

AWARD NUMBER: W81XWH-14-1-0188

TITLE: Perspiration Thresholds and Secure Suspension for Lower Limb Amputees in Demanding Environments

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14. ABSTRACT The objective of this project is to provide active lower limb amputees who work in demanding environments with a prosthesis and suspension that remains secure despite profuse residual limb perspiration. The specific aims are to: (1) Identify the environment and perspiration thresholds at which the current standard-of-care prosthesis fails to provide a secure suspension, and (2) Compare the performance of the current standard-of-care prosthesis with an innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration. We enrolled 12 individuals with lower limb amputation into an IRB-approved protocol to walk on a treadmill for up to 30-minutes in a chamber at 20, 30, and 35 degrees C at 50% relative humidity. The cross-over experimental design randomized the order of the study prostheses. The results show that despite greater perspiration while wearing the dynamic air exchange prosthesis, it provides greater adherence (less slippage) in demanding conditions than the current standard-of-care.					
15. SUBJECT TERMS Lower extremity amputation, lower limb amputation, amputee, transtibial amputation, artificial limb, prosthesis, skin temperature, perspiration, pistoning					
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Table of Contents

1. INTRODUCTION:	1
2. KEYWORDS:.....	1
3. ACCOMPLISHMENTS:	1
4. IMPACT:	7
5. CHANGES/PROBLEMS:	7
6. PRODUCTS.....	8
7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS	9
8. SPECIAL REPORTING REQUIREMENTS:.....	12
9. APPENDICES:	12

1. INTRODUCTION:

Active individuals with lower limb amputation often complain about uncomfortable residual limb skin temperatures and the accumulation of perspiration inside their prostheses that sometimes leads to an insecure prosthetic suspension (i.e., the prosthesis falls off during vigorous activity). The purpose of this project is to provide individuals who work in demanding environments with a prosthesis and suspension that remains secure despite profuse residual limb perspiration. The scope of this research includes: (1) identifying the environment and perspiration thresholds at which the current standard-of-care prosthesis fails to provide a secure suspension, and (2) comparing the performance of the current standard-of-care prosthesis with an innovative prosthesis that uses dynamic air exchange to expel accumulated perspiration. The work to achieve these aims includes: (1) fabricating, assembling, and fitting standard-of-care and dynamic air exchange prostheses to volunteer individuals with lower limb amputation, and (2) conducting a human subject experiment with subjects walking on a treadmill in at different environment temperatures. The dynamic air exchange prosthesis is expected to significantly surpass the thresholds at which the standard-of-care fails.

2. KEYWORDS:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The statement of work (SOW) for this project, approved revision dated 14 September 2016, includes two major tasks:

Major Task 1. Fabricate dynamic air exchange (DAE) prosthetic components at the Arusha Control site. Activities associated with this task include: purchasing supplies, receiving residual limb casts from the VA Puget Sound Health Care System (VAPSHCS) site, fabricating custom, moisture-wicking textile sock with a proximal elastomeric seal, fabricating prosthetic sockets, fabricating electronic components, fabricating housings, performing bench and quality assurance testing, and shipping components to the VAPSHCS site. The milestones for this task are shown in Table 1.

Table 1: Major task 1 milestones.

Task	Timeline (months)
Milestone 1.1: Deliver unit (1)	3
Quarterly Recurring Milestone 1.2+: Deliver units (as needed)	6, 9, ..., 30, 33

Major Task 2. Conduct a human subject experiment at the VAPSHCS site to compare the performance of the study prostheses. A human subject experiment with transtibial amputees (n=25) will be conducted involving two study prostheses (standard-of-care v. DAE) and their performance in three environmental conditions (20, 30, and 35 °C and 50% relative humidity; 30° C condition for enrollees after 9Mar2017 will be optional to facilitate recruitment). Subjects will walk on a treadmill in an environmental chamber and the time until loss of prosthetic suspension and the amount of perspiration accumulated/expelled will be measured. Hypotheses comparing the

performance of the two study prostheses will be tested, the results documented and disseminated to program officials, clinicians, and amputees.

The components of the innovative prosthesis that uses DAE to expel accumulated perspiration will be fabricated at the Arusha Control site. Final assembly of prosthetic components and fitting of the prosthetic assemblies will occur at the VAPSHCS site.

Activities associated with this task include: obtaining and maintaining regulatory approvals, recruiting subjects, casting residual limbs, shipping casts to the Arusha Control site, receiving components from the Arusha Controls site, assembling final prostheses, conducting human subject tests, securing test data, analyzing test data, performing hypothesis tests, and documenting results.

The milestones for this task are shown in Table 2.

