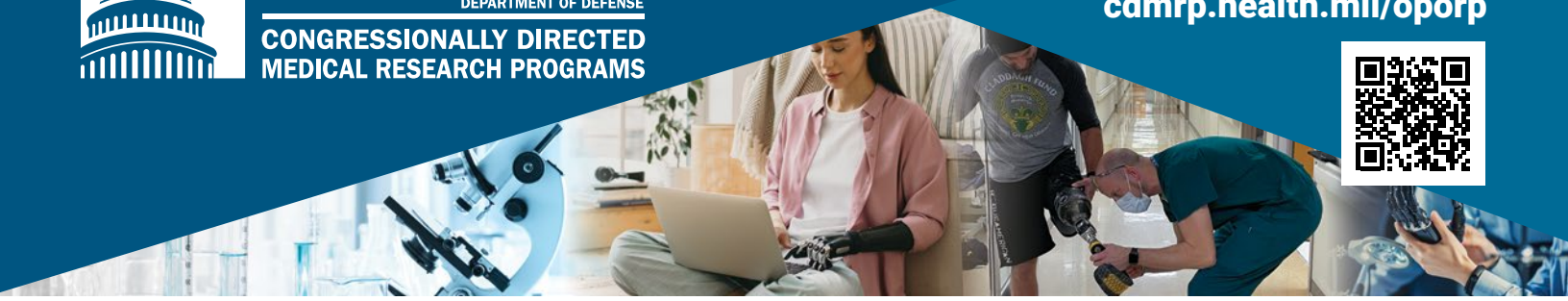


ORTHOTICS AND PROSTHETICS OUTCOMES RESEARCH PROGRAM

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

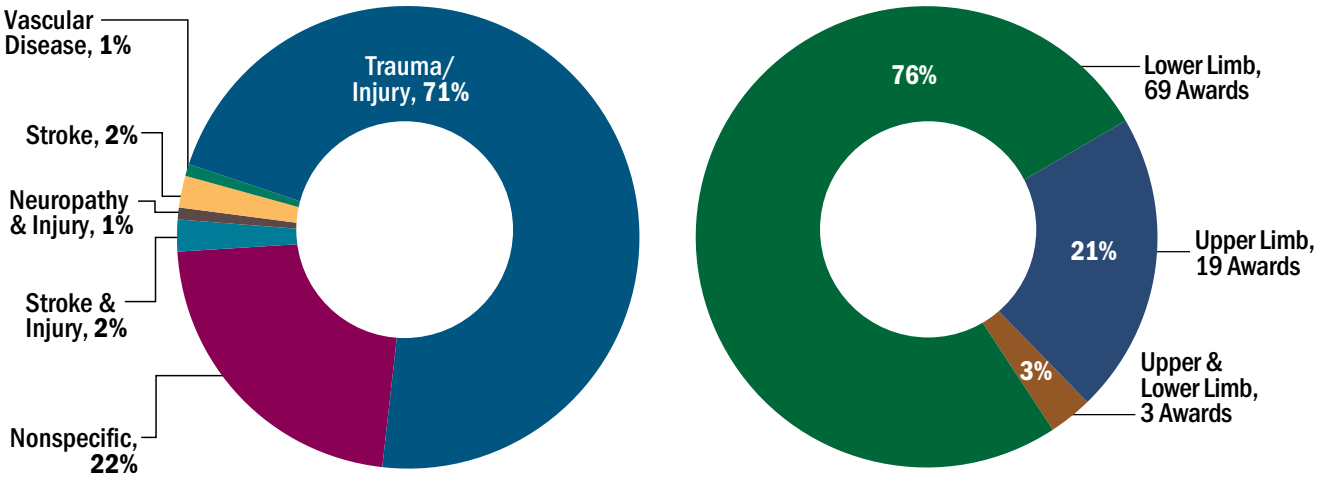
PROGRAM HISTORY

Every year, approximately 185,000 individuals in the United States will require a limb amputation.[1] Approximately 26,000 traumatic extremity injuries were sustained from deployments during Operation Iraqi Freedom/Operation Enduring Freedom/Operation New Dawn.[2] The average lifetime prosthetic and assistive device costs from these injuries range from $823K-$2.9M per person, depending on the type of limb loss/impairment.[3] Additionally, orthotic and prosthetic (O&P) users experience challenges relating to comfort and performance of their devices that directly impact quality of life, ability to return to work/duty, and assimilation into their prior community roles.

