AWARD NUMBER: DM170709

TITLE: Optimizing Orthotic and Prosthetic Components for Military Women with Limb Salvage or Amputation

SITE PRINCIPAL INVESTIGATOR: Trevor Kingsbury

RECIPIENT: Naval Medical Center San Diego,
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PREPARED FOR: U.S. Army Medical Research and Materiel Command
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13. SUPPLEMENTARY NOTES

14. ABSTRACT: Int repid Dynamic Exoskeletal Orthoses (IDEO) and Running-Specific Prostheses (RSPs) hav e been designed to allow people with lower extremity limb salvage (LS) and transtibial am putations (TTA) to more effectively run, an activity used to improve fitness and health, and to assess physical endurance in military populations. Exercise such as running is ex tremely important for and strongly associated with quality of life. Moreover, compared to us e of conventional orthoses and prostheses, use of IDEOs and RSPs has resulted in si gnificantly higher functional ability and quality of life for service members with LS and TTA. H owever, existing practices use a trial-and-error approach for prescription based on a male c ohort and do not necessarily optimize performance and satisfaction for women service m embers. Our goals are to determine the optimal IDEO and RSP components and develop q uantitative guidelines for prescribing orthoses and prostheses for running in women service m embers with LS and TTA so that these women can regain the greatest possible level of f unctional ability and return to an active lifestyle and/or active duty. The purpose of this study is to determine the physiological and biomechanical effects of using different IDEO and RSP st iffness and weight in women service members with LS or TTA, which will maximize r ecovery, restore function, and improve quality of life for women with LS or TTA. The specific g oal s of this project are: 1.Verify inter- and intra-session reliability of the Naval Medical Center San Diego Gait Analysis/Biomechanics Laboratory and VA Applied Biomechanics Lab. 2. Quantify metabolic rates, biomechanics, and satisfaction of running in 10 females with unilateral LS using IDEOs with different stiffness and weight. 3. Quantify metabolic rates, biomechanics, and satisfaction of running in 10 females with unilateral TTA using RSPs with different stiffness and weight. 4. Based on Specific Aims 2 and 3, we will disseminate evidence-based IDEO and RSP prescription and design guidelines for women with LS or TTA through public presentations and peer-reviewed publications.

15. SUBJECT TERMS: NONE LISTED

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PROJECT: "Optimizing Orthotic and Prosthetic Components for Military Women with Limb Salvage or Amputation"

TABLE OF CONTENTS:

	Page
1. Introduction	4
2. Keywords	4
3. Accomplishments	5-12
4. Impact	13-14
5. Changes/Problems	14-15
6. Products	16-18
7. Participants & Other Collaborating Organizations	18-19
8. Special Reporting Requirements	20
9. Appendices: None	20

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Intrepid Dynamic Exoskeletal Orthoses (IDEO) and Running-Specific Prostheses (RSPs) have been designed to allow people with lower extremity limb salvage (LS) and transtibial amputations (TTA) to more effectively run, an activity used to improve fitness and health, and to assess physical endurance in military populations. Exercise such as running is extremely important for and strongly associated with quality of life. Moreover, compared to use of conventional orthoses and prostheses, use of IDEOs and RSPs has resulted in significantly higher functional ability and quality of life for service members with LS and TTA. However, existing practices use a trial-and-error approach for prescription based on a male cohort and do not necessarily optimize performance and satisfaction for women service members. Our goals are to determine the optimal IDEO and RSP components and develop quantitative guidelines for prescribing orthoses and prostheses for running in women service members with LS and TTA so that these women can regain the greatest possible level of functional ability and return to an active lifestyle and/or active duty. The purpose of this study is to determine the physiological and biomechanical effects of using different IDEO and RSP stiffness and weight in women service members with LS or TTA, which will maximize recovery, restore function, and improve quality of life for women with LS or TTA. The specific goals of this project are:

1. Verify inter- and intra-session reliability of the Naval Medical Center San Diego Gait Analysis/Biomechanics Laboratory and VA Applied Biomechanics Lab.
2. Quantify metabolic rates, biomechanics, and satisfaction of running in 10 females with unilateral LS using IDEOs with different stiffness and weight.
3. Quantify metabolic rates, biomechanics, and satisfaction of running in 10 females with unilateral TTA using RSPs with different stiffness and weight.
4. Based on Specific Aims 2 and 3, we will disseminate evidence-based IDEO and RSP prescription and design guidelines for women with LS or TTA through public presentations and peer-reviewed publications.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Running-Specific Prosthesis (RSP), Intrepid Dynamic Exoskeletal Orthotic (IDEO), Military Women's Health, Injury Prevention, Running, Clinical Optimization

