



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

PERSONNEL AND
READINESS

DEC 28 2021

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

Dear Mr. Chairman:

The Department's report in response to Senate Report 116-103, page 238, accompanying S. 2474, the Department of Defense Appropriations Bill, 2020 on Orthotics and Prosthetics Outcomes Research (OPOR) is enclosed.

The report summarizes the projects selected for fiscal year (FY) 2020 funding, and covers the total congressional appropriations for OPOR (\$15M). The FY 2020 OPOR Program (OPORP) Programmatic Panel selected 14 projects (26 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 14 projects reflect a diverse set of distinctive OPOR 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 our Service members, veterans, and 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 Richard C. Shelby
Ranking Member



PERSONNEL AND
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DEC 28 2021

The Honorable Betty McCollum
Chair
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chair:

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cc:
The Honorable Ken Calvert
Ranking Member



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PERSONNEL AND
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DEC 28 2021

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

Dear Mr. Chairman:

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cc:
The Honorable James M. Inhofe
Ranking Member



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WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

DEC 28 2021

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Enclosure:
As stated

cc:
The Honorable Mike D. Rogers
Ranking Member

Report to the Congressional Defense Committees



**In Response to: The Joint Explanatory Statement, Page 94,
Accompanying H.R. 1158, the Consolidated Appropriations
Act, 2020 (Public Law 116–93), Orthotics and Prosthetics
Outcomes Research**

December 2021

The estimated cost of this report for the Department of Defense (DoD) is approximately \$3,500.00 for Fiscal Years (FYs) 2020–2021. This includes \$2,500.00 in expenses and \$900.00 in DoD labor.

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BACKGROUND AND PURPOSE

This report is in response to the request in the Joint Explanatory Statement, page 94, accompanying H.R. 1158, the Consolidated Appropriations Act, 2020 (Public Law 116–93), for the Assistant Secretary of Defense for Health Affairs (ASD(HA)) to report to the congressional defense committees on Orthotics and Prosthetics Outcomes Research (OPOR). 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 ASD(HA), 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) provides execution management for the RDT&E OPOR 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.

FY 2020 OPORP RESEARCH

Congress appropriated \$15 million (M) for the FY 2020 OPORP. Senate Report 116–103, page 238, accompanying S. 2474, the Department of Defense Appropriations Act, 2020, states that “[t]he focus of this research should be on outcomes-based best practices through analysis of the merits of clinical options currently available, not on the development or improvement of new and existing technology.”

The OPORP implemented its FY 2020 programmatic strategy through Clinical Research Award (CRA) and Clinical Trial Award (CTA) program announcements. The FY 2020 program announcements, released in March 2020, offered Funding Levels 1 and 2 based on the scope of research as 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 two 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.

- The maximum period of performance is four years.
- The maximum allowable total (direct and indirect) cost for the entire period of performance is \$2.0M for FY 2020.

- **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.
 - The maximum period of performance is two years.
 - 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 that provide strong support for evidence-based practice and/or have the potential to drive changes in clinical practice. Preliminary data relevant to the proposed clinical trial are required.
 - The maximum period of performance is four years.
 - The maximum allowable total (direct and indirect) cost for the entire period of performance is \$4.0M.

The Congressionally Directed Medical Research Programs (CDMRP) received FY 2020 CRA and CTA pre-applications (Letters of Intent) on July 15, 2020, and received applications on July 29, 2020. OPORP oversaw the peer review conducted in September 2020, followed by programmatic review in December 2020.

The FY 2020 OPORP Programmatic Panel recommended projects for FY 2020 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.
- Military relevance.
- Relative impact.

FY 2020 OPORP appropriations invested in research, after final US Army Medical Research & Development Command (USAMRDC) and CDMRP management costs (5.03 percent), totaled approximately \$13.6M. Table 1 shows the overall submission responses, the allocation and number of applications recommended for funding for each award mechanism, and the funding levels. Tables 2 and 3 summarize details of each project selected for FY 2020 OPORP CRA and CTA funding, respectively.

