OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
READINESS

JAN 19 2016

The Honorable John McCain
Chairman
Committee on Armed Services
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

The enclosed report responds to Senate Report 113-85, page 191, which accompanied S. 1429, the Department of Defense Appropriations Bill, 2014, on the status of the Orthotics and Prosthetics Outcomes Research Program (OPORP). This report provides a list of the projects that received funding, the amount of funding provided to each project, and the anticipated effect on patient care.

The U.S. Army Medical Research and Materiel Command received the $10 million Fiscal Year 2014 Defense Health Program OPORP congressional special interest appropriation on April 4, 2014. A total of $9,333,098 was available for research after budgeted management costs. In October 2014, the OPORP released a program announcement to solicit research that evaluates the comparative effectiveness of and functional outcomes associated with orthotic and prosthetic clinical interventions and/or other rehabilitation interventions for Service members and veterans who have undergone limb salvage or limb amputation. After peer and programmatic review, the OPORP funded 11 projects.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families. A similar letter is being sent to the other congressional defense committees.

Sincerely,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Jack Reed
Ranking Member

PERSONNEL AND
READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

JAN 19 2016

The Honorable William M. "Mac" Thornberry
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

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Brad Carson
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As stated

cc:
The Honorable Adam Smith
Ranking Member

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

PERSONNEL AND
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JAN 19 2016

The Honorable Thad Cochran
Chairman
Subcommittee on Defense
Committee on Appropriations
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

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Sincerely,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Richard J. Durbin
Vice Chairman

PERSONNEL AND READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

JAN 19 2016

The Honorable Rodney P. Frelinghuysen
Chairman
Subcommittee on Defense
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report responds to Senate Report 113-85, page 191, which accompanied S. 1429, the Department of Defense Appropriations Bill, 2014, on the status of the Orthotics and Prosthetics Outcomes Research Program (OPORP). This report provides a list of the projects that received funding, the amount of funding provided to each project, and the anticipated effect on patient care. We submitted an interim report on August 26, 2014.

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Sincerely,

Brad Carson
Acting Principal Deputy

Enclosure:
As stated

cc:
The Honorable Peter J. Visclosky
Ranking Member

REPORT TO THE CONGRESSIONAL DEFENSE COMMITTEES IN RESPONSE TO SENATE REPORT 113-85, PAGE 191, ACCOMPANYING S. 1429, THE DEPARTMENT OF DEFENSE APPROPRIATIONS BILL, 2014

ORTHOTICS AND PROSTHETICS OUTCOMES RESEARCH PROGRAM (OPORP)

SUBMITTED BY THE OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS

SUPPORTED BY THE U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND, CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

October 2015

The estimated cost of this report or study for the Department of Defense is approximately $1,400 in Fiscal Year 2015. This includes $900 in expenses and $500 in DoD labor.
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1. PURPOSE

The Orthotics and Prosthetics Outcomes Research Program (OPORP) was established by Congress in Fiscal Year 2014 (FY14) with a $10 million (M) Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) congressional special interest (CSI) appropriation to support military relevant personal assistive technology outcomes research. This report is in response to Senate Report 113-85, page 191, which requests the Assistant Secretary of Defense for Health Affairs to provide a report, not later than 180 days after the enactment of the Act, to the congressional defense committees on the status of the OPORP. The Committee requested a list of the projects that received funding, the amount of funding provided to each project, and the anticipated effect on patient care.

2. BACKGROUND

In Senate Report 113-85, the Senate Appropriations Committee noted that "too little is known about which orthotic and prosthetic supports, treatments, and technologies generate the best outcomes for which patients," and that "[the] Committee believes that continued research on orthotics and prosthetics outcomes can further improve care for Service members with limb loss and limb impairment and support evidence-based practice by allowing doctors to match Service members and veterans with the orthotic or prosthetic that best works for them. Therefore, the Committee provides $10,000,000 in support of such comparative outcomes research."

The goal of the OPORP is to improve our understanding and advance the implementation of the most effective prescriptions for orthotic and prosthetic devices, treatment, rehabilitation, and secondary health effect prevention options for patients, clinicians, other caregivers, and policymakers. The OPORP funds military-relevant, personal assistive technology research projects for the development of devices and associated rehabilitation treatments that provide demonstrable improvement in user functionality and quality of life for Service members.

As directed by the Assistant Secretary of Defense for Health Affairs, the Defense Health Agency (DHA), Research, Development, and Acquisition (RDA) Directorate manages and executes the DHP RDT&E appropriation, which includes the FY14 OPORP DHP CSI appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides execution management support aligned with specific DHA RDA Directorate research program areas.

