AWARD NUMBER: W81XWH-15-1-0470

TITLE: The Effect of a Microprocessor Prosthetic Foot on Function and Quality of Life in Transtibial Amputees Who Are Limited Community Ambulators

PRINCIPAL INVESTIGATOR: Audrey Zucker-Levin

CONTRACTING ORGANIZATION: University of Tennessee, Health Science Center, Memphis, TN 38163

REPORT DATE: September 2016

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
September 2016	Annual	01 Sep 2015 – 31 Aug 2016

4. TITLE AND SUBTITLE
The Effect of a Microprocessor Prosthetic Foot on Function and Quality of Life in Transtibial Amputees Who Are Limited Community Ambulators

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-1-0470

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Phyllis A. Richey,PhD. and Audrey Zucker-Levin, PhD, PT, GCS Emeritus (Joint-PIs)

E-Mail: prichey@uthsc.edu; azuckerl@uthsc.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

UNIVERSITY OF TENNESSEE
62 S DUNLAP STREET RM 300
MEMPHIS TN 38103-4903

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. Participants in the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6-month period of time in addition to receiving physical therapy training. All outcome measures will be evaluated three times during the 6 month study period. Onc HRPO approval for the project was received in April 2016, initial recruitment efforts via Partner Prosthetic clinics was undertaken and identified over 700 potentially eligible individuals, 40 of whom are veterans. Similar efforts with the Regional DAV are also in progress. Active recruitment began in July 2016 that has yielded 9 individuals screened for eligibility and 1 enrolled/randomized Recruitment, enrollment/randomization will continue in the coming quarter/year.

15. SUBJECT TERMS
Trans-tibial amputee (TTA), microprocessor controlled prosthetic foot (MPF), randomized clinical trial, functional performance, ambulatory safety, falls, quality of life, community ambulator

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	17	19b. TELEPHONE NUMBER *(include area code)*

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

This project is a 2-arm, parallel, randomized, controlled clinical trial designed to determine if a microprocessor controlled prosthetic foot (MPF), with greater range of motion and active power, will translate into improved functional performance, ambulatory safety (risk of falls) and quality of life in trans-tibial amputees (TTA) who function as limited community ambulators. We will assess these outcomes in 54 veterans with TTA by randomizing participants, in a 1:1 ratio, into an intervention and a comparison group. The blocked randomization schedule will be generated by a computer program with a block size of 4; this will guarantee that we have approximately the same number of participants in each treatment group throughout the trial. Participants in the intervention group will receive an MPF, while the comparison group will continue with their currently prescribed prosthetic foot. All participants will be followed with weekly contact over a 6 month period of time and receive physical therapy training to minimize deviations resulting from habit or lack of training, education to maximize use of the mechanical properties of their current foot, strengthening and stretching based on published guidelines for TTA, balance training and training on traversing environmental barriers. All outcome measures will be evaluated three times during the 6 month study period: At baseline, at the 3-month follow up visit and at the 6 month follow up visit. We believe the immediate benefit of this project will determine if an innovative MPF, designed to facilitate toe clearance by optimizing ankle angle and foot position, will improve functional performance, ambulatory safety (risk of falls), and quality of life in the typical veteran amputee. This study will also have significant long term benefit for all typical amputees, both veterans and the general public, as they face medical, social and psychological complications associated with falling (broken bones, head trauma, depression, social isolation and death), decreased function and poor quality of life that directly impacting their families and caregivers.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).
Trans-tibial amputee (TTA)
Microprocessor controlled prosthetic foot (MPF)
Randomized clinical trial
Functional performance
Ambulatory safety
Falls
Quality of life
Community ambulator

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

The major goals of this project as stated in the approved SOW are as follows:

1. Perform Preliminary Study Requirements (Months 1-6)
2. Recruit, Coordinate and Train Study Personnel for Clinical Trial (Months 3-6)
3. Participant Recruitment, Phone (Pre-) Screening, Screening Eligibility Baseline Randomization Evaluations (Months 7-24)
4. Participant Randomization (Months 7-24)
5. Participant Fit with Microprocessor Foot; Intervention Group (N=27; Months 7-24)
6. Physical Therapy Sessions and Prosthesis Accommodation Period (N=54; Months 7-24)
7. 3-Month Follow Up Visit and Prosthesis Accommodation Period (N=54; Months 10-27)
8. 6-Month Follow Up Visit and subject closure (N=54; Months 10-30)
9. Data Analysis/Dissemination of Findings (Months 28-36)
10. Assess Prosthesis related quality of life (N=54; Months 7-36)

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.