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. *If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.*

Statement of Work Tasks

Major Task 1: Inter-site test setup verification (Milestone 1)

Subtask 1.1: Regulatory review and approval for all experiments
Target: months 1-6
Year 1, 1st Quarter Report: Nothing to report.
Year 1, 2nd Quarter Report: Funding was received and put on contract with Leidos, initiation of a subcontract with Denver Research Institute was started. The PI on the project retired and a PI change letter was submitted. IRB documents were compiled in preparation for submission to the NMCSD and CU IRBs.
Year 1, 3rd Quarter Report: IRB approval was received at CU in late November and was subsequently submitted to HRPO. IRB application was submitted at NMCSD and will go to board next quarter.
Year 1, 4th Quarter Report: IRB was reviewed at NMCSD and is pending CO signature. HRPO approval for CU is still pending at this time but is expected in early year 2, quarter 1. The subcontract with DRI is tentatively approved with a start date for work to be done at CU of February 1, 2019.
Year 2, 1st Quarter Report: IRB is still awaiting signature from the CO at NMCSD, once the approval letter is issued, HRPO approval can commence. Contracting mechanism for the project hit ceiling and a new contract is currently being established with NMLC. As of 6/10 NMLC cannot procure funds in FY19 and are requesting that funding be reissued for the next budget year.
Year 2, 2nd Quarter Report: NMCSD de-obligated the funds on 6/17 and returned the FY19 money. The contracting office at NMCSD assured the PI that as early at 10/1 NMLC could quickly execute FY20 funds upon receipt. IRB approval was granted at NMCSD and HRPO review is pending. T
Year 2, 3rd Quarter Report: Navy Medicine West Received FY20 funding on November 4, 2019. NMCSD received HRPO approval on November 5, 2019. NMCSD received funding on November 26, 2019.
Year 2, 4th Quarter Report: The requirements for a new contract were submitted and received by NMLC on January 8th, 2020. At the time of this report the package is still in queue at NMLC.

Sub task 1.2: Recruit and schedule 6 patients studied at both sites
Target: months 7-8

Year 1, 1st Quarter Report: Nothing to report
Year 1, 2nd Quarter Report: Nothing to report
Year 1, 3rd Quarter Report: Established telecons between University of Colorado and NMCSD to discuss collection protocols, travel logistics, and potential roadblocks.
Year 1, 4th Quarter Report: Had a planning meeting in San Diego where logistics of travel and data collection were discussed. NMCSD team constructed a list of potential subjects familiar to the lab from clinical affiliation and each were assessed for DEERS eligibility and meeting inclusion criteria.
Year 2, 1st Quarter Report: Nothing to report
Year 2, 2nd Quarter Report: Nothing to report
Year 2, 3rd Quarter Report: The first subject was recruited, consented, and tested at CU Boulder on December 13/14. Mr. Kingsbury was in Boulder at the time of collection and a simultaneous site visit/kickoff meeting was held. Patient was retested at NMCSD on January 9th for the repeatability component of the study.
Year 2, 4th Quarter Report: Nothing to report – travel restrictions preventing possible recruitment activities.

Subtask 1.3: Collect biomechanical, metabolic, satisfaction data from running
Target: months 8-10

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming

Year 2, 3rd Quarter Report: The first subject was recruited, consented, and tested at CU Boulder on December 13/14.
Year 2, 4th Quarter Report: Nothing to report

Subtask 1.4: Analyze and verify the inter-site setup and data
Target: months 8-11

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Milestone 1 Goal: Milestone Achieved: Publish and disseminate results
Target: months 8-11

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Major Task 2: Determine effects of using the Intrepid Dynamic Exoskeletal Orthotic (IDEO) with different stiffness & weight in 10 females with limb salvage (LS) for running (Milestone 2)

Subtask 2.1: Recruit female patients with LS
Target: months 11-16
Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Sub task 2.2: Collect biomechanical, metabolic, satisfaction data from running
Target: months 12-20

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

What were the major goals of the project? (continued):

Subtask 2.3: Analyze data from runners with limb salvage
Target: months 20-22

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Subtask 2.4: Publication, dissemination and clinical implementation
Target: months 22-30

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Milestone 2 Goal: Milestone Achieved: Publish and disseminate results
Target: months 22-30