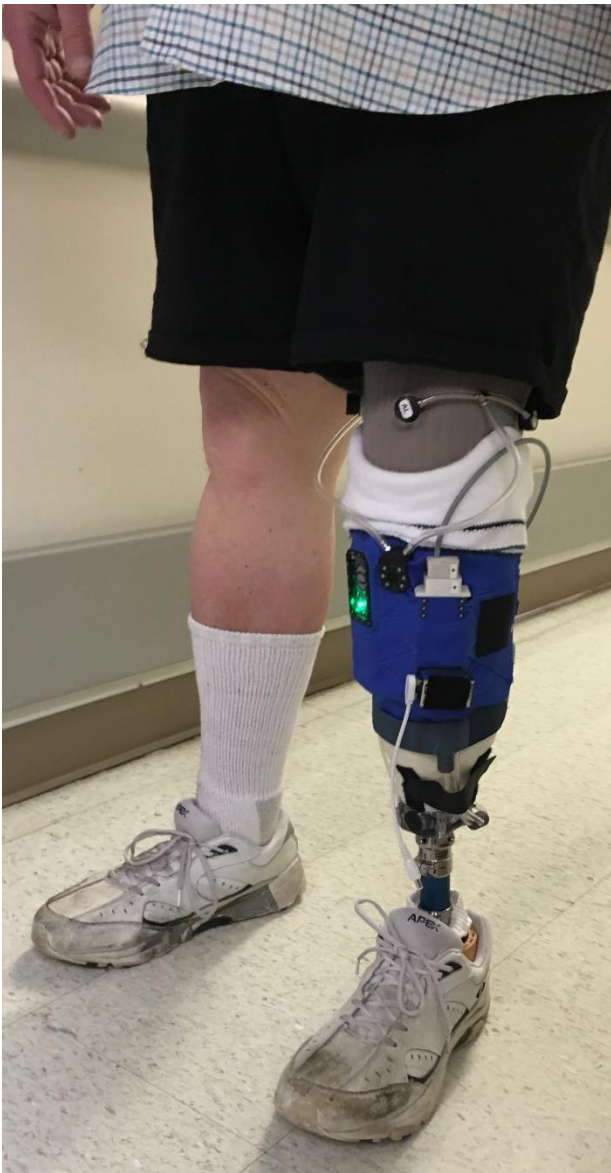
Table 2: Major task 2 milestones.

Task	Timeline (months)
Subtask 2.1: Obtain (and maintain) approval from all governing Institutional Review Boards (HRPO/IRB)	1-3
Subtask 2.2: Commission climate chamber	1-2
Subtask 2.3: Conduct human subject experiment	3-33
Milestone 2.1: Recruit subject (1)	3
Milestone 2.2: Recruit subjects (4)	6
Milestone 2.3: Recruit subjects (4)	9
Subtask 2.4: Analyze preliminary data & report results	9-12
Quarterly Recurring Milestone 2.4+: Recruit subjects (as available)	12, 15, ..., 30, 33
Subtask 2.5: Analyze data & report results	33-36

What was accomplished under these goals?

Major Task 1. The work during this project included ongoing fabrication of components to be used in assembling the study prostheses for our human subject experiments. We fabricated components for a total of 15 complete prostheses and delivered them to the VA site for final assembly and human subject testing. In addition, we also fabricated backup hardware for human subject testing including: proximal port snap housings, molded pump housings, distal liner pins with wrench flats for ease of installation, electronic circuit boards, on-board control switch assemblies, 9-volt battery holders, vacuum manifolds, hose barb O-ring installations, custom socks, and fabric harnesses for system packaging.

Major Task 2. We have maintained approvals from our governing institutional review boards (HRPO and VA IRB), continued recruiting and enrolling participants, and conducted an analysis of our study data. A total of 17 transtibial amputees were enrolled over the duration of the study. We fabricated and assembled a total of 15 standard-of-care prostheses and 15 innovative prostheses for these individuals (see Figures 1 and 2). Twelve subjects completed the entire human subject testing protocol.



(a)



(b)

Figure 1: Dynamic air exchange prosthesis with blue system harness worn by a subject (a) while standing and (b) sitting.

