



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

FEB - 8 2023

The Honorable Jon Tester
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The Department's response to the Joint Explanatory Statement, pages 154-155, accompanying H.R. 133, the Consolidated Appropriations Act, 2021 (Public Law 116-260), "Orthotics and Prosthetics Outcomes Research," is enclosed.

The report summarizes the projects selected for Fiscal Year (FY) 2021 funding, and covers the total congressional appropriations for orthotics and prosthetics outcomes research (\$15 million). The FY 2021 Orthotics and Prosthetics Outcomes Research Program (OPORP) Programmatic Panel selected 10 projects (29 percent of compliant applications received) for funding based on peer-reviewed ratings and evaluations from researchers, clinicians, biostatisticians, bioethicists, technology transfer experts, and consumer advocates. Further, the panel considered the relevance of each project to the Defense Health Program mission and the OPORP, as evidenced by adherence to the intent of the award mechanism, OPORP portfolio composition, military relevance, and relative impact. These 10 projects reflect a diverse set of distinctive orthotics and prosthetics outcomes research topics of scientific inquiry, with potential for significantly improving the well-being of Service members, veterans, and others with limb deficits.

Thank you for your continued strong support for the health and well-being of our Service members, veterans, and their families. I am sending similar letters to the other congressional defense committees.

Sincerely,

A handwritten signature in black ink, appearing to read "Gilbert R. Cisneros, Jr.", written in a cursive style.

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Susan Collins
Ranking Member



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FEB - 8 2023

The Honorable Ken Calvert
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

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As stated

cc:
The Honorable Betty McCollum
Ranking Member



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PERSONNEL AND
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FEB - 8 2023

The Honorable Jack Reed
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

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As stated

cc:
The Honorable Roger F. Wicker
Ranking Member



UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
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FEB - 8 2023

The Honorable Mike D. Rogers
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Adam Smith
Ranking Member

Report to the Congressional Defense Committees



Orthotics and Prosthetics Outcomes Research

February 2023

The estimated cost of this report for the Department of Defense (DoD) is approximately \$3,900.00 for Fiscal Years 2022–2023. This includes \$2,900.00 in expenses and \$1,100.00 in DoD labor.

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BACKGROUND AND PURPOSE

This report is in response to the Joint Explanatory Statement, pages 154-155, accompanying H.R. 133, the Consolidated Appropriations Act, 2021 (Public Law 116–260), which requests that the Assistant Secretary of Defense for Health Affairs provide a report to Congress on orthotics and prosthetics outcomes research. The Joint Explanatory Statement specifies this report should include the peer-reviewed projects that receive funding, the funding amount awarded to each project, and the anticipated effect on patient care.

As requested by the Office of the Assistant Secretary of Defense for Health Affairs, the Defense Health Agency manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Development Command (USAMRDC) Congressionally Directed Medical Research Programs (CDMRP) provides execution management for the RDT&E Orthotics and Prosthetics Outcomes Research Program (OPORP) Congressional Special Interest funds. The Department initiated the OPORP in 2014 to provide support for 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 deficits.

FISCAL YEAR 2021 OPORP RESEARCH OVERVIEW

Congress appropriated \$15 million (M) for the Fiscal Year (FY) 2021 OPORP. The FY 2021 OPORP supports research that will provide the high-level scientific evidence required to inform development of clinical practice guidelines. Evidence-based research serves as the foundation for clinical practice guidelines and recommendations to optimize patient care. OPORP research studies focus on the optimization of patient outcomes that include orthoses or prostheses form, fit, control, and/or function.

FY 2021 OPORP AWARD MECHANISMS

The CDMRP OPORP implemented its FY 2021 investment strategy through its Clinical Research Award (CRA) and Clinical Trial Award (CTA) program announcements. The FY 2021 program announcements, released in March 2021, offered Funding Levels 1 and 2 based on the scope of research outlined below:

- **CRA Funding Levels**
 - Funding Level 1: Pilot and early-stage research studies that have potential to make significant advancements toward clinical translation. Preliminary data are encouraged, but not required.
 - The maximum period of performance is 2 years.
 - The maximum allowable total (direct and indirect) cost for the entire period of performance is \$350,000.