1. Perform Preliminary Study Requirements (Months 1-6)
    a. Prepare study documents and apply for Local IRB (UTHSC) and USAMRM Human Research Protection Office (HRPO) approval- Complete, HRPO approval received Apr 5, 2016.
        - Updated consent form submitted Apr 26, 2016- Approved May 5, 2016
    b. Complete Manual of Operations finalizing procedures sections and forms for recruiting and reporting – completed May 2, 2016
    e. Develop database management system – completed May 26, 2016
    f. Develop and finalize all study data collection forms - May 2, 2016
    g. Submit amendments, adverse events and protocol deviations – None to report.
    h. Maintain, update and perform data integrity test on study DBMS – In progress.

2. Train Study Personnel for Clinical Trial
   a. Train staff, evaluation physical therapist, treating physical therapist and prosthetists for project – completed May 27, 2016
      - Trial run through of Screening and Baseline visits for the study
      - Eligibility and Randomization training – Completed March 31, 2016
      - Adverse Events Training with Dr. Mihalko, MD – Completed April 1, 2016
   b. Develop participant recruitment materials – completed May 13, 2016
      - Participant Flyer - Completed Mar 16, 2016
      - Participant Flyer with Tear-offs – Completed Mar 16, 2016
      - Business Card – Completed Mar 16, 2016

3. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit (Months 7-24) – In Progress
   a. Participant recruitment – In progress, have performed initial targeted recruitment via Partner Prosthetic clinics and have begun the same with Regional DAV, to identify targeted mailings to prospective participants.
      - Identify prospective participants for targeted recruitment
      - Perform phone (pre-) screening, schedule qualifying participants to baseline session – In Progress
   b. Confirm pre-screening at in person Screening Eligibility Visit – In Progress
      - Sign informed consent
      - Evaluate functional level of participant
      - Evaluate fit of current prosthesis
   c. Participant Recruitment, Phone (Pre-) Screening, Screening Eligibility Evaluations – In Progress
   d. Baseline Randomization Evaluations – In Progress

4. Participant Randomization – In Progress

5. Participant Fit with Microprocessor Foot; Intervention Group – In Progress

6. Physical Therapy Sessions and Prosthesis Accommodation Period– In Progress

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.

During this reporting period we provided a 4 CEU professional development seminar for prosthetists in the Memphis area. The course titled "The VALOR Study: Introduction, Methodology and Technology, including the Proprio Foot," was offered by Ossur trainers on February 11, 2016 at the University of Tennessee Health Science Center.

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.

Nothing to Report

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.

During the next reporting period we will continue to perform the following actions to accomplish the goals and objectives listed:

1. Continue to perform ongoing study requirements
    a. Submit amendments, adverse events and protocol deviations as necessary
    b. Maintain, update and perform data integrity test on study DBMS
2. Participant recruitment, phone (pre-) screening, in person screening eligibility visit and baseline randomization visit
3. Participant Recruitment
4. Identify prospective participants for targeted recruitment
5. Confirm pre-screening at in person Screening Eligibility Visit
    a. Sign Informed Consent
    b. Confirm pre-screening in person
    c. Perform screening evaluation including evaluation of functional level of participant
    d. Evaluate prosthetic fit
6. Participant Randomization
    a. Randomize participants into Intervention (N=27) or Comparison (N=27) Groups
    b. Schedule visits for prosthetic clinics (Intervention group) and physical therapy visits
7. Participant Fit with Microprocessor Foot
    a. Provide participants randomized into Intervention group new prosthetic foot and train on use of foot during 2-4 prosthetic clinic over 2 week period

