AWARD NUMBER: W81XWH-16-2-0059

TITLE: Development of Adaptive Vacuum Suspension to Improve Prosthetic Fit and Residual Limb Health

PRINCIPAL INVESTIGATOR: Dr. Chandan K. Sen

CONTRACTING ORGANIZATION: TRUSTEES OF INDIANA UNIVERSITY INDIANA UNIVERSITY
980 INDIANA AVE RM 2232
INDIANAPOLIS IN 46202-5130

REPORT DATE: OCTOBER 2019

TYPE OF REPORT: Annual Report (Year 3)

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**
October 2019	Annual	30 Sep 2018 - 29 Sep 2019

4. TITLE AND SUBTITLE

Development of Adaptive Vacuum Suspension to Improve Prosthetic Fit and Residual Limb Health

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-16-2-0059

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Dr. Chandan K. Sen

Email:

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

TRUSTEES OF INDIANA UNIVERSITY INDIANA UNIVERSITY
980 INDIANA AVE RM 2232

INDIANAPOLIS IN 46202-5130

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 multi-institutional application addresses the FY15 PRORP Clinical Trial Award Focus Area of Prosthetic and/or Orthotic Device Function and targets military combat related orthopaedic injuries that significantly impact unit readiness and return-to-duty/work rates. The project calls for the rapid implementation of clinical trials focusing on the development and optimization of novel technologies that improve prosthesis function to reduce secondary physical health effects associated with using a prosthetic limb such as limb injury and osteoarthritis through: (1) real-time adaptation of prosthesis suspension in response to user activity level, (2) monitoring and adjusting prosthesis suspension to preserve residual limb health, and (3) providing end-user and prosthetist feedback on metrics of prosthesis performance. Current techniques for fitting a prosthetic socket lack quantitative measures. Prosthetists aim to limit movement inside the socket; however, the degree of movement is determined by visual inspection by the prosthetist. Further, limited research has been conducted to determine the relationship between movement of the limb inside the socket and limb health. Previously, project team members developed novel technologies to monitor movement at the socket interface using elevated vacuum suspension pressure data, innovative techniques to quantify changes in the residual limb health in response to prosthetic suspension, and functional performance expertise using a variety of modalities that will be leveraged in this research. Objective/Hypotheses/Specific Aims: The overall objective of proposed studies is to develop an adaptive socket system that detects in-socket residual limb motion and dynamically adjusts internal socket negative pressure to optimize fit and performance. Specific Aim 1: Test relationship of pressure variance waveforms with residual limb movement in-socket. Hypothesis 1: Pressure data will detect distal displacement and lateral shift of the residual limb inside the socket. Specific Aim 2: Characterize the effects of residual limb movement in-socket on residual limb health. Hypothesis 2: Increased socket motion decreases residual limb perfusion and disrupts skin barrier function. Specific Aim 3: Compare the long-term effects of adaptive EVS to pin-locking and suction suspension systems. Hypothesis 3.1: Adaptive EVS improves amputee performance and residual limb health as compared to pin-locking/lanyard, suction, and static EVS. Hypothesis 3.2: Adaptive EVS improves functional performance, pistoning control, and user comfort as compared to pin-locking/lanyard, and static EVS.

15. SUBJECT TERMS: NONE LISTED

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
U	U	U	UU	**16**	**19b. TELEPHONE NUMBER** *(include area code)*

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. INTRODUCTION:

The overall objective of proposed studies is to develop an adaptive socket system that detects in-socket residual limb motion and adjusts internal socket negative pressure to optimize fit. Novel technologies to be tested include a "smart" vacuum suspension system capable of monitoring socket movement relative to the residual limb. Probe-based and imaging modalities to assess residual limb circulation and skin health will be employed to assess the functional significance of the adaptive socket system in comparison to existing standard of care suspension systems.

2. KEYWORDS:

prosthesis, transtibial, transfemoral, residual limb, vacuum, suspension

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.

IRB/HRPO approval – months 1-6 (100%)

Aim 1: Determine the optimal vacuum level that minimizes in-socket limb movement with the goal of preserving residual limb health. (overall 100%)

- Recruit and enroll 10 transfemoral and 10 transtibial amputees, months 6 – 8 (complete)
- Fabricate study sockets for participants, months 8 - 11 (complete)
- Analyze and interpret results, months 9 - 12 (complete, published)

Aim 2: Characterize the effects of residual limb movement in-socket on residual limb health. (overall 90%)

- Recruit and enroll 15 transfemoral and 15 transtibial amputees, months 9-12 (15 enrolled, as per interim analysis no further enrollments were required, sufficient data was obtained for the settings required for Aim 3)
- Analysis and interpret results, months 9 – 12 (100%, interim analysis completed data provided to OWW for vacuum level setting for the main study i.e., Aim 3, optimizing limb health outcomes published)
- Image analysis pending OSU data release.