- Funding Level 2: Research that has potential to make significant advancements toward clinical translation. Proposed projects may include large-scale studies that, if successful, will produce high-quality outcomes that provide strong support for evidence-based practice and/or have the potential to drive changes in clinical practice. Preliminary data and/or published data from the literature that are relevant to the orthotic and/or prosthetic device outcomes and support the rationale for the proposed research are required.
 - o The maximum period of performance is 4 years.
 - o The maximum allowable total (direct and indirect) cost for the entire period of performance is \$2.0M.
- **CTA Funding Levels**
 - Funding Level 1: Pilot and early-stage clinical trials that support exploratory studies involving limited human exposure (e.g., small sample size) with potential to make significant advancements toward clinical translation. Preliminary data are encouraged, but not required.
 - o The maximum period of performance is 3 years.
 - o The maximum allowable total (direct and indirect) cost for the entire period of performance is \$350,000.
 - Funding Level 2: Clinical trials with potential to make significant advancements toward clinical translation. Proposed projects may include large-scale trials that, if successful, will produce high-quality outcomes with robust, statistically relevant participant numbers to provide strong, definitive support for evidence-based practice and/or have the potential to drive changes in clinical practice. Pragmatic clinical studies, randomized controlled trials, and comparative effectiveness studies are welcome and encouraged. Preliminary data relevant to the proposed clinical trial are required.
 - o The maximum period of performance is 4 years.
 - o The maximum allowable total (direct and indirect) cost for the entire period of performance is \$4.0M.

FY 2021 OPOP APPLICATION REVIEW

The CDMRP received FY 2021 CRA and CTA pre-applications (Letters of Intent) on July 15, 2021, and received applications on July 29, 2021. The OPOP oversaw the peer review conducted in September 2021, followed by programmatic review in December 2021.

The FY 2021 OPORP Programmatic Panel recommended projects for FY 2021 funding through the programmatic review process using criteria published in the program announcements:

- Ratings and evaluations of peer reviewers comprised of researchers, clinicians, biostatisticians, bioethicists, technology transfer experts, and consumer advocates.
- Relevance to the mission of the DHP and the OPORP, as evidenced by the following:
 - Adherence to the intent of the award mechanism.
 - Program portfolio composition.
 - Programmatic relevance to military health.
 - Relative impact.

FY 2021 OPORP INVESTMENT

FY 2021 OPORP appropriations invested in research, after final USAMRDC and CDMRP management costs, totaled approximately \$13.5M (Table 1). Table 2 shows the overall submission responses, the allocation and number of applications recommended for funding for each award mechanism, and the funding levels. Tables 3 and 4 summarize details of each project selected for FY 2021 OPORP CRA and CTA funding, respectively.

Table 1. FY 2021 OPORP Budget

Budget Allocations	Amount
FY 2021 Congressional Appropriation	\$15,000,000
Less: SBIR/STTR* Withholdings (3.34%)	(\$501,000)
Less: USAMRDC Withholds (2%)	(\$289,980)
Less: CDMRP Management Costs	(\$675,042)
Less: Modifications to Ongoing OPORP Awards	(\$71,280)
Amount Available for FY 2021 Research	\$13,462,698

*SBIR/STTR: Small Business Innovation Research/Small Business Technology Transfer

Table 2. FY 2021 OPORP Submission Responses and Recommendations

OPORP Program Announcement	Compliant Pre-Applications Received	Compliant Applications Received	Applications Funded (%)	OPORP Investment
CRA Funding Level 1	16	13	4 (31%)	\$1,317,604
CRA Funding Level 2	11	10	1 (10%)	\$1,983,796
CTA Funding Level 1	3	2	1 (50%)	\$349,225
CTA Funding Level 2	14	9	4 (44%)	\$9,812,073
Totals	44	34	10 (29%)	\$13,462,698

Table 3. FY 2021 OPORP CRA Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Enhancing Motor Function in Individuals with Lower Limb Amputation Through Peer-Based Balance and Fall Recovery Skill Training	University of Nevada, Las Vegas – Las Vegas, NV	<p>Frequent falls postamputation remain a serious concern for individuals with lower limb amputation (LLA), as poor post-amputation rehabilitation can lead to a high risk of injury from falls, ineffective locomotor patterns, abandoned devices, and ultimately, poor patient outcomes.</p> <p>Rehabilitation for individuals with LLA involves an intense process of learning and relearning to execute complex motor skills that involve generating, controlling, and coordinating movement between an altered sensory-motor system interface and the prosthesis. The goal of this study is to evaluate the effectiveness of peer-based prosthetic skill training in individuals with LLA. Knowledge gained from this study will benefit individuals with LLA by improving rehabilitation and advanced prosthetic skills learning, potentially allowing quicker return to duty or to work and minimizing the risk of secondary injuries.</p>	\$349,773