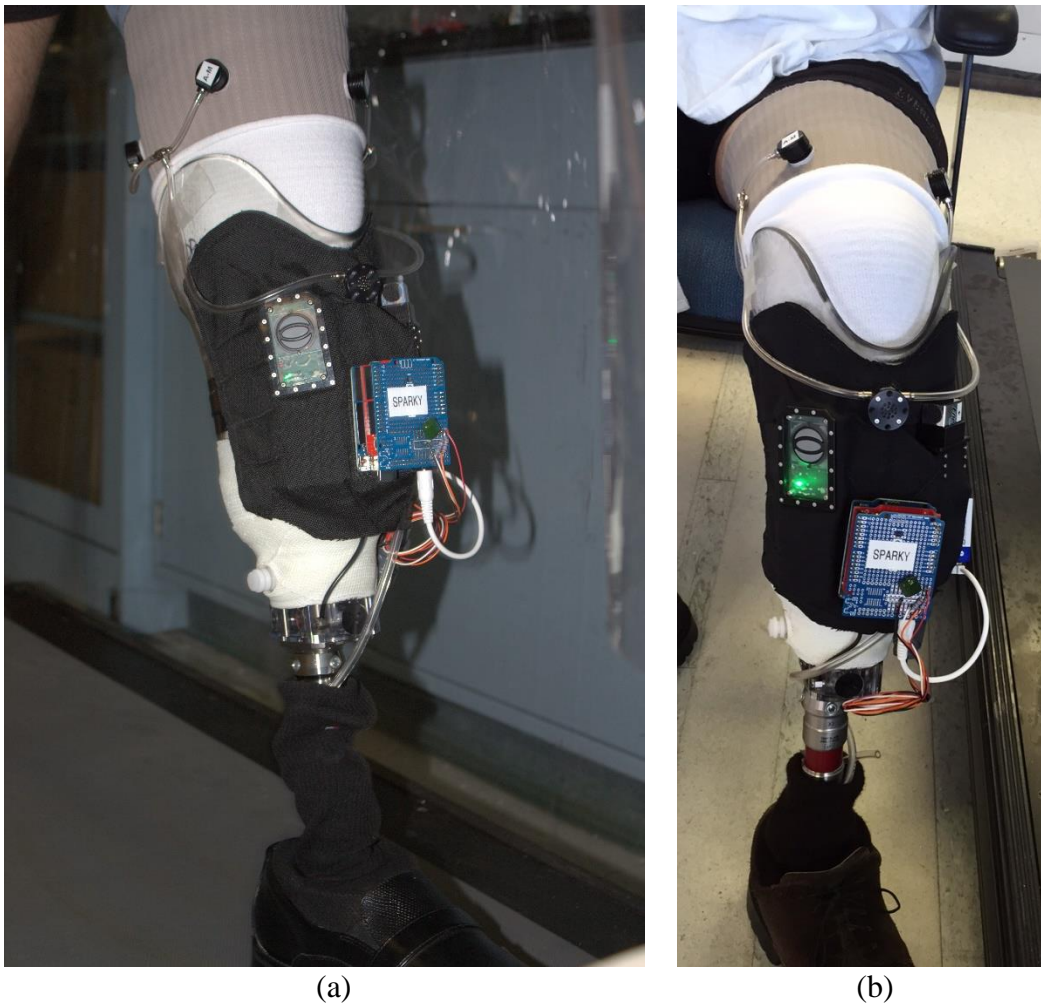


Figure 2: Dynamic air exchange prosthesis with black system harness worn by a subject (a) while standing and (b) sitting. Note the “SPARKY” circuit board was for experimental data collection purposes only.

Subtask 2.1: Obtain (and maintain) approval from all governing Institutional Review Boards (HRPO/IRB). Our use of human subjects has undergone initial and continuing reviews by the US Army Medical Research and Materiel Command's (USAMRMC) Office of Research Protections, Human Research Protection Office (HRPO) and the VA Puget Sound Health Care System (VAPSHCS) Institutional Review Board (IRB). Approvals were granted to enroll no more than 40 subjects.

Continuation documents for protocol A-18175, Perspiration Thresholds and Secure Suspension for Lower Limb Amputees in Demanding Environments, were reviewed by the USAMRMC HRPO on 25Apr2017 and found to follow Federal, Dept. of Defense, and US Army human subjects protection requirements.

The VAPSHCS IRB approved continuation of protocol 00695, Perspiration Thresholds and Secure Suspension for Lower Limb Amputees in Demanding Environments, on 29Mar2017. This approval will expire on 28Mar2018.

There have been no adverse events or unanticipated problems involving risks to subjects or others. We plan to close this study to enrollment but keep the study open for data analysis before the next renewal date.

Subtask 2.2: Commission climate chamber. This subtask was completed during year one of the study.

Subtask 2.3: Conduct human subject experiments. We conducted human subject experiments throughout the reporting period (see Table 1). Enrollment for the study was progressing slower than anticipated. After conferring with the study sponsor, we revised our human subject protocol to make the middle temperature condition (30° C) optional and thereby reduce the required number of study visits to decrease the participation burden and potentially increase recruitment and enrollment. We also hired a new human subject recruiter (effective 2Jun2017) to accelerate our human subject enrollment.

Table 1: Human subject quarterly and cumulative enrollment over the period (two-year grant plus approved one-year no-cost extension). All human subject procedures are performed at the VAPSHCS site.

Enrollment	Year One				Year Two				Year Three				Total
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	
Quarterly Actual/Target	0/0	0/1	3/2	2/2	3/2	1/2	1/2	0/2	2/4	0/4	5/4	0/0	17/25
Cumulative Actual/Target	0/0	0/1	3/3	5/5	8/7	9/9	10/11	10/13	12/17	12/21	17/25	17/25	17/25

Subtask 2.4: Analyze preliminary data & report results. This subtask was completed at the end of year two.

Subtask 2.5: Analyze preliminary data & report results. We have conducted an analysis of twelve participants (50±13 yo, 92±18 kg, 1.81±0.07 m, 16±15 years post-amputation, n=8 trauma, n=2 secondary to infection, n=3 secondary to diabetes) who completed the protocol. All were fit a modified patellar tendon bearing socket and two study suspensions: (1) a distal PIN locking liner and (2) the DAE system that allows expulsion of any accumulated perspiration. Subjects were randomized to study prosthesis and asked to walk at their self-selected speed on a treadmill in an environmental chamber at 50% relative humidity (RH) and 20, 30, and 35° C, presented in random order (some subjects participated in the abbreviated protocol at 20 and 35° C). A 26 cm² absorbent patch was also placed on the lateral calf of the contralateral limb. While in the chamber, subjects rested while seated for 30 min, then walked for 30 min or until they lost confidence in the security of their prosthetic suspension, and then rested outside the chamber (~50% RH, 20° C) while seated for 30 min. Perspiration amounts were measured by tare weight (g) at the end of the protocol. Liner slippage was measured by marking the skin at the proximal border of the liner prior to the protocol and measuring the distance (mm) between the mark and the liner at the end of the protocol.

No subject lost confidence in the security of their suspension; all walked for 30 min in all conditions. Liner slippage was similar for the DAE and PIN at 20° C (large standard deviation for the DAE) but greater for the PIN than the DAE at 30° C and 35° C (see Table 2). The DAE accumulated more perspiration (see Table 3) and resulted in more total perspiration (accumulated + expelled) than PIN at each temperature. Individual results were highly variable as indicated by the large standard deviations. The DAE prosthesis expelled 50, 14, and 24 percent of the total perspiration at 20, 30, and 35° C, respectively. No difference in contralateral limb perspiration was observed across temperature.

Table 2: Liner slippage (mean ± standard deviation) while wearing the PIN and Dynamic Air Exchange (DAE) prostheses at different temperatures.