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Major Task 3: Determine effects of using a running-specific prosthesis (RSP) with different stiffness & weight in 10 females with transtibial amputation for running (Milestone 3)

Subtask 3.1: Recruit female patients with TTA
Target: months 22-26
Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: One female patient with an amputation was recruited and studied at CU Boulder testing all stiffness and weight conditions.
Year 2, 4th Quarter Report: Nothing to report

Sub task 3.2: Collect biomechanical, metabolic, satisfaction data from running
Target: months 23-31

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: One female patient with an amputation was recruited and studied at CU Boulder testing all stiffness and weight conditions.
Year 2, 4th Quarter Report: Nothing to report

Subtask 3.3: Analyze data from runners with transtibial amputation
Target: months 30-33

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Subtask 3.4: Publication, dissemination and clinical implementation
Target: months 30-33

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Milestone 3 Goal: Milestone Achieved: Publish and disseminate results
Target: months 30-33

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Major Task 4: Using data from Aims 2 & 3, disseminate evidence-based prescription & design guidelines for women with LS and TTA (Milestone 4)

Subtask 4.1: Compile, analyze, and disseminate results from Specific Aims 2 and 3
Target: months 33-36
Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

Milestone 4 Goal: Milestone Achieved: Dissemination of prescription & design guidelines
Target: month 36

Year 1, 1st Quarter Report: Activity upcoming
Year 1, 2nd Quarter Report: Activity upcoming
Year 1, 3rd Quarter Report: Activity upcoming
Year 1, 4th Quarter Report: Activity upcoming
Year 2, 1st Quarter Report: Activity upcoming
Year 2, 2nd Quarter Report: Activity upcoming
Year 2, 3rd Quarter Report: Activity upcoming
Year 2, 4th Quarter Report: Activity upcoming

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Noteworthy Period of Performance activities:

Year 1, 1st Quarter Report: Awaiting acceptance of funds.

Year 1, 2nd Quarter Report: Funding was received at Naval Medical Center San Diego on July 27, 2018. Money was put on contract #N62645-17-F-0520 with Leidos on August 1. On August 31, 2018, the PI Marilynn Wyatt retired. Work was done to change the PI on the project to Trevor Kingsbury. Leidos hired Mr. John Collins to serve as the Biomechanist at NMCSD for the project on September 10, 2018.

Year 1, 3rd Quarter Report: IRB was approved at the University of Colorado Boulder on November 26, 2018. Difficulty in establishing subcontract with Denver Research Institute, as a result funding not release for Dr. Grabowski to begin work.

Year 1, 4th Quarter Report: IRB was submitted and awaiting CO signature for approval at NMCSD. University of Colorado Boulder submitted IRB to HRPO for approval. Awaiting approval as of this reporting date. Dr. Grabowski met with the research team in San Diego for a planning session where NMCSD staff evaluated lists of potential subjects that were known to the research team.

Year 2, 1st Quarter Report: IRB is still awaiting signature from the CO at NMCSD, once the approval letter is issued, HRPO approval can commence. Contracting mechanism for the project hit ceiling and a new contract is currently being established with NMLC.

Year 2, 2nd Quarter Report: NMCSD de-obligated the funds on 6/17 and returned the FY19 money. The contracting office at NMCSD assured the PI that as early at 10/1 NMLC could quickly execute FY20 funds upon receipt. IRB approval was granted at NMCSD and HRPO review is pending.

Year 2, 3rd Quarter Report: Navy Medicine West Received FY20 funding on November 4, 2019. NMCSD received HRPO approval on November 5, 2019. NMCSD received funding on November 26, 2019. The first subject was recruited, consented, and tested (Aims 1&3) at CU Boulder on December 13/14. Mr. Kingsbury was in Boulder at the time of collection and a simultaneous site visit/kickoff meeting was held.

Year 2, 4th Quarter Report: The requirements for a new contract were submitted and received by NMLC on January 8th, 2020. Abstracts for the American Society of Biomechanics and Military Health Systems Research Symposium 2020 meetings were written and on track for submission. Further patient recruitment is halted due to COVID-19 travel restrictions. Due to need to travel every patient to site(s) for testing, no patients are being actively recruited at this time. CU Boulder is closed to staff and students and only essential care is being delivered at NMCSD.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

1. Study PI attended Military Health System Research Symposium (MHSRS) and attended breakout sessions where women's health research was discussed (August 2018)
2. NMCSD staff received onsite training for the Parvo metabolic cart (January 2019)
3. Study PI(s) and AI(s) attended American Society of Biomechanics and Military Health System Research Symposium and attended breakout sessions where women's health research was discussed (August 2019)

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Abstracts looking at the strut stiffness of the IDEO braces were prepared for American Society of Biomechanics and MHSRS 2020 meeting scheduled for August 2020.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Year 3 Quarter 1: 1 March 2020 - 31 May 2020

- Contact potential patients for future recruitment pending COVID-19 restrictions.
- Reach out to other MTFs to assist in subject recruitment (specifically WRNNMC).