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
2	The Relationship Between Residual Limb Skin Health Measurements and Clinical Outcomes	Henry M. Jackson Foundation – Bethesda, MD (for Brooke Army Medical Center)	<p>Individuals who wear prosthetic sockets frequently experience a variety of skin-related health problems at the skin-socket interface, in part due to the friction and pressure created between the prosthesis and the residual limb. These skin problems can interfere with rehabilitation when patients discontinue use of their prosthesis while waiting for the skin to heal. To date, little is known about how to predict when the skin is going to break down or how to preemptively prevent these injuries. The goal of this study is to evaluate and identify skin health metrics that can be used as predictors for skin breakdown. Knowledge gained from this study will improve the residual limb health of prosthesis wearers by giving clinicians additional tools to help create individualized treatment plans for patients based on skin adaptation after amputation.</p>	\$302,105

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
3	Assessing the Role of the Socket Trim Line on Reactive Balance in People with Transfemoral Amputation	Rosalind Franklin University of Medicine and Science – North Chicago, IL	<p>Approximately 50 percent of people with lower limb amputation fall annually; individuals who have transfemoral amputations (TFA) experience the highest rates of falls. Reactive stepping is a common response initiated by prosthetic users to prevent falls. The effectiveness of the reactive step in preventing falls is directly linked to the strength of the hip muscle of the leg taking the step. For individuals with TFA, it is suspected their ability to prevent falls and engage their hip muscles is impacted by the socket trim, or the location of the socket edge on the residual limb. The goal of this study is to evaluate the height of socket trim lines, low versus high, and their impact on prosthesis-side hip function and fall risks in individuals with TFA. Knowledge gained from this study will contribute to clinical guidelines on socket design, provide evidence to support a more personalized approach to socket selection, and lead to improved rehabilitation and quality of life for individuals with TFA.</p>	\$350,000

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
4	Digital Weight-Bearing Shape Capture Socket Technology to Preserve Limb Health and Improve Rehabilitation Outcomes	Indiana University, Bloomington – Indianapolis, IN	Socket fit and design are important for successful rehabilitation and continued prosthesis use for individuals with lower extremity amputations. Shape capture of the residual limb has proven useful for generating the ideal socket fit. In recent years, Computer-Aided Design (CAD) of shape capture has been implemented over traditional hand-casting techniques. Current CAD methods use an optical tracking system and a non-weight bearing environment to simulate prosthetic fit. The goal of this project is to test the use of an electromagnetic tracking system for shape capture of the residual limb, the Symphonie Aqua Digital System (Romedis GmbH), which captures the limb under a full weight-bearing environment. Knowledge gained from this study will support use of the digital shape capture technology to provide quantitative, patient-centric, and objective limb health data to users and providers to enable customized care for improved limb health, function, and outcomes.	\$315,726

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
5	Evaluation of Functional Performance of Persons with Limb Difference to Optimize Pattern Recognition Control of Powered Upper Limb Prostheses	Liberating Technologies, Inc. – Holliston, MA	<p>Many individuals with upper limb amputation are fitted with prostheses controlled by multiple sensor channels and pattern recognition algorithms that measure muscle contractions using electromyographic (EMG) signals. Sensors on these devices can undergo multiple configurations and a variety of patterns. The goal of this study is to improve control algorithms and pattern recognition systems in upper limb prostheses by altering the number and placement of sensors on the upper limb. The configuration of these sensors will be conducted on individuals with prosthetic arms, enabling researchers to directly evaluate their effect on prosthetic device fit and improvement of prosthetic control while conducting activities of daily living. Knowledge gained from this study will contribute to clinical care decisions and policy discussions regarding the functional and quality of life benefits of myoelectric prosthetic limbs.</p>	\$1,983,796

Table 4. FY 2021 OPORP CTA Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Carbon Fiber Orthosis Cuff Design	University of Iowa – Iowa City, IA	Carbon fiber custom dynamic orthoses (CDOs) dramatically improve outcomes in patients who have sustained traumatic lower extremity injuries, but discomfort or a poor fit can discourage patients from wearing the device regardless of functional benefits. CDOs are comprised of three unique parts: a proximal cuff, a strut, and a footplate, all of which can be altered to improve prosthetic fit and comfort. There are multiple proximal cuff designs, but little data to guide clinicians on the selection of proximal cuffs or to support the use of one design over another. The goal of this study is to determine the effects of proximal cuff design on patient outcomes, limb mechanics and loading, and CDO mechanical characteristics. Knowledge gained from this study will provide objective data and clinical guidelines to support clinicians in choosing the optimal proximal cuff design to improve user comfort, satisfaction, and quality of life.	\$349,225