	20° C	30° C	35° C
# of subjects	11	7	10
PIN locking liner (mm)	5±4	15±14	24±18
Dynamic Air Exchange (mm)	5±12	8±13	12±20

Table 3: Perspiration (mean ± standard deviation) while wearing the PIN and Dynamic Air Exchange (DAE) prostheses at different temperatures.

	20° C	30° C	35° C
# of subjects	11	8	12
Accumulated in PIN locking liner (g)	0.1±0.2	0.7±0.9	0.9±1.6
Accumulated in Dynamic Air Exchange (g)	0.3±0.9	1.8±2.4	2.9±5.0
Expelled by Dynamic Air Exchange (g)	0.3±0.3	0.3±0.2	0.9±1.5
Contralateral limb PIN locking liner (g)	0.2±0.2	0.5±0.4	0.6±0.4
Contralateral limb Dynamic Air Exchange (g)	0.3±0.6	0.3±0.2	0.6±0.3

Regardless of chamber temperature, all subjects walked for 30 min without losing adherence, suggesting a more demanding protocol is needed to identify loss of suspension thresholds. The PIN slipped as much or more than DAE for all three conditions. Further, the DAE expelled a portion of the accumulated perspiration at each temperature, but subjects perspired more while wearing it compared to the PIN. These results suggest that despite greater perspiration while wearing the DAE, it may provide greater adherence (less slippage) in demanding conditions.

A limitation of this work is the small sample size. We found recruiting for this study more challenging than our previous work involving human subjects. One reason may have been the time commitment required to participate (originally six study visits involving treadmill walking but later revised to only four study visits). Over the course of the study, we enhanced our recruitment techniques and added additional staff, but did not reach our target recruitment. A second limitation of this study is our use of a PIN suspension as the standard-of-care. This suspension is most commonly used at the VAPSHCS, but other sites use suction suspensions as the standard-of-care. Perspiration could result in different adherence and pistoning between the PIN and suction systems. Future work could distinguish these differences.

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 at the American Academy for Orthotists and Prosthetists Annual Meeting and in the Journal of Rehabilitation Research and Development (see references in Section 6 of this report) to reach the clinician and patient communities. An additional journal publication is in preparation to disseminate the final results.

Findings have also been presented to DOD program officials and selected invitees (including Veterans Affairs Central Office officials) at Ft. Detrick, MD, on 27Sep2016 (see citation in Section 6 of this report).

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 7Apr2016 and 7Apr2017.

To enhance understanding of health care research and the impact of federal funding, the PI briefed the Honorable Adam Smith, the U.S. Representative from Washington State and ranking member of the House Armed Services Committee, on the plans for this research on 4Aug2014.

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?

This project has the potential to impact how prosthetic sockets are designed for lower limb amputees living and working in demanding environments. Individuals with lower limb amputations are currently saddled with the unfortunate reality of having to stop their physical activities, doff their prosthesis and dry their residual limb before resuming their activities to prevent or minimize prosthesis slippage (i.e., pistoning) or complete loss of prosthetic adherence. The dynamic air exchange system has the potential to ameliorate these problems.

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:

Changes in approach and reasons for change

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

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

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

Nothing to report.

6. PRODUCTS

Publications, conference papers, and presentations

The PI gave a podium presentation describing the results from this research at the American Academy of Orthotists and Prosthetists 43rd Annual Meeting & Scientific Symposium held on March 2, 2017 in Chicago, IL. The abstract for this presentation can be found in the conference proceedings and the appendix of this report. Both the presentation and the abstract acknowledged federal support.

Klute GK, Berge JS, King C. “Perspiration and secure suspension for lower limb amputees in demanding environments.” Proceedings of the American Academy of Orthotists & Prosthetists, 43rd Academy Annual Meeting & Scientific Symposium, March 2, 2017.

Journal publications

The PI published a manuscript describing the dynamic air exchange prosthesis and its performance in a similar rest-walk-rest protocol with lower limb amputees (n=5) while wearing thermally-insulative garments in a laboratory environment (~30% relative humidity and 20° C). The results revealed the DAE prosthesis expelled more than a third of the total perspiration, suggesting it may enable longer uninterrupted periods of perspiration-inducing activity. This manuscript can be found on-line (open access) and in the appendix of this report. The manuscript acknowledges federal support.

Klute GK, Bates KJ, Berge JS, Biggs W, King C. Prosthesis management of residual-limb perspiration with subatmospheric vacuum pressure. *J Rehabil Res Dev*, 2016;53(6). 10.1682/JRRD.2015.06.0121.

An additional journal publication describing the final results is in preparation. Federal support will be acknowledged.

Books or other non-periodical, one-time publications

Nothing to report.

Other publications, conference papers, and presentations

The PI presented a project summary with results to DOD personnel and selected invitees at Ft. Detrick on 27Sep2016.

Klute, GK. “Perspiration thresholds and secure suspension for lower limb amputees in demanding environments.” U. S. Army Medical Research and Material Command, Clinical and Rehabilitative Medicine Research Program, Socket Technology and Related Limb Health In-Progress Review, Ft. Detrick MD, September 27, 2016.