8. Physical Therapy Sessions and Prosthesis Accommodation Period 1
    a. Provide all participants 2 sessions per week of physical therapy for 4 weeks
    b. Provide weekly phone visits during 8 week accommodation period 1 to all participants in both groups
9. Perform 3-month evaluation
    a. Perform repeat of all baseline evaluation measures

10. Begin Prosthesis Accommodation Period 2
    a. Provide weekly phone visits during 12 week accommodation period 2 to all participants in both groups

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?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

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 Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

During this reporting period it was determined that one of our originally proposed recruitment strategies to contact potentially eligible participants from lists generated by the Veterans Administration VISN 9 Research Data Warehouse would not produce viable candidates who wear a prosthetic device, nor would it identify functional levels. Therefore, we changed our recruitment strategy to utilize the resources of our partner prosthetic clinics and the regional Disabled American Veterans (DAV) association. This strategy has been successful in identifying a large sample of potential participants that we are currently pursuing for study recruitment.

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.

During the current reporting period we experienced a delay in recruitment launch due to late HRPO approval (April 2016). We are addressing this delay by accelerating recruitment via Partner Prosthetic clinics. This process has produced identification of over 700 individuals, 40 of whom are veterans, to target for recruitment. Additionally, we have also been performing similar efforts collaborating with the Regional DAV to identify additional prospective participants for targeted mailings. This recruitment effort is proving to be successful and we anticipate continued success in yielding an appropriate volume that will result in meeting the desired enrollment/randomization number.

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.

As described above in actual delays during this reporting period, we experienced a significant delay receiving HRPO approval to initiate study recruitment. In response to this delay we choose to provide funding support to only the essential staff necessary during the study start up period. Therefore, only the joint PIs, Drs. Richey and Zucker-Levin, the previous study coordinator, Mrs. Middlekauff and current study coordinator, Mr. Hood were supported during that time, which produced a significant decrease in the expenditures anticipated during this reporting period. The delay in initiation of recruitment has also translated into a delayed expenditure of participant-related study items (e.g. Partner Prosthetic clinic expenses, the Proprio MPF, participant incentives, etc). By taking these expenditure-saving measures during this reporting period we will have the funds available in the coming reporting periods to fulfill the goals of this project.

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

None

Significant changes in use or care of vertebrate animals.

Not Applicable

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.

  Nothing to Report

- **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).*

  Nothing to Report

- **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).*

  Nothing to Report

- **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.*

  Nothing to Report

- **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.

  Nothing to Report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

  Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. 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.

  Nothing to Report

- **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. Examples include:

  - *data or databases;*
  - *biospecimen collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

During the current reporting period the study database has been developed as the informatics solution to support the day-to-day management of the study.

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."

Example:	
Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*

Name:	Phyllis Richey, PhD
Project Role:	Joint-Principal Investigator
Research Identifier:	1
Nearest person month worked:	12
Contribution to Project:	Dr. Richey is fulfilling the role of co-Principal Investigator as outlined in the SOW

Name:	Audrey Zucker-Levin, PhD, PT, GCS Emeritus
Project Role:	Joint-Principal Investigator
Research Identifier:	2
Nearest person month worked:	12
Contribution to Project:	Dr. Zucker-Levin is fulfilling the role of co-Principal Investigator as outlined in the SOW
Name:	Janet Middlekauff
Project Role:	Study Coordinator
Research Identifier:	3
Nearest person month worked:	9
Contribution to Project:	Mrs. Middlekauff has worked with IRB submissions, HRPO submissions, data collection form development, database development, data collection form development, and clinical trials.gov registration. Mrs. Middlekauff left the University as of May 15, 2016.
Name:	Matt Hood
Project Role:	Study Coordinator/Informatics
Research Identifier:	4
Nearest person month worked:	9
Contribution to Project:	Mr. Hood has worked on database development and data collection form development. Mr. Hood assumed the duties previously held by Mrs. Middlekauff as of May 16, 2016. These include: participant recruitment, screening, conducting evaluation visits, retention, and scheduling, prosthetic clinic communication and scheduling.

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.