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report

Background: Currently, there are no science-based objective methods for prescribing lower extremity orthotic or prosthetic components for women service members with limb salvage (LS) or transtibial amputations (TTA) who wish to run. Existing clinical practices use a trial-and-error approach for prescription and use Intrepid Dynamic Exoskeletal Orthotic (IDEO) or Running-Specific Prosthetic (RSP) components that are based on males, but do not necessarily optimize performance for female service members. Our overall goal is to optimize the prescription and design of IDEO and RSP components for women so that female service members with LS or TTA can regain the greatest possible level of functional ability and return to an active lifestyle and/or active duty. The results of our clinical rehabilitation research will allow Military Treatment Facility (MTF) and Department of Veterans Affairs (VA) orthotists and prosthetists to provide the best possible rehabilitation for female service members, restoring functional ability while reducing the need to re-fit and re-prescribe IDEOs and RSPs; thus directly improving short-term health and rehabilitation for military women. Our results will also inform the design and may change the manufacturer-recommended components of IDEOs and RSPs, which could provide long-term functional benefits that would improve military women's health. Our proposed research has direct relevance to improving the health, rehabilitation, functional ability, performance, and quality of life for female service members who have sustained orthopaedic injuries during military combat or combat-related activities, and to expediting their return to work/duty following lower extremity trauma.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report." Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. **CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Year 1, 2nd Quarter: PI Marilynn Wyatt retired. Work was done to change the PI of the project at NMCSD. Year 2, 4th Quarter: New contract is pending at NMLC, NMCSD currently has no staff assigned to project. COVID-19 has closed CU Boulder to staff and students, all non-essential travel has been halted. No subject recruitment is possible.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Year 1

Year 1, 1st Quarter: Awaited funding, no work was done on project.
Year 1, 2nd Quarter: Money was put on contract on August first and staff was hired at NMCSD on September 10, effectively shifting the initiation of the project at NMCSD by six months.
Year 1, 3rd Quarter: The terms of the subcontract with DRI are still pending. As of this time, DRI is refusing the terms of the contract and will not accept funds. As a result no funded work can begin at CU. At NMCSD IRB delays are impacting the ability of the project to receive full approval.
Year 1, 4th Quarter: Terms of the subcontract with DRI will potentially allow funded work to start at CU in February, creating an 11 month delay. The IRB at NMCSD is still awaiting the signature of the CO.

Year 2

Year 2, 1st Quarter: NHRC contract hit ceiling, NMLC is unable to procure contract with FY19 funds.
Year 2, 2nd Quarter: FY19 funds were returned and FY20 funds issued
Year 2, 3rd Quarter: None
Year 2, 4th Quarter: New contract is pending at NMLC, NMCSD currently has no staff assigned to project. COVID-19 has closed CU Boulder to staff and students, all non-essential travel has been halted. No subject recruitment is possible. No timeline currently exists for resumption of recruitment.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

At present no contract exists at NMCSD for staffing, once the contract is in place and non-essential travel is approved to travel subjects to the sites for testing a high volume of work is anticipated, possibly starting quarter 2 in year 3.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

. Nothing to report.

Significant changes in use or care of vertebrate animals

Swine model eliminated from study

Significant changes in use of biohazards and/or select agents

Not Applicable

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

None to report at this time

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

None to report at this time

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Intended presentations at ASB and MHSRS 2020 meetings

- **Website(s) or other Internet site(s)**
List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Not Applicable

- **Technologies or techniques**
Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

None to report

- **Inventions, patent applications, and/or licenses**
Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Not Applicable

- **Other Products**

  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life.

None to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name: Trevor Kingsbury, MA
Project Role: Primary Investigator
Nearest Person Month worked 2
Contribution to Project: Mr. Kingsbury is be responsible for guiding the protocol through the IRB, HRPO, and other regulatory approval processes, coordinating activities across participating study sites, and coordinating participant accrual at NMCSD.