Aim 3: Compare the long-term effects of adaptive EVS to pin-locking and suction suspension systems (IRB approval at new Institution IU is ongoing, once approved and the award is transferred, Preparatory work for aim 3 is complete, 20% complete).

The PI moved to a new Institution in Aug 2018 – reported in Year 2 report. The Award transfer was initiated for the new Institution Indiana University (IU), the award transfer occurred on 04/15/2019. The award end date was 09/29/2019. Because of delays on the transfer process, a

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. Major Activities.

IRB/HRPO approval –

The IRB approval (1809327674) to conduct Aim 3 at IU has been obtained on 27 March 2019. The original IRB and the amendments have been approved by HRPO (A-19705.2c), received on June 11th 2019. Amendments. A major amendment that allowed for the elimination of the crossover design for Aim 3, the shortening of the study duration to 16 weeks, and the removal of Aim 2 at Indiana University. and Approval of the amendment by HRPO was received on Aug 7th 2019. A few minor amendments to include prosthetics fitting visits, recruitment flyers, addition personnel to the protocol have been performed.

Aim 1 – Aim 1 visits were completed during year one, data analysis/interpretation ongoing were performed in Y2 and published. The details of the progress have reported in Year 1 & 2 reports.

The studies resulted in a publication: In the publication, preliminary data from n=10 subjects were reported. The report concluded that after 16 wk of use, the elevated Vacuum system (EVS) improved residual-limb oxygenation during treadmill walking. The prosthesis-induced reactive hyperemia was attenuated with EVS following 16 wk of use. Skin barrier function was preserved with EVS but disrupted after control socket use.

Aim 2 – Aim 2 studies began in year two and we completed (n=15), prior to moving to IU from OSU. An interim analysis of the data was performed to determine if n=15 subjects provided sufficient data to complete Aim 2.

1. The data resulted in a publication. The major objective was to develop a standardized approach to quantitatively measure residual limb skin health using noninvasive imaging (hyperspectral imaging and laser speckle flowmetry) and probe-based approaches (laser doppler flowmetry, transcutaneous oxygen, transepidermal water loss, surface electrical capacitance). Using measurements from Aim 1 subjects a standardized approach to quantitatively measure residual limb health in individuals with lower limb loss was developed and reported. The study reported that compared to able-limb controls, resting residual limb physiology in people that have had transfemoral or transtibial amputation is characterized by lower transcutaneous oxygen tension and poorer skin barrier function.

2. The data from this study was presented at the MHSRS 2019 as invited oral presentation. The presentation concluded that socket movement is a critical factor that should be controlled in order to preserve limb health while using a prosthesis. simply maximize vacuum pressure setting and expect to achieve the best limb environment.

Aim 3. All preparatory work including IU IRB, HRPO approval have been achieved. The infrastructure to complete study visits at the New Institution have been completed. Screening process has already begun Sept 2019 and we have 14 consented subjected. Enrollment will begin within next two weeks.

2. Specific Objectives.

IRB/HRPO approval – gained approval to conduct Aim 1 and Aim 2 studies. HRPO approval will obtained to continue studies at IU once the IRB protocol is approved.

Aim 1 – Test the relationship of pressure variance waveforms with residual limb movement in socket.

Aim 2 – Characterize the effects of residual limb movement in socket on residual limb health.

Aim 3 - Compare the long-term effects of adaptive EVS to standard of care suspension systems.

3. Significant Results.

Aim 1 - Pistoning and horizontal movement was dependent on socket fit. Horizontal motion generally attributed 20-50% of the total motion depending on socket fit condition. Vacuum pressure data had a positive correlation to the inductive sensor data, indicating it can detect global and local changes in fit.

The loose socket generally resulted in the most horizontal movement and the tight resulted in the most distal movement. Interestingly, horizontal movement still occurred in the tight socket. Transfemoral subjects tended to have more horizontal motion than transtibial subjects, likely due to anatomy of the residual limb. Vacuum pressure profiles correlated positively with the data.

Aim 2 – One of the major objective, was to develop a standardized approach to quantitatively measure residual limb skin health using noninvasive imaging (hyperspectral imaging and laser speckle flowmetry) and probe-based approaches (laser doppler flowmetry, transcutaneous oxygen, transepidermal water loss, surface electrical capacitance). Using measurements from Aim 1 subjects a standardized approach to quantitatively measure residual limb health in individuals with lower limb loss was developed and reported. The study reported that compared to able-limb controls, resting residual limb physiology in people that have had transfemoral or transtibial amputation is characterized by lower transcutaneous oxygen tension and poorer skin barrier function.