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
2	Evaluation of the Northwestern University Subischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels	University of Washington – Seattle, WA	Prosthesis discomfort while standing or sitting contributes to decreased prosthesis wear time and decreased mobility in individuals with TFA. For the past 3 decades, ischial containment (IC) sockets have been the standard of care for individuals with TFA; however, their tight fit with the thigh and pelvis limits hip motion and causes socket discomfort. The goal of this study is to evaluate the use and comfort of the Northwestern University Sub-Ischial Socket as an alternative prosthesis for individuals with TFA and lower mobility levels. Knowledge gained from this study will support use of the Northwestern University Sub-Ischial Socket to improve mobility of individuals with TFA.	\$2,768,756

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
3	Power Forward Study: A Cross-Sector, Multisite Clinical Trial of a Powered Knee-Ankle-Foot Orthosis	Shirley Ryan AbilityLab – Chicago, IL	<p>Knee ankle foot orthoses (KAFOs) have high abandonment rates due to functionality and reliability concerns. KAFOs are designed to control instabilities in the knee and lower limb; however, current options cause the wearer to adopt an unnatural gait because of mobility restrictions the KAFO places on the knee. The Nomad® is a newly commercialized powered KAFO (P-KAFO) that provides the user with active assistance and stability while walking and standing and minimizes the adoption of an unnatural gait. The goal of this study is to quantify the real-world usability and impact of the Nomad® with respect to function, mobility, balance, and quality of life for individuals with lower-limb impairments. Knowledge gained from this study will provide information to users and providers on the utility of P-KAFOs over more traditional KAFOs.</p>	\$1,679,729

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
4	From Opinion to Evidence: Multisite Evaluation of Custom Dynamic Orthosis Best Practices	University of Iowa – Iowa City, IA	<p>The current clinical process for prescribing carbon fiber custom dynamic orthoses (CDOs) is based on trial and error and lacks a well-defined starting point. Even skilled practitioners do not consistently achieve an optimal fitting configuration on the first try, which slows the rehabilitation process. Previous studies have shown that changing the alignment, or relative angle between the leg and foot, yields the greatest benefit in improved CDO functionality. The goal of this study is to provide a guideline for clinicians to use during CDO fittings that is supported by data. The researchers will evaluate multiple CDO configurations to determine which configuration provides the greatest user comfort and function among individuals who have limited function due to traumatic lower leg injury. Knowledge gained from this study will establish evidence-based guidelines that will improve CDO prescription and support user rehabilitation.</p>	\$3,969,294

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
5	Protecting Limb Health Through Optimal Socket Pressure Distribution	The Ohio Willow Wood Company – Mt. Sterling, OH	Clinical practice for fitting a prosthetic socket depends almost entirely on the skill and experience of the prosthetist, who has few objective measures to determine whether the best socket fit has been achieved. Poor socket fit is cited as a contributing factor to the high occurrence of skin injuries, prosthetic discomfort, and device abandonment. The goal of this project is to develop an understanding of how socket design and distribution of pressure on the limb affects residual limb skin health, and user comfort and satisfaction. The study will also objectively define parameters that can be used for socket fitting to support clinical guidelines. Knowledge gained from this project will improve prosthetic socket design, which can greatly improve residual limb health and patient quality of life.	\$1,394,294

SUMMARY

The FY 2021 OPORP appropriation invested in research totaled approximately \$13.5M after final USAMRDC, CDMRP, and SBIR/STTR management costs. The FY 2021 OPORP Programmatic Panel recommended 10 projects (29 percent of 34 compliant applications) for funding. The panel recommended these projects for funding based on peer-reviewed ratings and evaluations from researchers, clinicians, biostatisticians, bioethicists, technology transfer experts, and consumer advocates. Further, the panel members considered the relevance of each project to the DHP mission and OPORP, as evidenced by adherence to the intent of the award mechanism, OPORP portfolio composition, military relevance, and relative impact. These 10 projects reflect a diverse set of distinctive orthotics and prosthetics outcomes research topics of scientific inquiry, with potential for significantly improving the well-being of Service members, veterans, and others with limb deficits.