AWARD NUMBER: W81XWH-18-1-0559

TITLE: Novel Lower-Limb Prostheses: Comparing Adherence, Perspiration, and Residual Limb Skin Health in a Hot, Humid Environment and During Activities of Daily Living

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CONTRACTING ORGANIZATION: Seattle Institute for Biomedical and Clinical Research
Seattle, WA

REPORT DATE: December 2022

TYPE OF REPORT: Final

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
December 2022	Final	01Sep2018 – 31Aug2022

4. TITLE AND SUBTITLE

Novel Lower-Limb Prostheses: Comparing Adherence, Perspiration, and Residual Limb Skin Health in a Hot, Humid Environment and During Activities of Daily Living

5a. CONTRACT NUMBER
W81XWH-18-1-0559

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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8. PERFORMING ORGANIZATION REPORT NUMBER

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

U.S. Army Medical Research and Development 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

Three prostheses were compared to determine which was most effective at maintaining a secure adherence during profuse perspiration. Skin health and comfort were also measured. The three study prostheses were: a prosthesis with a battery and body weight activated pump that discretely expelled perspiration, a prosthesis with a perforated liner to allow perspiration to seep away from the skin, and the participants' as-prescribed prosthesis.

Twenty individuals with a lower limb amputation walked on a treadmill for 30-minutes in a climate chamber (35 degrees C and 50% relative humidity) after wearing each study prosthesis for two weeks. Eight completed all procedures. The COVID-19 pandemic hampered study enrollment. The prosthesis with a perspiration expelling pump provided the most secure adherence while the prosthesis with a perforated liner accumulated the least perspiration. Simply wearing a prosthesis resulted in very dry residual limb skin, but barrier function was not compromised. All three study prostheses were reasonably comfortable to wear.

15. SUBJECT TERMS

Lower extremity amputation, lower limb amputation, amputee, transtibial amputation, artificial limb, prosthesis, perspiration, adherence, pistoning, skin health

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

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1. INTRODUCTION:

Active individuals with lower limb amputation who work in demanding environments often complain about the accumulation of perspiration inside their prostheses that can lead to an insecure prosthetic suspension (i.e., the prosthesis becomes loose or falls off during vigorous activity). The purpose of this research is to provide these individuals with a prosthesis and suspension that remains secure despite profuse residual limb perspiration without compromising residual limb health and comfort.

The scope of this research is to compare three lower limb prosthetic suspension systems. Our aim is to identify which of the study prostheses is most effective at maintaining a secure adherence when worn in conditions that result in profuse perspiration. We also aim to identify how the three study prostheses effect residual limb skin health and comfort when participants pursue their usual activities in the home, work, and community environments. The three different study prostheses are: (1) the as-prescribed prosthesis of volunteer participants (RX), (2) a new-to-market prosthetic liner with perforations that allows perspiration to seep away from the skin (PERF), and (3) an innovative prosthesis that has a hybrid pump system (battery and body weight activated) enabling air to flow between the prosthesis and the residual limb skin, expelling any accumulated perspiration (DAE-RED). Participants wore each of these prostheses in the home, work, and community environments for two weeks, after which we measured their residual limb health and comfort. Participants then walked on a treadmill in a chamber whose climate was similar to Middle East-like conditions (35 °C (95 °F) and 50% relative humidity). After 30-minutes, we measured the slippage of their prosthesis relative to their limb and how much perspiration was expelled.

A one year no-cost extension for this research was approved to continue work through 31Aug2022.

2. KEYWORDS:

Lower extremity amputation, lower limb amputation, amputee, transtibial amputation, artificial limb, prosthesis, perspiration, adherence, pistoning, skin health

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The statement of work for this project includes two major tasks.

Major Task 1:

Manufacture Dynamic Air Exchange - Rising Edge Design (DAE-RED) prosthetic components at the Arusha Control Inc. site. This task includes the manufacture of modular system components including vacuum pump and solenoid circuit boards, airflow systems, lock and forming apparatus, manifolds, and modular enclosures. It also includes the manufacture and modification of thermoformed test sockets for study participants and the manufacture of subject-specific components including custom liners with airflow ports, socks, and molds. The recurring milestone for this task is the delivery of components to the Veterans Affairs Puget Sound Health Care system (VAPSHCS) site for human subject testing. The milestones for this task are shown in Table 1.

Table 1: Major task 1 milestone (revised based on approved no-cost extension).