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:	<i>Glenn K. Klute, PhD</i>
Project Role:	<i>PI</i>
Researcher Identifier (e.g. ORCID ID):	<i>GKLUTE</i>
Nearest person month worked:	<i>5.4 (15% per year for 3 years)</i>
Contribution to Project:	<i>No changes.</i>
Funding Support:	<i>VA Research Career Scientist (A9248-S) Dept. of Veterans Affairs, Rehabilitation R&D Service This award supports Dr. Klute's research (salary only) to improve the quality of life and functional status of Veteran lower limb amputees.</i>

Name:	<i>Charles King, CPO</i>
Project Role:	<i>Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>9 (25% per year for 3 years)</i>
Contribution to Project:	<i>No changes.</i>
Funding Support:	<i>No changes.</i>

Name:	<i>Jocelyn S. Berge, MSE</i>
Project Role:	<i>Investigator</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>30 (83% FTE over 3 years)</i>
Contribution to Project:	<i>No changes.</i>
Funding Support:	<i>No changes.</i>

Name:	<i>Kelsey Rose Kracht</i>
Project Role:	<i>Research Assistant</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>2 (100% for 2 months)</i>
Contribution to Project:	<i>Preparation and maintenance of regulatory and contract documents, human subject test planning and preparation.</i>
Funding Support:	<i>No other support during tenure.</i>

Name:	<i>Jonathan Schreven</i>
Project Role:	<i>Research Assistant</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>12 (100% for 12 months)</i>
Contribution to Project:	<i>Design, fabrication, and testing of thermal chamber, data analysis, assistance with dissemination and documentation.</i>
Funding Support:	<i>Center for Limb Loss Prevention & Prosthetic Engineering (A9243C), Dept. of Veterans Affairs, Rehabilitation R&D Service</i>

Name:	<i>Daniel M. Daley, CPO</i>
Project Role:	<i>Research Prosthetist</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>4 (100% for 2 months)</i>
Contribution to Project:	<i>No changes.</i>
Funding Support:	<i>Center for Limb Loss Prevention & Prosthetic Engineering (A9243C), Dept. of Veterans Affairs, Rehabilitation R&D Service</i>

Name:	<i>G. Eli Kaufman, CP</i>
Project Role:	<i>Research Prosthetist</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>1 (15% for 9 months)</i>
Contribution to Project:	<i>Order prosthetic supplies, assemble prosthetic systems, fit prostheses to test subjects, perform adjustments and alignments, participate in research team meetings to discuss findings, assist in formulating study conclusions, and assist in result documentation.</i>
Funding Support:	<i>Center for Limb Loss Prevention & Prosthetic Engineering (A9243C), Dept. of Veterans Affairs, Rehabilitation R&D Service</i>

Name:	<i>Jennifer Hicks</i>
Project Role:	<i>Program Assistant</i>
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	<i>1 (15% for 4 months)</i>
Contribution to Project:	<i>Preparation and maintenance of regulator documents, human subject recruiter.</i>
Funding Support:	<i>Center for Limb Loss Prevention & Prosthetic Engineering (A9243C), Dept. of Veterans Affairs, Rehabilitation R&D Service</i>

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

The PI has been awarded one investigator-initiated grants since the last reporting period. There was no change in the PI's level of effort for this award (W81XWH-14-1-0188) and there is no overlap with the project described in this report.

A novel clutch mechanism for a more intuitive, stable prosthetic knee
Amazon Inc. 9/2017 - 8/2018
Catalyst (no grant number)
PI: Paul Pomeroy
Role: Investigator

The PI had two grants end since the last reporting period. There was no change in the PI's level of effort for this award (W81XWH-14-1-0188).

Social Activity Networks and the Mobility of Lower Limb Amputees
Dept. of Veterans Affairs, Rehabilitation R&D Service 10/2014 - 9/2017
I21 RX001603
PI: Glenn K. Klute, PhD

Torsional stiffness and user preference: lower limb amputee lab test
Dept. of Veterans Affairs, Rehabilitation R&D Service 10/2015 - 9/2017
I21 RX001933
PI: Glenn K. Klute, PhD

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS:

Department of Defense Quad Chart (updated 31 Jan 2018) for this project can be found in Appendix A.

Budget Expenditure to Date

FY14-FY2017 Projected Expenditure: \$674,942
FY14-FY2017 Actual Expenditure: (\$673,110)

9. APPENDICES:

This final report includes three appendices:

- A. Department of Defense Quad Chart (updated 31 Jan 2018).
- B. Reprint of national conference abstract: Klute GK, Berge JS, King C. "Perspiration and secure suspension for lower limb amputees in demanding environments." Proceedings of the American Academy of Orthotists & Prosthetists, 43rd Academy Annual Meeting & Scientific Symposium, March 2, 2017.

- C. Reprint of peer-reviewed journal manuscript: Klute GK, Bates KJ, Berge JS, Biggs W, King C. Prosthesis management of residual-limb perspiration with subatmospheric vacuum pressure. *J Rehabil Res Dev*, 2016;53(6). 10.1682/JRRD.2015.06.0121.

Perspiration Thresholds & Secure Suspension for Lower Limb Amputees in Demanding Environments

Log Number OR130260, Award Number W81XWH-14-1-0188



PI: Glenn K. Klute, PhD

Org: Seattle Institute for Biomedical and Clinical Research

Award Amount: \$674,942

Objective: Provide active lower limb amputees who work in demanding environments with a prosthesis that remains secure despite profuse perspiration.

Study Aims:

- Identify environment & perspiration thresholds at which the current standard-of-care prosthesis fails to provide secure suspension.
- Compare the performance of the current standard-of-care prosthesis with an innovative prosthesis that expels perspiration.

Approach: Conduct within-subject experiment with transtibial amputees (n=25) walking on a treadmill in up to three environmental conditions (20, 30, and 35° C and 50% relative humidity; 30° C condition became optional for enrollees after 9Mar2017 to facilitate recruitment) wearing standard-of-care and innovative prostheses.