3. FY14 OPORP RESEARCH INVESTMENTS

The USAMRMC received the $10M FY14 DHP OPORP CSI appropriation on April 4, 2014. A total of $9,333,098 was available for research after budgeted management costs.

In October 2014, the OPORP released the FY14 OPORP Orthotics and Prosthetics Outcomes Research Award (OPORA) Program Announcement (PA) to solicit research that evaluates the comparative effectiveness of and functional outcomes associated with orthotic and

prosthetic clinical interventions and/or other rehabilitation interventions for Service members and veterans who have undergone limb salvage or limb amputation. The OPORA PA offered two different funding levels, based on the scope of the proposed research as described below:

- Funding Level 1: Research that is already supported by preliminary data and has the potential to make significant advancements toward clinical translation.
  - Period of Performance: Maximum of 2 years.
  - Funding: $500,000 maximum allowable total (direct and indirect) costs.

- Funding Level 2: Advanced translational studies that have the potential for near-term clinical investigation.
  - Period of performance: Maximum of 3 years.
  - Funding: Between $500,000 and $3.5M total (direct and indirect) costs, depending on the individual research project.

Pre-applications were received for this PA in November 2014, and screened by the FY14 OPORP Scientific Working Group (SWG) in December 2014 to determine which principal investigators (PIs) would be invited to submit a full application based on the evaluation criteria specified in the PA. Invited full applications were received in January 2015, and peer reviewed for technical merit in March 2015, comprised of scientific experts, clinicians, biostatisticians, technology transfer experts, and military and civilian orthotics and prosthetics consumers. Funding recommendations were made during programmatic review in April 2015 by the SWG based on the following programmatic review criteria specified in the PA:

- Ratings and evaluations of the reviewers, and
- Relevance to the mission of the DHP, CDMRP, and the OPORP as evidenced by the following:
  - Adherence to the intent of the award mechanism;
  - Military relevance;
  - Program portfolio composition;
  - Relative impact; and
  - Relative transition potential.

The SWG recommended funding 11 of the 50 peer reviewed FY14 OPORA applications for a total investment of approximately $9.33M. The submission response, funding recommendations, and initial PI requested budgets[1] for the OPORA are summarized in **Table 1**.

[1] PI requested budgets often differ from the final award amounts mainly due to cost savings realized during pre-award negotiations.

Table 1. FY14 OPORP OPORA Submission Responses and Recommendations

FY14 OPORA PA	Compliant Pre-Applications Received	Pre-Applications Invited to Submit Full Applications	Compliant Applications Received	Applications Recommended for Funding (%)	PI Requested Budget
Funding Level 1	68	42	33	8 (24.2%)	$3,978,800
Funding Level 2	34	20	17	3 (17.6%)	$5,354,298
Totals	***102***	***62***	***50***	***11 (22.0%)***	***$9,333,098***

Tables 2 and 3 summarize the FY14 OPORP OPORA, including information on the award recipient, a description of the project highlighting the anticipated effect on patient care, and the final awarded amounts after negotiations.

Table 2. FY14 OPORP OPORA Funding Level 1 Projects (Total Investment of $3,881,617 for 8 Projects)

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
1.	Determining Clinically Relevant Changes in Community Walking Metrics to Be Tracked by the VA as Part of Routine Care in Lower Limb Amputee Veterans	Modus Health, LLC Washington, DC	The objective of this study is to define clinically meaningful change in the walking function of lower limb prosthetic users in order to assess whether a patient is improving or declining in function over time. Research has indicated that patients with similar actual walking function may perceive their walking function very differently making self-report in some patients unreliable. A new Department of Veterans Affairs (VA) initiative supports the use of activity monitors to collect specific community walking metrics to address this issue. However, little is known about the natural fluctuations in these walking metrics from week-to-week when walking function is stable, versus clinically relevant changes in walking function. Therefore, it will be important to define meaningful change in walking function when interpreting the impact of prosthetic components, rehabilitation, and other treatments on real world walking. The specific aims of this study are 1) to determine small meaningful change in the community metrics and 2) to determine substantial meaningful change in the community metrics.	$465,470