	Timeline
Major Task 1: Manufacture DAE-RED Prosthetic Components	Months
Subtask 1.1: Manufacture modular system components including: vacuum pump and solenoid circuit boards, airflow systems, lock and forming apparatus, manifolds, and modular enclosures.	1-42
Subtask 1.2: Manufacture and modify thermoformed test sockets.	1-42
Subtask 1.3: Manufacture subject-specific components including custom liners with airflow ports, socks, and molds.	1-42
Milestone Achieved: Deliver components for human subject testing (see target enrollment table in Appendix A).	As needed

Major Task 2:

Conduct human subject experiment (n=25) at the VAPSHCS site. This task includes the preparation and submission of regulatory documents, the recruitment of human subjects, the assembly of study prostheses from components delivered from the Arusha Control Inc. site, fitting human subjects with all three study prostheses, conducting human subject experiments, and processing and analysis of data. The milestones for this task include obtaining and maintaining VAPSHCS Institutional Review Board (IRB) approval for conducting human subjects research, obtaining and maintaining US Army Medical Research and Materiel Command (USAMRMC), Office of Research Protections (ORP), Human Research Protection Office (HRPO) approval for conducting human subjects research, conducting human subject experiments, analysis of data, and reporting of interim and final results. The milestones for this task are shown in Table 2.

Table 2: Major task 2 milestones (revised based on approved no-cost extension).

	Timeline
Major Task 2: Conduct Human Subject Experiments	
Subtask 2.1: Prepare and submit regulatory documents	1
Subtask 2.2: Recruit human subjects	1-42
Subtask 2.3: Assemble study prostheses from delivered components.	2-42
Subtask 2.4: Conduct human subject experiments	2-42
Subtask 2.5: Process and analyze data	2-48
Milestone Achieved: VAPSHCS IRB Approval	2
Milestone Achieved: HRPO Approval	3
Milestone Achieved: Analyze interim data and report results.	24
Milestone: Analyze data and report results.	48

What was accomplished under these goals?

Major Task 1.

The work of this project for Major Task 1 included ongoing fabrication of components to be used in assembling the study prostheses for our human subject experiments.

Subtask 1.1: This completed work included manufacturing the modular system components (Subtask 1.1) which included vacuum manifolds, solenoid circuit boards. It also included various assemblies for the vacuum pump, airflow systems, and system enclosures.

Subtask 1.2: This completed work included fabricating and modifying thermoformed test sockets with custom lock and forming apparatus.

Subtask 1.3: This completed work included manufacturing subject specific components including custom liners with airflow ports, socks and molds.

The DAE-RED prosthetic components were delivered to the VA site for final assembly and human subject testing, meeting the *recurring milestone* for Major Task 1 to deliver to the VA site completed components of the Dynamic Air Exchange – Rising Edge Design Prosthesis (Figure 1) for human subject testing for all enrolled participants.

Figure 1: Dynamic Air Exchange – Rising Edge Design (DAE-RED) prosthesis.

As recruitment was below target due to the COVID-19 pandemic, we endeavored to improve the manufacturability and reliability of the study prosthesis. We built additional fixturing and tooling to speed production and improve quality. We made minor design modifications to reduce weight and improved operational reliability with a cleaning procedure and tool based on field testing results.

<u>Major Task 2.</u>

The work of this project for Major Task 2 was to conduct a human subject experiment at the VAPSHCS site.

Subtask 2.1: Prepare and submit regulatory documents. The *milestone* of VAPSHCS IRB approval was obtained during the second month of the award. The *milestone* of DOD HRPO approval was obtained during the third month of the award. These approvals were maintained for the duration of the award.

Subtask 2.2: Recruit human subjects. This subtask was conducted over the entire duration of the award. The key barrier to reaching our enrollment target was challenges associated with the COVID-19 pandemic.

Subtask 2.3: Assembled study prostheses from delivered components. We assembled components for a total of 20 complete DAE-RED prostheses which included socks, sockets, and assembled vacuum systems. This subtask was conducted over the entire duration of the award.

Subtask 2.4: Conduct human subject experiments.

Twenty eligible individuals (25 target) provided informed consent to participate in this institutional review board-approved protocol and were enrolled in the study. Eight subjects completed all study procedures. The COVID-19 pandemic hampered study enrollment and completion. Of the 12 who did not complete all study procedures, one withdrew due to health issues, one didn't feel strong enough to complete the protocol, one left the country, five had prosthetic fitting issues, and four were lost to follow up after consent or fabrication of their first socket.