Innovative Prosthesis Design

A battery-powered pump creates a small pressure differential (vacuum) between the proximal and distal regions of the donned prosthesis. This pressure differential, when carefully controlled, causes air flow inside the prosthesis, providing a means for expelling perspiration into an exterior chamber while maintaining a secure suspension.

Accomplishments: 17 individuals with transtibial amputation have been enrolled to date. 12 have completed all study procedures. 15 standard-of-care and 15 innovative prostheses have been fabricated.

Timeline and Cost

Activity	FY15	FY16	FY17
Maintain IRB approvals & operate climate chamber			
Recruit participants			
Fabricate prosthetic components			
Conduct human subject tests			
Analyze & report results			
Estimated Budget (\$K)	\$342	\$267	\$66

FY17 Activities

- Maintain HRPO/IRB approvals
- Fabricate prosthetic components
- Enroll lower limb amputee participants (n=17 to date)
- Conduct human subject experiments (n=12 to date)
- Perform preliminary analysis & report results

Budget Expenditure to Date

FY14-FY17 Projected Expenditure: \$674,942
 FY14-FY17 Actual Expenditure: (\$673,110)

Updated: 31Jan2018



Perspiration and Secure Suspension for Lower Limb Amputees in Demanding Environments

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³Arusha Control, Inc., Cumberland, MD.

INTRODUCTION

Lower limb amputees often complain about uncomfortable residual limb skin temperatures, accumulation of perspiration inside their prostheses, and loss of confidence in suspension security (Klute, 2014; Klute, 2016; Hagberg, 2001). This study compared a prosthesis designed to unobtrusively expel perspiration with a standard-of-care prosthesis in hot and humid environments.

METHOD

Subjects: Five transtibial amputees provided informed consent to participate in this institutional review board-approved protocol (49±12 yo, 93±14 kg, 1.82±0.06 m, 19±15 years post-amputation, n=4 trauma, n=1 secondary to infection). All participants considered themselves moderately active community ambulators.

Procedures: Subjects (n=5) were fit a modified patellar tendon bearing socket and two study suspensions: (1) a distal PIN locking liner and (2) an innovative suspension that included a pump to induce dynamic air exchange (DAE) between the liner and the residuum, allowing expulsion of any accumulated perspiration. Subjects were randomized to study prosthesis and asked to walk at their self-selected speed on a treadmill in an environmental chamber at 50% relative humidity (RH) and 20, 30, and 35° C, presented in random order. A 26 cm² absorbent patch was also placed on the lateral calf of the contralateral limb. While in the chamber, subjects rested while seated for 30 min, then walked for 30 min or until they lost confidence in the security of their prosthetic suspension, and then rested outside the chamber (~50% RH, 20° C) while seated for 30 min. Perspiration amounts were measured by tare weight (g) at the end of the protocol. Liner slippage (n=2) was measured by marking the skin at the proximal border of the liner prior to the protocol and measuring the distance (mm) between the mark and the liner at the end of the protocol.

Data Analysis: A linear mixed model was used to determine if differences in contralateral limb perspiration were statistically significant (p<0.05). Others were not statistically analyzed.

RESULTS

No subject lost confidence in the security of their suspension; all walked for 30 min in all conditions. One subject experienced pistoning at 30 and 35° C while wearing the PIN, but was confident to continue the protocol. Liner slippage (n=2) was greater for the DAE than PIN at 20° C but greater for PIN than DAE at 35° C (Table 1). The DAE accumulated more perspiration (Table 2) and resulted in more total perspiration (accumulated + expelled) than PIN at each

temperature. Individual results were highly variable as indicated by the large standard deviations. The DAE prosthesis expelled 51, 11, and 20 percent of the total perspiration at 20, 30, and 35° C, respectively. No difference in contralateral limb perspiration was observed across temperature (p>0.05).

	20° C	30° C	35° C
PIN	5±5	17±19	46±34
DAE	21±29	17±23	33±43

Table 1. Liner slippage (mean ± standard deviation) from two subjects (mm).

	20° C	30° C	35° C
Accumulated in PIN	0.0±0.1	0.6±0.8	1.3±1.8
Accumulated in DAE	0.3±1.0	2.0±2.8	4.1±5.9
Expelled by DAE	0.3±0.2	0.3±0.2	1.0±1.4
Contralateral limb PIN	0.2±0.1	0.5±0.5	0.5±0.3
Contralateral limb DAE	0.5±0.9	0.3±0.2	0.5±0.4

Table 2. PIN and DAE perspiration (mean ± standard deviation) from five subjects (g).

DISCUSSION

Even at 35° C, all subjects were able to walk for 30 min without losing adherence, suggesting a more demanding protocol is needed to identify loss of suspension thresholds. The DAE liner slipped more than PIN at 20° C, but the PIN slipped more than DAE at 35° C, suggesting the heavier DAE may be beneficial in more demanding conditions. The DAE expelled a portion of the accumulated perspiration at each temperature, but subjects perspired more while wearing it compared to the PIN.

CONCLUSION

These interim results suggest that despite greater perspiration while wearing the DAE, it may provide greater adherence (less slippage) in demanding conditions. Enrolling additional subjects is warranted.

CLINICAL APPLICATIONS

Dynamic air exchange technology may improve the mobility and comfort of individuals who need to maintain a secure suspension in demanding conditions.