We performed analysis for Aim 2 on n=15 with unilateral limb loss (8 transfemoral; 7 transtibial), who wore an elevated vacuum suspension prosthesis. These subjects were recruited as part of the randomized crossover study proposed in Aim 2. Subjects completed 4 data collection visits; one baseline visit and three experimental visits. Each visit was scheduled one month apart. Post-activity TEWL and TCOM correlated with socket movement (near significant $p=0.07$ and significant $p=0.03$ respectively) so that when socket movement decreased, health outcome improved. These outcomes did not correlate with the average atmospheric pressure within the socket ($p=0.3$ for both).

When socket fit was accounted for by normalizing the average atmospheric pressure by socket movement, TEWL and TCOM indicate a stronger correlation with movement ($p=0.02$ and $p=0.01$, respectively). Pre-activity SEC and TEWL, and post-activity SEC, did not correlate (all $p>0.3$) with either socket movement or average atmospheric pressure.

4. Other Achievements.
The following publications as part of the progress of this project:

Wernke MM, Schroeder RM, Haynes ML, Nolt LL, Albury AW, Colvin JM. Progress Toward Optimizing Prosthetic Socket Fit and Suspension Using Elevated Vacuum to Promote Residual Limb Health. Rehabil Res Dev. 2016;53(6):1121-1132.

Rink CL, Wernke MM, Powell HM, Tornero M, Gnyawali SC, Schroeder RM, Kim JY, Denune JA, Albury AW, Gordillo GM, Colvin JM, Sen CK. Standardized Approach to Quantitatively Measure Residual Limb Skin Health in Individuals with Lower Limb Amputation. Adv Wound Care (New Rochelle). 2017 Jul 1;6(7):225-232.

Wernke, M.M., et al. Progress Toward Optimizing Prosthetic Socket Fit and Suspension Using Elevated Vacuum to Promote Residual Limb Health. Adv Wound Care (New Rochelle) 6, 233-239 (2017).

Roy, S., Mathew-Steiner, S. & Sen, C.K. Limb Health and Prosthetics. in IntechOpen, DOI: 10.5772/intechopen.83819. (Available from: https://www.intechopen.com/online-first/residual-limb-health-and-prosthetics, 2019).

Roy, S., Mathew-Steiner, S. & Sen, C.K. Prosthetics and limb health in extreme sports. in Extreme and Rare Sports: Performance Demands, Drivers, Functional Foods, and Nutrition (eds. Datta, S. & Bagchi, D.) (CRC Press, Boca Raton, FL, 2019).

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.

Training Activities:

Dr. Matt Wernke presented Multiaxial In-Socket Movement and Its Relationship to Fit in the 44th Academy Annual Meeting and Scientific Symposium. February 16, 2018. Podium Presentation.

Training Activities contd:

Presented (podium) in 2018 Military Health System Research Symposium. Kissimmee, FL. August 21, 2018.

Presented on How Does Socket Motion Impact Limb Health? A Preliminary Report in the American Orthotic and Prosthetic Association Annual Meeting. Vancouver, BC Canada. September 28 2018. Poster Presentation.

Presented (podium) in 2019 Military Health System Research Symposium. Kissimmee, FL. 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.

In addition to the aforementioned training and professional development activities, results were disseminated to the military community at the 2018, 2019 Military Health System Research Symposium. Both oral and poster presentations.

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.

Aim 3 – Begin enrollment at all site, data collection, analysis and interpretation of data. We anticipate to reach our recruitment goals within this year.

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).

Aim 1 – First work to correlate in socket motion with vacuum pressure waveform. This exciting discovery means that vacuum pressure waveform data that is recorded in an elevated vacuum suspension socket system can be used as measure of socket fit. Importantly, this data will drive the concept of an "adaptive" socket system (tested in Aim 3) that will automatically respond to changes in socket fit by adjusting the vacuum level to eliminate motion.
Aim 2. Data will underscore the effect of residual limb movement health on residual limb health in socket using noninvasive measurements such as TEWL, TCPO2, perfusion and hydration levels.

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.*

Results will support industry partner Ohio Willow Wood with the design and development of the "adaptive" socket system (tested in Aim 3).

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. 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.

No changes in any of the major objectives of proposed study. We eliminated the crossover design for Aim 3, thus, significantly shortening of the study duration to 16 from 32 weeks. This decision was implemented following discussion with other participating investigators.

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.

There were significant delays in getting the Aim 3 started that included: a. Award transfer process. b. Reassembling the research team including hiring of a prosthetist and clinical research nurse coordinator. c. Redesigning existing space at new PI Institution for completing the study visit and socket fitting activities. Solutions. a. An NCE has been obtained to extend the study period to March 2021, this will give us additional 18 months to complete the Aim 3 studies. b. The PI obtained Institutional support in redesigning adequate space dedicated for completing the activities related to the project. c. All necessary resources, and equipment have been purchased and are in place.