Subjects were randomized to PERF or DAE-RED to wear in their home, community, and work environments. After two weeks, skin hydration and transepidermal water loss (Courage & Khazaka, GER) were measured along with the Socket Comfort Score [Hanspal; 2003 Disabil Rehabil 25(22): p. 1278-80)]. In a 35° C and 50% relative humidity chamber, subjects acclimated for 30 minutes then treadmill walked for 30 minutes at self-selected speed. After resting for 30 minutes at 20° C and 30% relative humidity, perspiration and liner slippage were measured. Subjects then wore their RX for two weeks, after which the procedures above were repeated. Finally, the subject wore the remaining study prosthesis for two weeks and the procedures repeated.

The *milestone* of analyzing interim data and reporting results was achieved. We reported interim results at four national conferences. Details of these conferences are provided in Section 6. Products.

Subtask 2.5: Process and analyze data.

We have conducted an analysis of the eight participants (91±11 kg, 1.75±0.08 m, 47±15 years; 6 trauma, 1 diabetic, 1 infection) who completed the protocol.

The results (see Table 1) indicate residual limb perspiration was greatest for the DAE-RED and least for the PERF. Contralateral limb perspiration remained relatively constant. Liner slippage was smallest for the DAE-RED and greatest for RX. After wearing the DAE-RED, RX, and PERF for two weeks, the skin hydration of both the residual and contralateral limbs were less than 30 (arbitrary units). Skin hydration of less than 30 is an indicator of very dry skin (greater than 40 indicates sufficiently moisturized skin). After the two-week exposure, the transepidermal water loss of the residual limb was less than 15 g/h/m^2 for all three study prostheses. Transepidermal water loss between 10 and 15 g/h/m^2 is an indicator of healthy skin. The transepidermal water loss of the contralateral limb was less than 10 g/h/m^2 for all three study prostheses, which indicates very healthy skin.

Table 1. Perspiration, liner slippage, and skin health metrics (mean ± std. deviation).

	DAE-RED	**RX**	**PERF**
Perspiration residual limb (g)	2.0±1.9	1.3±1.4	0.5±0.6
Perspiration contralateral limb (g)	0.7±0.6	0.6±0.4	0.5±0.4
Liner slippage (mm)	3±5	15±15	6±7
Skin hydration residual limb (0:130 scale, arbitrary units)	18±2	21±2	26±2
Skin hydration contralateral limb (0:130 scale, arbitrary units)	25±2	23±2	29±2
Transepidermal water loss residual limb (g/h/m2)	12.3±0.1	12.5±0.2	9.3±0.2
Transepidermal water loss contralateral limb (g/h/m2)	5.7±0.1	5.6±0.2	7.3±0.2

The socket comfort scores (see Table 2) suggest there is little difference between the study prostheses, and all are reasonably comfortable.

Table 2. Socket comfort scores (mean ± standard deviation). Question: On a 0 - 10 scale, if 0 represents the most uncomfortable socket fit you can imagine, and 10 represents the most comfortable socket fit, how would you score the comfort of the socket fit of your artificial limb…

	BASELINE	DAE-RED	RX	PERF
…at the moment?	8.1±1.4	6.9±2.0	8.1±1.4	6.8±2.1
…on average, over the last 7 days?	7.8±1.3	7.3±1.3	8.1±1.2	7.0±1.7
…at best, over the last 7 days?	8.5±0.8	8.0±1.1	8.8±1.0	8.1±1.4
…at worst, over the last 7 days?	6.1±1.0	5.6±1.3	6.9±1.0	5.3±2.1

Conclusions: In a hot and humid environment, the PERF accumulated the least perspiration while the DAE-RED provided better adherence (less slippage). Contralateral limb perspiration remained relatively constant, suggesting repeatable test conditions. In the field, skin hydration of both residual and contralateral limbs was very dry (<30) for all three study prostheses, but barrier function was maintained as indicated by the low transepidermal water loss (<15; healthy skin). All three study prostheses were reasonably comfortable to wear.

Major Task 2 had one *milestone* to analyze data and report results. This milestone will be achieved at an international conference in 2023. One journal manuscript describing the final results is in preparation for dissemination in 2023. Details are provided in Section 6. Products.