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Prosthesis management of residual-limb perspiration with subatmospheric vacuum pressure

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Abstract—For the ambulatory person with lower-limb amputation, insufficient management of perspiration can result in inadequate prosthesis adherence, reduced mobility, and discomfort. This study compared a dynamic air exchange (DAE) prosthesis designed to expel accumulated perspiration with a total surface bearing suction socket (Suction) that cannot. Five people with unilateral transtibial amputation participated in a randomized, crossover experiment. All subjects were given a 1 wk acclimation period to each study prosthesis while we measured their step activity levels. A rest-walk-rest protocol, including a 30 min treadmill walk at a self-selected speed while wearing thermally insulative garments, was then used to observe residual-limb skin temperatures and perspiration. Afterward, subject opinions about the prostheses were assessed with questionnaires. During the weeklong acclimation period, no statistical difference in step activity levels were detected between prostheses ($p = 0.22$), but this may have been due to self-reported behavioral modifications. During the rest-walk-rest protocol, no differences in skin temperatures were observed ($p = 0.37$). The DAE prosthesis accumulated 1.09 +/- 0.90 g and expelled 0.67 +/- 0.38 g of perspiration, while the Suction prosthesis accumulated 0.97 +/- 0.75 g. The questionnaire results suggest that participants were receptive to both prostheses. The DAE prosthesis was able to expel more than a third of the total perspiration, suggesting it may enable longer uninterrupted periods of perspiration-inducing activity.

Key words: activity level, amputation, comfort, dynamic air exchange, lower limb, perspiration, prosthesis, skin temperature, suction, sweat.

INTRODUCTION

People with lower-limb amputation often complain about uncomfortable residual-limb skin temperatures and the accumulation of perspiration within their prostheses [1–6]. Even short bouts of walking can cause substantial increases in residual-limb skin temperatures [7–8] and result in cumulative increases throughout the course of a typical day [9]. The physiological response to an increase in activity can include both vasodilation and sympathetic stimulation of the residual limb's sweat glands [10]. A little moisture can actually increase the skin coefficient of friction [11–12], but if perspiration continues, a threshold is exceeded [13–14] where adherence of the prosthesis to the residual limb becomes insecure. Many people with amputation can sense the impending loss of adherence during vigorous activities and are able to stop, doff the prosthesis, wipe it and the limb dry, and then don it again. However, some circumstances may not afford such accommodations, or it may be socially undesirable to do so.

Abbreviations: DAE = dynamic air exchange, PEQ = Prosthesis Evaluation Questionnaire, VA = Department of Veterans Affairs.

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One approach to maintaining secure adherence under perspiration-inducing conditions is to keep skin temperatures below where perspiration begins. Webber and Davis incorporated a helical channel in the socket wall to cool the residual limb [15]. Ghoseiri et al. constructed a socket with a thermoelectric heat pump coupled to an aluminum heat-transfer structure integral with the socket wall [16]. Han et al. used heat pipes to concentrate heat flux to a compact heat sink where a fan could convect heat from the prosthesis to the surroundings [17]. Wernke et al. tested a liner with phase change material and found residual-limb skin temperatures to be lower at the end of an exercise bout and, for patients that perspired, that less accumulation occurred than with a liner without phase change materials [18].

An alternative approach is to expel perspiration from the prosthesis as it accumulates. This design transports perspiration by means of a miniature pump and solenoid airflow control system that can create a small pressure differential (vacuum or negative gauge pressure) between the proximal and distal regions of the donned prosthesis. This pressure differential, when carefully controlled, can be used to cause airflow (dynamic air exchange) between the prosthetic liner and the skin. This air flow can provide the means for expelling perspiration into an exterior reservoir and may also provide evaporative cooling of the residual limb.

To compare the performance of this novel prosthesis with a standard-of-care prosthesis (total surface bearing suction socket), we conducted a within-subject crossover experiment to measure differences in (1) activity levels, (2) residual-limb skin temperatures, (3) perspiration accumulation by both prostheses and expulsion by the novel prosthesis, and (4) subjective experiences.

METHODS

Moderately active people with unilateral transtibial amputation were recruited to participate in this institutional review board-approved study. Participants were between the age of 18 and 70 yr, wore their prosthesis at least 4 h/d, were at least 6 mo postamputation, were able to walk at a steady pace for at least 30 min on a treadmill, and did not have a dysvascular condition or diabetes. Participants were also able to detect the touch of a Semmes-Weinstein 5.07 monofilament (10 g force; CHS Services Inc; East Setauket, New York), used to make skin con-

tact, bend, and depart the skin at each temperature sensor site and the proximal edge of the moisture-wicking sock with airflow seal that encircled the limb while wearing one of the study prostheses.

Two study prostheses were worn by each participant: a novel, dynamic air exchange (DAE) prosthesis and a standard-of-care (Suction) prosthesis. Both were fit by a certified prosthetist. The DAE prosthesis (**Figure 1**) included a custom moisture-wicking textile sock with a proximal elastomeric airflow seal (**Figure 2**); a modified-pin lock elastomeric liner (**Figure 3**); and a total contact socket with a custom-designed, battery-operated negative gauge pressure-generating device and associated components attached to the socket exterior. The DAE system uses a small pump (CTS Series, Parker Hannifin; Hollis, New Hampshire) in fluid communication with occlusion-preventing liner ports (four proximal, one distal) to obtain a small proximal-to-distal pressure differential (~10 kPa) across the residual limb for secure adherence. A solenoid valve (High Density Interface solenoid valve, The Lee Company; Westbrook, Connecticut), which can be opened on demand by the user, allowed air flow through the sock weave from proximal to distal, ventilating the subject's skin. Depending on fit, the air flow may be up to 1.4 L/min. The pressure differential also enabled expulsion of perspiration accumulating at the distal end of the residual limb. The Suction prosthesis included an elastomeric liner, a total surface bearing suction socket with an expulsion valve, and an elastomeric sleeve. For both systems, a passive energy-storing prosthetic foot (LP Vari-Flex with EVO, Össur; Foothill Ranch, California) with aluminum pylon was attached to the socket. When needed, an additional wool or synthetic sock was worn exterior to the liner to improve socket fit.