The Orthotics and Prosthetics Outcomes Research Program (OPORP) was established by Congress in fiscal year 2014 (FY14) with a $10M appropriation and has since been appropriated a total of $125M to support research to improve the health and well-being of O&P users, particularly Service Members and Veterans, living with limb loss and limb impairment. The OPORP supports research on outcomes-based practices through analysis of the merits of clinical orthotic and prosthetic device options that are clinically available and not on the development or improvement of new devices or improvement of existing technology.

PROGRAM PORTFOLIO

A significant portion of the OPORP research portfolio addresses **trauma/injury** populations. To widen the impact of its research dollars, the OPORP expanded its scope in FY23 to include research investments in other causes of limb loss or limb impairment, including **stroke**, **neuropathy**, **diabetes**, **vascular disease**, and **infection**.



FY14-FY22 OPORP Research Investment Areas

[1] https://www.amputee-coalition.org/resources/limb-loss-statistics/
[2] https://pubmed.ncbi.nlm.nih.gov/27849455/
[3] https://pubmed.ncbi.nlm.nih.gov/20803406/

STRATEGIC PLAN:

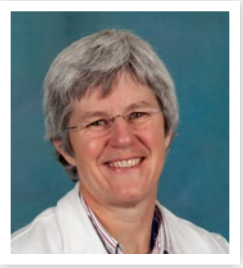
The OPORP continually evaluates its strategic plan and program goals to ensure that they are aligned with the most important research and clinical care needs of the program and its stakeholders. The FY23 OPORP Strategic Plan has been posted on the Congressionally Directed Medical Research Programs website (https://cdmrp.health.mil/oporp/pdfs/OPORP%20Strategic%20Plan.pdf) and includes the following strategic goals for FY23-FY27, if appropriated:

Optimize patient-specific technology prescription

Optimize patient-specific rehabilitation regimens

Support standardized assessment of patient outcomes related to prosthetics and orthotics

The OPORP supports outcomes research using two award mechanisms intended to generate clinically meaningful evidence with potential to optimize patient outcomes and inform clinical or policy decisions (Clinical Research Award) and for rapid implementation of clinical trials with the potential of having a significant impact on the health and well-being of individuals with limb loss and/or limb impairment (Clinical Trial Award). Since FY14, OPORP funding has contributed to the development of 3 patents, 75 publications, 128 presentations, and 6 follow-on studies. Below are examples of some impactful research accomplishments from the program.

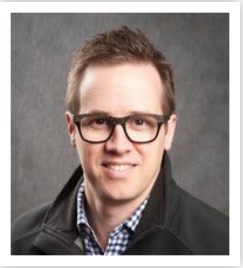


Improved Daily Comfort and Mobility for Lower-Limb Amputees Using Novel Release-Relock System

Joan Sanders, Ph.D., University of Washington

For people who have had a lower limb amputation, the prosthetic socket, a custom-built interface between their residual limb and their prosthesis, is the most important consideration for comfort and fit. The volume of the residual limb fluctuates and often reduces after connection to the prosthesis for an extended period. The resulting discomfort at the prosthetic socket interface negatively affects the individual's ability to perform daily living activities while using the prothesis. A typical accommodation is the addition of prosthetic socks to cushion the socket, but these have been found to further reduce residual limb volume. Other interventions include use of an elevated vacuum system to self-manage limb volume, but this has proven highly susceptible to air leaks, resulting in inconsistent relief for users.

With funding from an FY18 ORORP Clinical Research Award, Dr. Sanders tested the performance of her prototype socket, which was developed with an FY17 Peer Reviewed Orthopaedic Research Program Clinical Translational Research Award. This microprocessor-adjustable socket is comprised of three panels that adapt to the user's changing limb volume in response to sensor data from within the socket. Based on the successful testing of both systems during in-lab testing and take-home use, individuals with a lower limb amputation may soon have an option for a prosthetic socket that easily adjusts to accommodate residual limb volume fluctuation and decreases discomfort throughout the day.



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 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 Veterans Administration Health Care Systems, are now using the NBWT.

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