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

Findings from this research have been presented to two national audiences at the American Academy for Orthotists and Prosthetists Annual Meeting (2021 and 2022) and to an international audience at the International Society for Prosthetists and Orthotists World Congress (2023) to reach the clinician and patient communities. An additional journal publication is in preparation to disseminate the final results.

Findings have also been shared with DOD program officials and stakeholders via the Military Health System Research Symposium (written in 2021, written and oral in 2022).

To enhance interest in learning and careers in science, technology, and health care, findings of this research have also been presented to Cleveland High School (Seattle, WA) students and their teachers as part of National Biomechanics Day on 3Apr2019.

To enhance understanding of health care research and the impact of federal funding, the PI briefed the Honorable Patty Murray, the U.S. senator from Washington State, on research to benefit Veterans with lower limb loss on 28May2019 and 17Aug2022 (staff only). The PI also briefed Dr. Carolyn Clancy, the VHA Deputy Under Secretary for Health for the Office of Discovery, Education and Affiliate Networks (DEAN), on 29Apr2019.

An invited, regional presentation on the research conducted at the Center for Limb Loss and MoBility was given in-person to the 2021 Northwest Chapter of the American Academy of Orthotists and Prosthetists Annual Meeting held in Bellevue, WA, on 15Jul2021. This presentation, titled “Activity, work, and sweat”, included a description and interim results of the research supported by this award.

What do you plan to do during the next reporting period to accomplish the goals?

Nothing to report.

4. IMPACT:

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

The results of this research provides information to stakeholders regarding best prescription practices for individuals who ambulate in hot and humid environments. The DAE-RED is the superior prosthesis for individuals concerned about a secure adherence. The PERF is the superior prosthesis for those who want to minimize the accumulation of perspiration. Simply wearing a prosthesis results in very dry residual limb skin, but barrier function was not compromised. All three study prostheses were reasonably comfortable to wear.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Individuals with lower limb amputations may be more mobile in jobs and recreational pursuits that occur in hot and demanding environments.

5. CHANGES/PROBLEMS:

There have been no significant changes in the project or its direction.

Actual or anticipated problems or delays and actions or plans to resolve them

The COVID-19 pandemic was a barrier to reaching enrollment targets. Enrollment at the VA Puget Sound Health Care System (Seattle, WA) was administratively halted on March 16, 2020. Human subjects research was allowed to resume on September 8, 2020, with a limit of three face-to-face contacts per week for all of Dr. Klute’s studies. The face-to-face limit was lifted on July 6, 2021. However, some eligible individuals remained reluctant to participate in in-person research as the status of the pandemic and thorough safety precautions did not alleviate all concerns. A no-cost extension was requested to address the below target enrollment for which approval was received on 7Sep2021.

Changes that had a significant impact on expenditures

Nothing to report.

6. PRODUCTS

Publications, conference papers, and presentations

A podium presentation describing bench tests methods and results for comparing perforated liners was presented remotely during the American Academy of Orthotists & Prosthetists 2021 Annual Meeting & Scientific Symposium on May 4-7, 2021.

> Klute GK, Berge JS, Kaufman GE, King C. "Properties of Perforated Liners." Abstract in: Proceedings of the American Academy of Orthotists and Prosthetists 2021 Annual Meeting. May 4-7, 2021. Presented remotely on 6May2021.

A podium presentation describing the interim results of this study was accepted for oral presentation at the 2021 Military Health System Research Symposium in the scientific breakout session titled "Advancements in Prosthetic and Orthotic Technologies that Facilitate Return to Duty Following Neuromusculoskeletal Injuries." This symposium was cancelled on 29Jul2021 over concerns regarding the COVID-19 variant in Florida.

> Klute GK, Berge JS, Kaufman, GE, King C, "Effect of Hybrid Dynamic Air Exchange Suspension versus Perforated Elastomeric Liners on Problems Associated with Perspiration in Individuals with Lower Limb Amputation." Abstract (MHSRS-21-04294) in: Proceedings of the 2021 Military Health System Research Symposium (MHSRS). August 23-26, 2021.

A podium presentation describing this study's methods and interim results was presented in person at the American Academy of Orthotists & Prosthetists 2022 Annual Meeting & Scientific Symposium on March 5, 2022, in Atlanta, GA.