Name: Alena Grabowski, PhD
Project Role: Associate Investigator
Nearest Person Month worked 2
Contribution to Project: Dr. Grabowski is the site PI at CU Boulder and is responsible for all regulatory documents locally and through HRPO. She leads the data collection and be in charge of all staff at her lab.

Name: John David Collins, MA, ATC
Project Role: Associate Investigator
Nearest Person Month worked 4
Contribution to Project: Mr. Collins has been instrumental in preparation of regulatory documents and identifying potential subjects from prior clinical experience. He provides oversight to research activities at NMCSD and acts as the liaison between research sites. He also collects and processes data at NMCSD.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

University of Colorado at Boulder - Boulder, CO
Contributions:
Collaboration: Dr. Grabowski and her team are research collaborators on the project. They are a current data collection site and have approved IRB protocols at their local IRB board as well as HRPO.

8. SPECIAL REPORTING REQUIREMENTST

QUAD CHARTS:

Optimizing Orthotic and Prosthetic Components for Military Women with Limb Salvage or Amputation

CDMRP Clinical Research Intramural Initiative Military Women's Health Research Award
DHA-17-CRII-MWHRA

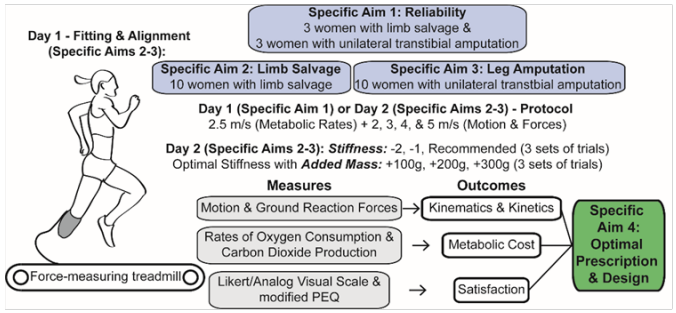
PI: Trevor Kingsbury **Org:** Naval Medical Center San Diego **Award Amount:** $749,869

Study/Product Aim(s)

Aim 1: Verify inter- & intra-session reliability of NMCSD & VA ECHCS labs.
Aim 2: Quantify metabolic rates, biomechanics, & satisfaction of running in 10 females with limb salvage (LS) using the Intrepid Dynamic Exoskeletal Orthotic (IDEO) with different stiffness & weight.
Aim 3: Quantify metabolic rates, biomechanics, and satisfaction of running in 10 females with unilateral transtibial amputation (TTA) using a Running-Specific Prosthesis (RSP) with different stiffness & weight.
Aim 4: Using data from Aims 2 & 3, disseminate evidence-based prescription & design guidelines for women with LS and TTA

Approach

- Provide clinical outcomes results to improve, guide,& develop women-specific orthotic and prosthetic technology.
- Use results to disseminate clinically relevant, evidence-based IDEO and RSP prescription and design guidelines.
- Provide patients with optimal prescription recommendations & function



Accomplishment: Overview of the experimental design. We will measure reliability between sites (Specific Aim 1), the effects of IDEO and RSP stiffness and weight (Specific Aims 2 and 3) to create evidence-based guidelines for women-specific orthotic and prosthetic prescription and design (Specific Aim 4).

Timeline and Cost
(Mar 2018 Start)

Activities CY	18	19	20
Obtain IRB approval			
Aim 1: Collect, analyze & publish data			
Aim 2: Collect, analyze & publish data			
Aim 3: Collect, analyze & publish data			
Aim 4: Disseminate guidelines			
Estimated Budget ($K)	**$273**	**$245**	**$232**

Updated: 3/1/2019

Goals/Milestones

CY18 Goal – IRB approval for Aims 1-3, Local & CDMRP IRB approval
CY18-19 Goal – Inter- & intra-session reliability
☐ Complete experimental trials
☐ Analyze, publish, and disseminate results
CY19-20 Goal – Quantify effects of IDEO stiffness & weight for running
☐ Complete experimental trials
☐ Analyze, publish, and disseminate results
CY19-20 Goal - Quantify effects of RSP stiffness & weight for running
☐ Complete experimental trials
☐ Analyze, publish, and disseminate results
CY20 Goal – Disseminate Guidelines
☐ Present at conferences and educational seminars
☐ Publish results in manuscripts
Comments/Challenges/Issues/Concerns: Subcontract delays
Budget Expenditure to Date: Projected Total: $749,869; Actual: $ 518, 243

9. APPENDICES: None