Table 1. FY 2020 OPORP Submission Responses and Recommendations

OPORP Program Announcement	Compliant Pre-Applications Received	Compliant Applications Received	Applications Funded (%)	OPORP Investment
CRA Funding Level 1	21	18	5 (28%)	\$1,609,549
CRA Funding Level 2	15	13	4 (31%)	\$7,881,669
CTA Funding Level 1	8	7	4 (57%)	\$1,397,737
CTA Funding Level 2	17	15	1 (7%)	\$2,734,009
Totals	61	53	14 (26%)	\$13,622,964

Table 2. FY 2020 OPORP CRA Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Evaluation of Mechanical Loads on an Osseointegrated Implant During Locomotor Activities of Daily Living	University of Maryland College Park – College Park, MD	Individuals with lower extremity amputations (ILEA) with osseo-integrated (OI) prosthesis have better overall functionality and performance when compared to a socket-based prosthesis. However, direct skeletal attachment created by the OI implant introduces high force and vibration transferred directly to the residual limb. These biomechanical concerns are largely unstudied in ILEA, and restrictions in activity are largely established without quantitative data. The goal of this study is to characterize the unique biomechanical concerns associated with this attachment method and determine the force and vibration transferred during activities of daily living. Knowledge gained from this project can be used to inform and establish clinical guidelines to assist clinicians and medical staff with addressing the biomechanical concerns associated with a direct skeletal attachment, which may influence the health of ILEA and improve patient outcomes.	\$349,778
2	Validation of Military-Relevant Assessments to Predict Successful Return to Duty Following Lower Limb Injury	Henry M. Jackson Foundation – Bethesda, MD (for Brooke Army Medical Center)	Major lower limb injury is common in the military and requires decisions regarding return to duty (RTD). There are currently no validated standardized assessments to predict successful RTD for injured Service members using orthotic and prosthetic devices. This project will focus on developing and validating a clinician-friendly decision support tool that is able to predict whether a Service member who has sustained a lower limb injury that requires the use of an orthotic and prosthetic device can successfully RTD based on standard military-relevant assessments. Knowledge gained from this study will produce a decision support tool in the form of an easily understandable decision tree based on patient-specific factors and assessment scores. Data from the study can be implemented into clinical care and provide an objective means to inform the RTD decision-making process.	\$215,234

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
3	Monitoring Prosthetic and Orthotic Function in the Community	University of South Florida – Tampa, FL	<p>With the increase in lower extremity trauma cases, there is need to better understand how lower limb prosthesis or orthosis function during daily activities to better inform clinical decisions. The goal of this study is to verify a portable monitoring and measurement system to measure prosthetic and orthotic function in the community and in RTD situations. The proposed mobile system will integrate commercially available inertial measurement units, a Smartwatch, and a smart phone database application for appropriate tracking of outcomes by researchers and clinicians. Knowledge gained from the study will inform the user and the clinical care team and will help improve prescription, care, and RTD strategies.</p>	\$344,537
4	Improved Patient Outcomes in Prostheses Fit Through Integrated 3D Digital Image Correlation and Finite Element Analysis	Virginia Polytechnic Institute and State University – Blacksburg, VA	<p>Poor prosthesis fit in individuals with an amputation can lead to pain, discomfort, soft tissue injuries, and mobility limitations. Load-bearing skin and muscles of the residual limb are also subjected to large shear and strains. These strains are measured in-vivo using finite element analysis (FEA) and are rarely validated with empirical measurements due to challenges in measuring strains on the residual limb during use. The goal of this preclinical project is to improve FEA estimates using direct measurements of strain from state-of-the-art digital image correlation, and compare these strain measurements between contemporary clinical socket-shaping strategies. Knowledge gained from this study will overcome the limitations of prior attempts to measure residual limb skin strain in vivo, provide crucial insight into the soft tissue strain distribution on the residual limb, and greatly improve the validity of FEA methods.</p>	\$350,000