> Klute GK, Berge JS, Kaufman GE, King C., "Perspiration in Individuals with Lower Limb Amputation: Hybrid Dynamic Air Exchange Suspension versus Perforated Elastomeric Liners." Abstract in: Proceedings of the American Academy of Orthotists and Prosthetists 2022 Annual Meeting. March 2-5, 2022.

A podium presentation describing the interim results of this study was presented at the 2022 Military Health System Research Symposium in the session "Advancements in Prosthetic and Orthotic Technologies." This conference will be held in person on September 12-15, 2022, at the Gaylord Palms Resort and Convention Center, Kissimmee, Fl.

> Klute GK, Berge JS, Kaufman GE, Carranza CR, King C, "Lower Limb Prosthetic Suspension in Hot and Humid Environments: Hybrid Dynamic Air Exchange Versus Perforated Elastomeric Liners." Abstract (MHSRS-22-07387). Abstract in: Proceedings of the 2022 Military Health System Research Symposium (MHSRS). September 12-15, 2022, Kissimmee, FL.

A podium presentation describing the final results of this study will be presented at the 2023 International Society for Prosthetics and Orthotics World Congress on 24Apr2023 in Guadalajara, MEX.

> Klute GK, Berge JS, Kaufman GE, Carranza CR, King C. “Perspiration and Lower Limb Suspension: Hybrid Dynamic Air Exchange versus As-Prescribed versus Perforated Liners”. Abstract to appear in: Proceedings of the 2023 International Society for Prosthetics and Orthotics at the World Congress to be held on 24-27Apr2023 in Guadalajara, MEX.

Journal publications

A journal publication describing the study final results is in preparation for dissemination in 2023. Federal support will be acknowledged.

Books or other non-periodical, one-time publications

Nothing to report.

Other publications, conference papers, and presentations

Nothing to report.

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Glenn K. Klute, PhD
Project Role:	PI
ORCID ID:	0000-0001-9527-9590
Nearest person month worked:	7.2 (15% per year for 4 years, supported by VA Puget Sound)
Contribution to Project:	Dr. Klute is the Principal Investigator of this project and has overall

	responsibility for the work. His contributions include hiring and supervising personnel, assembling prostheses, coordinating collaboration with Arusha Control Inc. (Charles King), designing and conducting experiments, analyzing and interpreting data, and disseminating results.
Funding Support	VA Research Career Scientist (IK6 RX002974), Dept. of Veterans Affairs, Rehabilitation Research and Development Service
Name:	Charles King, CPO
Project Role:	Investigator
Researcher Identifier:	
Nearest person month worked:	n/a - vendor
Contribution to Project:	Mr. King is responsible for manufacturing and delivering DAE-RED prosthetic components. His contributions include hiring and supervising fabrication/manufacturing engineers and technicians at Arusha Control Inc., participating in the design of experiments, analysis of data, and documentation of results.
Name:	Jocelyn S. Berge, MSE
Project Role:	Investigator
Researcher Identifier:	
Nearest person month worked:	35 (over 4 years)
Contribution to Project:	Ms. Berge is responsible for commissioning and operation of the climate chamber, recruiting participants, conducting human subject tests, calibrating instruments, performing data processing and analysis, interpreting experimental results, and documenting results. She also contributes to writing study manuscripts.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

There have been no changes in funding since the last reporting period. There remains no scientific overlap between the PIs awards and this grant.

There is no change in the PI's level of effort.

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS:

Please see Department of Defense Quad Chart in Appendix B.

Project Budget (total award):
Project Expenditure:
Unspent Balance:

9. APPENDICES:

This annual report includes two appendices:

A. Human subject enrollment table.
B. Department of Defense Quad Chart (updated 29Mar2023).

Appendix A: Human Subjects Enrollment Table and Regulatory Review

E00494.1a (VA Puget Sound Health Care System) and E00494.1b (Seattle Institute for Biomedical and Clinical Research)
Title: Novel lower-limb prostheses: comparing adherence, perspiration, and residual limb skin health in a hot, humid environment and during activities of daily living
Target required for clinical significance: 25
Target approved for clinical significance: 200

Table A: Human subject actual and target enrollment (quarterly and cumulative). Actual enrollment includes participants since the beginning of the project (1Sep2018) through the end of year four (31Aug2023). All human subject procedures were performed at VAPSHCS (site 1).