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
2.	An Instrumented Ankle-Foot Orthosis that Quantifies Clinical Diagnostic and Performance Measures for "Tuned" Walking	Georgia Tech Research Corporation Atlanta, GA	Many veterans and civilians are burdened with lower leg walking difficulties as the result of disease or trauma, with drop foot being one of the most common conditions requiring medical intervention and rehabilitation. Drop foot is a general term that describes a difficulty with the voluntary ability to lift the foot toward the shin, which can have a profound impact on mobility. To assist persons with drop foot, ankle foot orthoses (AFOs) are prescribed by orthotists. AFOs are lightweight, rigid shells or frames that attach to the ankle and foot to assist the user in maintaining the desired alignment of the ankle and foot for safe and functional walking. Although AFOs are regularly fitted on patients by orthotists, the procedure by which the AFO is fitted and customized is currently tradecraft and relies on the subjective judgment of the orthotist. In this study, patients with drop foot will receive the exact "dosage" of ankle stiffness required for getting the best assistance during their normal walking activities. The device parameters will be adjusted such that the mechanics of their movement will be as natural and efficient as possible. As a result, they will be able to walk faster, for longer distances, and for longer time periods without tiring, and will be better-equipped to navigate stairs and hills.	$497,697

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
3.	SSMART: Smart Sock Manufactured for Amputee Rehabilitation and Comfort	Florida State University Tallahassee, FL	The objective of this project is to develop a patient-friendly solution and test its efficacy to one of the most challenging problems faced by lower extremity amputees: daily volume changes of the residual limbs. Such change is one of the most difficult challenges to overcome when fitting a socket to an amputee because the socket is made of rigid materials and has very little to "give." This leads to adverse conditions such as pistoning (degree of motion in and out of the socket), skin abrasions and lesions, discomfort, and deteriorating limb health. The solution to be assessed in this project is a smart prosthetic sock (SSMART sock). The SSMART sock can automatically adjust its volume and shape in response to the residual limb change to always ensure proper fit. The SSMART sock is also extremely lightweight and has excellent cushioning capability for additional comfort and protection while allowing the freedom of limb movement. The SSMART sock will also have lightweight pressure sensors to monitor the pressure at the residual limb prosthesis interface. The efficacy of the SSMART sock will be evaluated by amputee volunteers and their feedback will be used to refine the technology and improve its performance.	$500,000

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
4.	Determining the Potential Benefit of Powered Prostheses	University of Michigan Ann Arbor, MI	Several active ankle-foot systems are being designed to provide external power during the push-off phase of gait. These devices have not yet been critically evaluated to determine their effectiveness during extended walking. Although the devices provide mechanical power, it is not clear whether the user effectively incorporates that power to reduce biological muscle requirements. The outcomes of this study will provide much needed insight into the effectiveness of such devices in people with transtibial amputation. The results will help to make future recommendations for clinicians who choose which device to provide a patient, funding agencies, such as Medicare, who decide what devices are covered, and those who design prosthetic technology.	$499,194
5.	A Novel Prosthetic Foot Designed to Maximize Functional Abilities, Health Outcomes, and Quality of Life in People with Transtibial Amputation	University of Washington Seattle, WA	People with lower limb amputation may need multiple prostheses, one for running and one for walking, in order to achieve optimal outcomes across a range of activities. Acquiring and maintaining multiple prostheses may not be ideal for many people with lower limb amputation, especially Service members who seek return to active duty. The proposed research is intended to address the need for objective, high-quality evidence of the functional outcomes that may be expected with use of novel technology that integrates features of both running and walking designs. The results of this research may rapidly contribute to improved patient outcomes for Service members, veterans, and civilians with lower limb amputation.	$500,000

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
6.	The Use of Quantitative SPECT/CT Imaging to Assess Residual Limb Health	Walter Reed National Military Medical Center Bethesda, MD	New socket technologies are being developed to aid in the maintenance of tissue health in the residual limb. However, limited technologies are available to assess the impact of these sockets on the health of the residual limb. This 2-year pilot study will provide important preliminary data to assess the utility of noninvasive quantitative imaging as a means to evaluate residual limb health. This type of evidence-based research is becoming critical for insurance companies to pay for higher-priced devices that may provide greater benefits to patients. As such, results from the proposed study could significantly reduce cost and burden to the DoD and VA systems by providing justification towards the prescription of prosthetic socket technologies that are the most effective at promoting the overall health/tissue viability of the residual limb.	$484,964
7.	Dynamic Corrective Force Device: A Balance Measure for Amputees	Liberating Technologies, Inc. Holliston, MA	Falling and fear of falling have detrimental consequences including loss of independence, functional deficits or disability, reduced quality of life, and may result in a lack of confidence in, and the discontinued use of, a particular prosthesis. The PI proposes to use existing sensor technologies to develop a body worn sensor system to quantitatively assess balance during standing and walking. The proposed system would provide a means to obtain quantitative outcome measures which allow the clinician to provide the patient with prosthetic components that optimize the trade-off between stability and dynamic function, ultimately improving the patient's balance and confidence in the prosthesis. Outcome measures addressing falling and fear of falling can assure the amputee that he/she has the appropriate components to achieve maximum function with minimum loss of balance and may result in increased patient confidence and quality of life with a prosthesis.	$499,382