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
5	Limb Health and Socket Pressure in Response to Powered Ankle Prostheses	Indiana University Bloomington – Bloomington, IN	Prosthetic fit is the primary concern of a majority of individuals with lower-limb amputation, since persistent discomfort can necessitate prosthesis disuse or abandonment. Relatively little is known about the impact of active transtibial prostheses on socket pressure, and no studies have examined their effects on direct measures of limb health. The goal of this study is to quantify the effects of powered transtibial prostheses on socket loading and direct measures of residual limb health. Knowledge gained from this project will provide data to inform selection of appropriate suspension systems and active assistance settings for powered prostheses to help military and non-military personnel maximize their mobility post-amputation, improve quality of life, and lead to higher rates of return to duty/work.	\$350,000
6	Optimizing Prosthetic Shock Absorption for High-Demand Mobility of Service Members with Leg Amputation	University of Nebraska Omaha – Omaha, NE	For individuals with lower limb amputation, “shock-absorbing” (SA) prostheses play a critical role in supporting health and comfort. However, there is currently no objective process which exists for prescribing SA modular components to Service members. The overall goal of this project is to characterize the independent and combined effects of prosthetic SA devices on musculoskeletal health outcomes during various military-relevant, high-impact mobility tasks. Knowledge gained from this research will generate evidence to inform clinical practice guidelines for prescribing SA components specifically tailored for high-demand activities to support health and function. Results will enable enhanced mobility to perform military duties and everyday activities upon return to a civilian life, supporting the health and well-being of Service members and Veterans with lower limb amputation.	\$1,999,991

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
7	Exploring the Impact of Microprocessor-Controlled Knees on Prosthesis Awareness and Overall Health	Virginia Commonwealth University – Richmond, VA	Prosthesis awareness represents the degree to which a person thinks about or pays attention to their prosthesis during activity, and no clinical measure currently assesses this functional ability. The goal of this research is to develop a measure of prosthesis awareness so clinicians can fully understand the walking ability of Service members and Veterans with limb loss. The newly created Prosthetic Limb Users Survey of Awareness can easily be adopted to provide a more comprehensive assessment of users' functional capabilities and as a companion to the widely-used Prosthetic Limb Users Survey of Mobility. Knowledge gained from this study will inform clinical decisions, facilitate assessments to improve functional mobility, and increase quality of life of those with limb loss.	\$1,971,886
8	A Wearable Sensing System for Continuous Assessment of Outcomes of Orthotic Hand Users in Real-World Settings	University of North Carolina at Chapel Hill – Chapel Hill, NC	The human hand is a complex system that can perform a variety of tasks, and recovery of hand function is the most challenging rehabilitation following a stroke or traumatic brain injury. The goal of this project is to optimize a wearable sensing system to capture real-time outcome measures of hand impairment by combining continuous monitoring of hand utility with clinical assessments and user objective feedback. A continuous assessment of hand functions in daily life can facilitate adaptive and personalized orthoses prescription, maximize the benefits of orthoses functions, and transform the current standard of care to restore hand functions in Service members and Veterans with impaired hand function. Knowledge gained from quantifying hand performance in real-world settings can also improve the quality of tele-rehabilitation and provide guidance for evidence-driven policy making for patient outcome evaluations.	\$1,999,998

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
9	Clinical Translatability of Reactive Hyperemia Measurements that Can Monitor Adaptation of Residual Limb Skin to Socket Wear	Henry M. Jackson Foundation – Bethesda, MD (for Brooke Army Medical Center)	People who wear prosthetic sockets frequently encounter skin-related health problems due to skin irritation and breakdown as a result of the increased mechanical burden at the skin-socket interface. The proposal seeks to develop a novel and innovative approach to measure the adaptation of residual limb skin to prosthetic socket wear by using optical coherence tomography to directly measure reactive hyperemia adaptations and compare that to indirect measurements using low-cost thermal imaging. The research will facilitate clinical decision-making on fit-related metrics associated with the usability of a prosthetic socket. Knowledge gained from these imaging techniques would then enable clinical decisions on prosthesis form by providing an evidence-based approach to inform clinical reasoning.	\$1,909,794