Enrollment	Year 1				Year 2				Year 3				Year 4				Total
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Actual	0	1	3	3	2	4	0	0	0	3	2	0	1	1	0	0	20
Target	1	2	3	3	3	3	3	3	2	2	0	0	0	0	0	0	25
Actual (cumulative)	0	1	4	7	9	13	13	13	13	16	18	18	19	20	20	20	20
Target (cumulative)	1	3	6	9	12	15	18	21	23	25	25	25	25	25	25	25	25

Regulatory Review:

- VAPSHCS IRB CRQ: A Continuing Review Questionnaire (CRQ) for protocol 01695 was submitted on 9Mar2022. The CRQ was reviewed and approved at the 30Mar2022 meeting. This approval will expire on 29Mar2023.
- HRPO: Documents for HRPO log numbers E00494.1a and E00494.1b were submitted for review by HRPO on 6May2021. Approval to enroll no more than 200 subjects in this greater than minimal risk study was received on 14Jan2019. Annual approval to continue was granted on 22Apr2022.
- ClinicalTrials.gov: The protocol for “Novel lower-limb prostheses: comparing adherence, perspiration, and residual limb skin health in a hot, humid environment and during activities of daily living” was reviewed by the Protocol Registration and Results System (PRS) administration and made public on the clinicaltrials.gov website on 2Apr2019. The ClinicalTrials.gov identifier for this study is NCT03900845.

Amendments submitted to the VAPSHCS IRB and HRPO (when required) for review since the previous reporting period:

- VAPSHCS IRB Project Revision Form (PRAF) 9: The VAPSHCS IRB requested an update to the informed consent document to include the Department of Defense review committees, the US Department of Treasury, and the Internal Revenue Service. PRAF 9 was reviewed and approved by the VAPSHCS IRB through expedited review with an effective date of 21Oct2021.

- VAPSHCS IRB PRAF 10: We submitted a study modification on 3Mar2022 to request permission to recruit at a regional conference where potential participants would be in attendance. PRAF 10 was reviewed and approved by the VAPSHCS IRB through expedited review with an effective date of 25Mar2022.

Appendix B: Department of Defense Quad Chart (updated 31Mar2023)

Novel lower limb prostheses: comparing adherence, perspiration, and residual limb skin health in a hot, humid environment and during activities of daily living

Log Number OR170314, Award Number W81XWH-18-1-0559

PI: Glenn K. Klute, PhD **Org:** Seattle Institute for Biomedical and Clinical Research **Award Amount:** $996,860

Objective

Provide secure prosthesis suspension without compromising residual limb health and comfort.

Study Aims

Compare 3 lower limb prosthetic suspension systems and

- Identify which is most effective at maintaining a secure adherence when worn in Middle East-like conditions (35 °C, 50% relative humidity).
- Identify which maximizes residual limb skin health and comfort when participants pursue their usual activities in the home, work, and community environments.

Approach

Conduct within-subject experiment with transtibial amputees (n=25 target enrollment) walking on a treadmill in an environmental chamber (30-minutes) and during daily living (two-weeks) while wearing 3 different prostheses.

Three study prostheses different suspensions were compared:

- Prosthesis with a novel battery- and body-weight activated pump that discretely expelled perspiration (image at below).
- Prosthesis with a perforated liner to allow perspiration to seep away from the skin.
- The participants' as-prescribed prosthesis.

Results:

1. The prosthesis with a perspiration expelling pump provided the most secure adherence.
2. The prosthesis with a perforated liner accumulated the least perspiration.
3. Simply wearing a prosthesis resulted in very dry residual limb skin, but barrier function was not compromised. All three study prostheses were reasonably comfortable to wear.

Timeline and Cost

Activities	Yr 1	Yr 2	Yr 3	Yr 4
IRB & HRPO approvals				
Recruit participants				
Conduct human subject tests				
Analyze & report results				
Expenditures ($k)	$354	$358	$224	$60

Updated: 31Mar2023

Year 4 Goals & Activities

☑ Maintain VAPSHCS IRB and HRPO approvals
☑ Recruit participants and conduct human subject experiments
  ☑ 20 individuals were enrolled
  ☑ 8 completed all study procedures
  ☑ COVID-19 hampered participation
☑ Fabricate study prostheses (continued)
☑ Perform analyses
☑ Report results

Budget Expenditure to Date

Year 4 Budget: $60,159
Year 4 Expenses: $59,676
Unspent balance: $483

Project Budget: $996,860
Project Expenses: $996,377