We did experience a change in the key personnel of this study during the reporting period. Specifically, on March 16, 2016 we requested approval to remove Dr. Darryl Weiman, MD as key personnel from the project due to a change in the study recruitment strategy

(described in detail in section 5 above). This change resulted in utilizing the Disabled American Veterans organization's vast local and regional resources to facilitate recruitment of potential study participants in lieu of the resources of the Memphis Veterans Administration Medical Center (VAMC) originally proposed. Since Dr. Weiman's role as co-investigator for the study was specifically to coordinate the recruitment process within the VAMC, his involvement in the study was no longer needed. Dr. Weiman was to devote 2% effort for this role. In the same request we asked to add Dr. Catherine Womack, MD as key personnel to the study to serve as the internal medicine specialist responsible for adjudicating any participant eligibility decisions in which medical history and current health habits, e.g medication and/or substance use, depression status, etc., are in question. Dr. Womack is a practicing Internal Medicine physician and experienced clinical trials researcher with a history of serving in this capacity on federally funded grants, two of which are within military populations. Dr. Womack was designated as devoting an effort equal to that originally budgeted for Dr. Weiman for this role. Therefore, the project did not have a change in the budget allocation to support Dr. Womack's role.

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.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name:	CFI Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None

Organization Name:	Human Technology Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Precision Prosthetics, Inc.
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Spears Prosthetics and Orthotics
Location of Organization:	Memphis, TN
Partner's contribution to the project:	Partner Prosthetic Clinic
Financial support:	None
In-kind support:	None
Facilities:	Prosthetic fitting and training sessions for intervention group participants
Collaboration:	Certified prosthetists participate in screening eligibility visit by performing part of the inclusion/exclusion evaluation procedures
Personnel exchanges:	None
Other:	None
Organization Name:	Disabled American Veterans (DAV)
Location of Organization:	Tennessee
Partner's contribution to the project:	Assisting with recruitment
Financial support:	None
In-kind support:	None
Facilities:	None
Collaboration:	Dissemination study informational materials to potential participants
Personnel exchanges:	None
Other:	None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating PI and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

Not Applicable

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

Attached

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

N/A

The effect of a microprocessor prosthetic foot on function, safety and quality of life in trans-tibial amputees who are limited community ambulators.

PI's: Zucker-Levin, A.R. & Richey, P.A. **Org:** Tennessee, University of Health Science Center **Award Amount:** $1,492,955

Background: The vast majority (62%) of service member and veteran amputees are over 65 years of age and function as limited community ambulators at high risk for tripping and falling possibly due to the limited function of the traditional prosthesis they are prescribed. We hypothesize that a microprocessor controlled prosthetic foot would improve functional performance, ambulatory safety and quality of life in these low level functioning veterans.

Study Aims: Primary (3)

To determine if a microprocessor controlled prosthetic foot, with greater range of motion and active power, will improve functional performance (SA:1), Ambulatory Safety (SA:2), and Quality of Life (SA:3) in trans-tibial amputees who function as limited community ambulators.

Secondary Aim:

To determine if a microprocessor controlled prosthetic foot, with greater range of motion and active power, will improve prosthesis-related QOL in trans-tibial amputees who function as limited community ambulators.

3 Year Project Timeline

Activity	Year 1	Year 2	Year 3
Process/Approvals			
Recruitment/Evaluation			
Intervention			
3-month follow up			
6-month follow up			
Analysis/Dissemination			

Updated: (September 30, 2016)

Goals/Milestones (N=54 except where noted)

Year 1–

☑ Define processes/Obtain all approvals for safety and compliance.

☑ Begin participant recruitment and baseline evaluation including randomization into intervention and comparison groups

☑ Begin Prosthetic Fitting Period (2 weeks) intervention group (N=27)

☑ Begin 4 week Physical Therapy sessions for both groups

❑Begin 3 month follow up visits

❑Begin Accommodation phase 1 with weekly phone visits

Year 2–

❑Complete participant recruitment and evaluation

❑Complete Prosthetic Fitting Period and Physical Therapy Sessions

❑Continue 3 month and begin 6 month follow up visit

❑Complete accommodation phase 1

❑Begin accommodation phase 2 with weekly phone visits

Year 3–

❑Complete 3 and 6 month follow up visits

❑Complete accommodation phase 2

❑Complete data analyses

❑Disseminate findings in journal and conference venues