Table 3. FY 2020 OPORP CTA Summary

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
1	Clinical Outcomes Associated with At-Home Use of Passive MPKs versus Two Different Powered Prosthetic Knees by K4-Level Individuals with Transfemoral Amputations	Liberating Technologies, Inc. – Holliston, MA	Powered prosthetic knees have the potential to restore lost knee power, but these devices have rarely been evaluated outside of the laboratory in a real-world environment. This proposal will investigate the tradeoffs between two powered knees and passive microprocessor-controlled knees (MPKs) to identify the prosthetic knee that is best suited for K4-level (more active) users. The study will determine the best prosthetic, using observations and self-reported outcomes from real-world use of the devices. Results of this study will maximize patient benefit by providing data to inform evidence-based prescription and use of powered knee technologies for K4-level individuals, optimize device cost, influence clinical practice, and inform policy decisions. Knowledge gained will also provide data that can be disseminated to inform the design of future devices by understanding the needs of users as well as the capabilities and limitations of current devices.	\$349,522
2	Quantifying Biofeedback Training and Retention Effects on Functional Outcomes in Above-Knee Prosthesis Users	San Jose State University – San Jose, CA	Individuals with above-knee amputation (AKA) experience significant mobility limitations, including those that lead to chronic secondary injuries, such as osteoarthritis and degenerative joint disease. Gait retraining is an essential component of rehabilitation for individuals with AKA, but is typically limited to a therapist providing verbal cues based on subjective observations. This study aims to supplement traditional gait retraining by using wearable sensors to quantify a patient’s motion and communicate instructions through biofeedback to improve functional outcomes and decrease the prevalence of secondary injury. Knowledge gained will maximize patient mobility outcomes through optimizing gait retraining protocols, increasing full mobility potential, and remote therapy.	\$348,636

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
3	Personalizing MPK Prescription for Individuals with Transfemoral Amputation	Georgia Tech Research Corporation – Atlanta, GA	Significant evidence indicates microprocessor knees (MPKs) have numerous benefits over non-MPKs for individuals with transfemoral amputation (TFA). However, studies lump the various knees together as a group rather than teasing out differences between individual MPK technologies for individual prescription. The objective of this study is to personalize prosthetic prescription by creating a clinical decision algorithm for selection of an ideal MPK for an individual patient with TFA based on objective and patient-reported data collected from that specific user. Knowledge gained has potential to improve immediate clinical outcomes in everyday life for individuals with a TFA by objectifying the selection of an MPK for the treating prosthetist or clinician, and to create a framework for clinical practice guidelines regarding MPK choice that will allow a clinician to make decisions based on evidence collected within a clinic.	\$349,842
4	Optimizing Prosthetic Prescription to Mitigate the Effects of Perspiration	Seattle Institute for Biomedical and Clinical Research – Seattle, WA	Individuals with lower limb amputation often report uncomfortably warm skin temperatures and accumulation of perspiration inside their prostheses, leading to movement of the residual limb relative to the prosthetic liner. The objective of this work is to provide a clinically-available prosthesis to the Warfighter with a lower limb amputation that is stable, secure, and comfortable, despite the accumulation of perspiration that naturally occurs during moderate to vigorous activities or in demanding environments. The study proposes a novel approach to measure the stability, suspension, and comfort of three study-provided liners using the Comprehensive Lower-Limb Amputee Socket Survey (CLASS). The CLASS will assess the subject's baseline liner prescription and compare it to one of the study liners. Knowledge gained will provide evidence to optimize patient outcomes by identifying clinical prescription options that best address the problems of perspiration accumulation.	\$349,737

No.	Project Title	Awardee	Anticipated Effect on Patient Care	OPORP Investment
5	Optimizing Ankle-Foot Orthotic Prescription Using an Emulation Test-Drive Strategy	Henry M. Jackson Foundation – Bethesda, MD (for VA Puget Sound Health Care System)	Matching an ankle-foot orthoses (AFO) with optimal mechanical properties to the unique needs and abilities of a given patient is challenging, and the inability to “test-drive” different designs is an unmet clinical need that impedes patient care. This study will investigate a test-drive strategy using a programmable robotic exoskeleton to emulate multiple AFO devices without the user having to physically change devices. The user can swap different design features in real-time to predict function, mobility, and preference outcomes with commercially available AFOs. Knowledge gained could resolve the long-standing uncertainty in AFO prescription while improving standard of care, mobility, and satisfaction as well as giving the user a new tool for far greater participation in the clinical decision-making process.	\$2,734,009

SUMMARY

The FY 2020 OPORP appropriation invested in research totaled approximately \$13.6M after final USAMRDC and CDMRP management costs. The FY 2020 OPORP Programmatic Panel recommended 14 projects (26 percent of 53 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 14 projects reflect a diverse set of distinctive OPOR topics of scientific inquiry, with potential for significantly improving the well-being of Service members, Veterans, and others with limb deficits.