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
8.	Raman Spectroscopy and 3D Imaging as Decision Support Tools in the Assessment of Neuronal Fibrosis and Sarcopenia in Veterans and Combat Casualty Amputees	VA Medical Center Atlanta, GA	Probability of wound healing, prosthetic fit, and subsequent ambulation are not well understood; but the benefits of returning to ambulation are profound and include: improved quality of life, safety, return to occupational function, increased cardiovascular health (by decreased sedentary behavior), and decreased cost of care. The synergistic coupling of data regarding muscle quality and nerve fibrosis with noninvasive imaging techniques, such as computed tomography and Raman spectroscopy, provides a unique, patient specific, and biologically-based approach to better understanding the likelihood of ambulating after major amputation. The PI proposes to use this data from combat casualty and veteran patients to generate objective metrics for determination of patients at risk for reduced ambulation and poor prosthetic fit by identifying the relationship between nerve damage and scarring with muscle wasting. This may result in an improved likelihood and quality of ambulation and overall patient population health and well-being by protecting muscle mass and improving mobility.	$434,910

Table 3. FY14 OPORP OPORA Funding Level 2 Projects (Total Investment of $5,335,579 for 3 Projects)

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
1.	Improved Training Program for Fall Prevention of Warfighters with Lower Extremity Trauma	Mayo Clinic and Foundation Rochester, NY	After standard rehabilitation for amputation or limb salvage, many Service members still struggle with falls, which can exacerbate physical and emotional injury and delay healing. When individuals trip or slip, they are still likely to fall and injure themselves, in spite of advances in rehabilitation care. This project describes a secondary rehabilitation program, implemented after traditional therapy, designed to reduce falls in Service members with amputations or salvaged limbs. The PI's previous research has demonstrated that training with a novel technology and method significantly reduces fall risk and the probability of fall-related injuries in active-duty Service members with unilateral amputations. The goals of this work are to augment existing rehabilitation by providing fall-prevention training, to help Service members return to full high-level functional capabilities and emotional wellness, and to shorten the time required to return to active duty or to a productive, active civilian life.	$3,145,058

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
2.	The Effect of a Microprocessor Prosthetic Foot on Function and Quality of Life in Transtibial Amputees Who Are Limited Community Ambulators	VA Medical Center Memphis, TN	One of the newest prosthetic feet on the market is the microprocessor controlled prosthetic foot (MPF) designed to raise the toe when stepping forward which, theoretically, should make walking easier and safer by reducing the risk of falling. Unfortunately, the MPF is currently not prescribed for the typically-functioning below-knee amputee because of guidelines that limit its prescription to higher functioning individuals. The purpose of this study is to determine if exchanging a typically prescribed prosthetic foot for an MPF will provide a suitable alternative for veteran amputees and improve their walking efficiency, safety, and quality of life.	$1,492,522

No.	Project Title	Performing Organization	Project Description	Final Budget Awarded
3.	Comparing Running-Specific and Traditional Prostheses During Running: Assessing Performance and Risk	Regis University Denver, CO	Returning to running is a main goal of many Service members after they have a lower limb amputation because they want to reach their highest level of function and/or to return to duty. Individuals with lower extremity amputation (ILEA) may run with running-specific prostheses (RSPs) or traditional prostheses (designed for walking). RSPs are assumed to have advantages over running with traditional prostheses, but no direct comparisons of people running with both prosthesis designs have been made. Additionally, some research has shown that running with prostheses may put ILEA at a greater risk for injury than people without amputations. This research has focused on injury risks when running with RSPs, but it is unknown whether these risks are amplified or reduced when running with traditional prostheses. Consequently, direct comparisons of RSPs and traditional prostheses during running are needed to guide clinicians and administrators on both performance and injury risks related to training with and using these devices for recreation and/or combat. The purpose of this project is to provide clinical, administrative, and field relevant objective running outcomes by directly comparing the running biomechanics of ILEA using RSPs and traditional prostheses across a wide range of speeds.	$697,999