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.

  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).*

Wernke MM, Schroeder RM, Haynes ML, Nolt LL, Albury AW, Colvin JM. Progress Toward Optimizing Prosthetic Socket Fit and Suspension Using Elevated Vacuum to Promote Residual Limb Health. Rehabil Res Dev. 2016;53(6):1121-1132.

Rink CL, Wernke MM, Powell HM, Tornero M, Gnyawali SC, Schroeder RM, Kim JY, Denune JA, Albury AW, Gordillo GM, Colvin JM, Sen CK. Standardized Approach to Quantitatively Measure Residual Limb Skin Health in Individuals with Lower Limb Amputation. Adv Wound Care (New Rochelle). 2017 Jul 1;6(7):225-232.

Wernke, M.M., et al. Progress Toward Optimizing Prosthetic Socket Fit and Suspension Using Elevated Vacuum to Promote Residual Limb Health. Adv Wound Care (New Rochelle) 6, 233-239 (2017).

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).*

Roy, S., Mathew-Steiner, S. & Sen, C.K. Limb Health and Prosthetics. in IntechOpen, DOI: 10.5772/intechopen.83819. (Available from: https://www.intechopen.com/online-first/residual-limb-health-and-prosthetics, 2019).

Roy, S., Mathew-Steiner, S. & Sen, C.K. Prosthetics and limb health in extreme sports. in Extreme and Rare Sports: Performance Demands, Drivers, Functional Foods, and Nutrition (eds. Datta, S. & Bagchi, D.) (CRC Press, Boca Raton, FL, 2019).

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.*

Dr. Matt Wernke presented Multiaxial In-Socket Movement and Its Relationship to Fit in the 44th Academy Annual Meeting and Scientific Symposium. February 16, 2018. Podium Presentation.

Presented (podium) in 2018 Military Health System Research Symposium. Kissimmee, FL. August 21, 2018.

Presented on How Does Socket Motion Impact Limb Health? A Preliminary Report in the American Orthotic and Prosthetic Association Annual Meeting. Vancouver, BC Canada. September 28 2018. Poster Presentation.

Presented (podium) in 2019 Military Health System Research Symposium. Kissimmee, FL. August, 2019.

- **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.

None

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

None

- **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.

None

- **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;*
  - *physical 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.*

None

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.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

PERSONNEL

Name:	Dr. Chandan K. Sen, PhD
Project Role:	PI
Researcher Identifier (ORCID ID):	0000-0002-2936-417X
Nearest person month worked:	2
Contribution to Project:	Dr. Sen is responsible for the overall coordination and leadership of the project; including experimental design, analysis and interpretation of study outcomes.

Name:	Dr. Sashwati Roy, PhD
Project Role:	Co-I
Researcher Identifier (ORCID ID):	NA
Nearest person month worked:	1
Contribution to Project:	Dr. Roy serves as the Director of Clinical Research at IU Health Comprehensive Wound Center. She is closely working with the clinical research team and ensure compliance, recruitment and retention.

Name:	Dr. Subhadip Ghatak, PhD
Project Role:	Co-I
Researcher Identifier (ORCID ID):	NA
Nearest person month worked:	2
Contribution to Project:	Dr. Dr. Ghatak will acquire residual limb health measurements while closely working with Dr. Roy and optimizing the measurements.

Name:	Dr. Gayle Gordillo, MD
Project Role:	Co-I
Researcher Identifier (ORCID ID):	NA
Nearest person month worked:	0.2
Contribution to Project:	Her role is to support analysis and interpretation of residual limb skin health outcomes.

Name:	Ms Tammy Garrett, RN, BSN, CCCRP
Project Role:	Research nurse coordinator
Researcher Identifier (ORCID ID):	NA
Nearest person month worked:	2
Contribution to Project:	Mrs. Garett is a research nurse that supports Subject screening, IRB and other study related activities.

Name:	Ms Jennifer Mohnacky, RD
Project Role:	Clinical Research Manager
Researcher Identifier (ORCID ID):	NA
Nearest person month worked:	1
Contribution to Project:	Study staff management, help in reporting, IRB, HRPO approvals, DSMB.

Name:	Ms Swathi Kerra
Project Role:	Clinical Research Manager
Researcher Identifier (ORCID ID):	NA
Nearest person month worked:	1
Contribution to Project:	Clinical Research Assistant on the project and supports study setup in redcap and CT.gov.

Name:	Mr. Jeff Denune, CPO
Project Role:	Prosthetist
Researcher Identifier (ORCID ID):	NA
Nearest person month worked:	1
Contribution to Project:	His primary role in socket shape capture, fabrication and fittings related to the project.

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.

No change in key personnel in past year.

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.*

None

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (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.

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