Participants were randomly assigned to begin the study with either the DAE or Suction prosthesis, fit with a step activity monitor (StepWatch3, Orthocare Innovations; Mountlake Terrace, Washington) to measure their activity levels, and given a 1 wk acclimation period before they returned to the laboratory for a 2 h assessment. Subjects were then switched to the other study prosthesis, given a second 1 wk acclimation period, and again returned to the laboratory for a 2 h assessment.

During the laboratory assessment, subjects were asked to change into a polypropylene insulating layer (long-sleeved shirt and shorts), a polar fleece pull-over, a polar fleece cap, and knee length socks. All prosthetic components with potential to accumulate moisture were

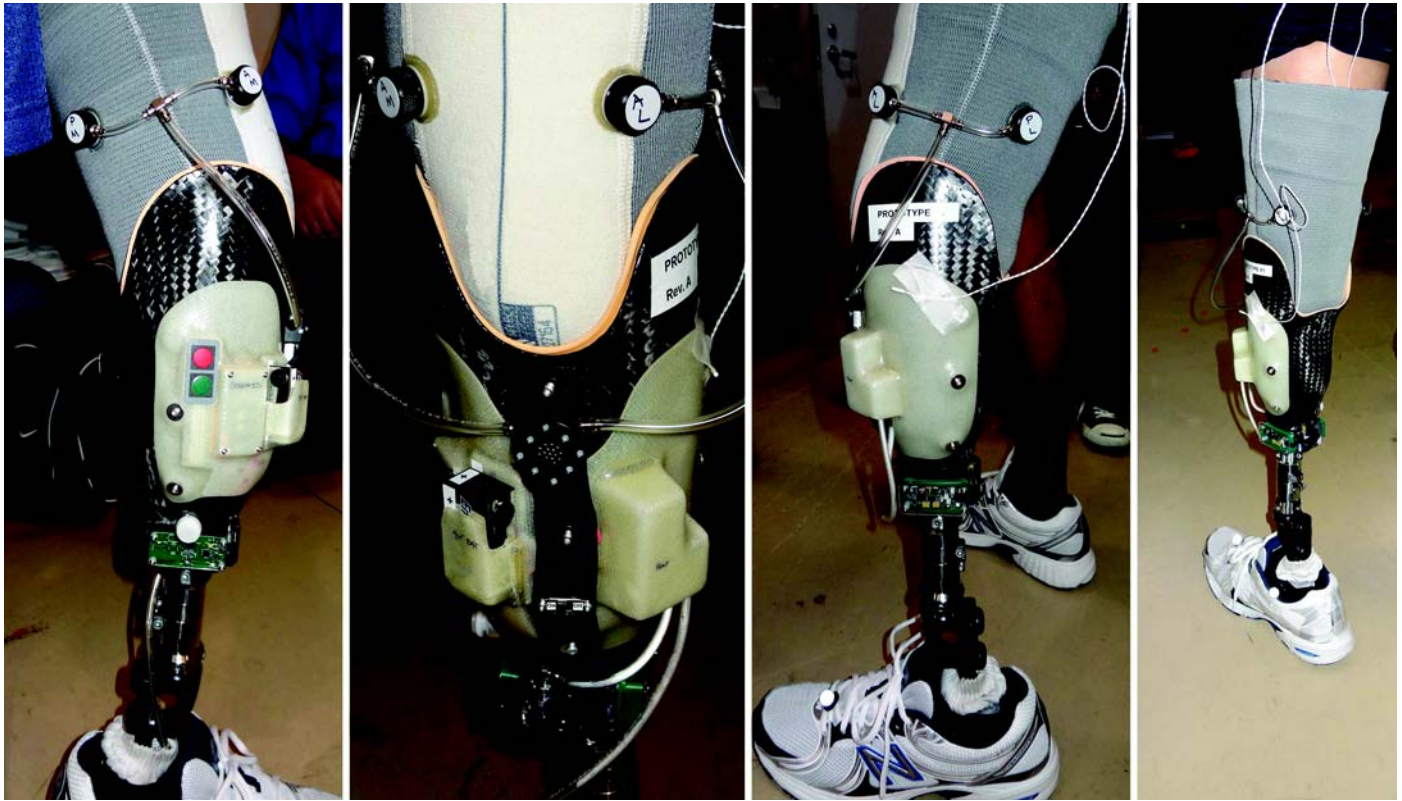


Figure 1. Medial, anterior, lateral, and posterior views (from left to right) of the dynamic air exchange prosthesis.

weighed. Two small thermistors (model MA 100BF, Thermometrics; Edison, New Jersey), powered and sampled at 0.125 Hz with a portable data acquisition unit (SmartReader Plus 8, ACR Systems Inc; Surrey, Canada), were taped to the residual-limb skin over the medial and lateral borders of the gastrocnemius muscle. The paired thermistor wires were routed up the limb on the medial and lateral sides. The prosthesis was donned over the thermistors.

Each subject then rested while seated for 30 min, walked at self-selected speed on a treadmill (Bertec Instrumented Treadmill, Bertec Corporation; Columbus, Ohio) for 30 min, and then rested again while seated for 30 min. For the session with the DAE prosthesis, subjects were asked to activate the dynamic air exchange function at the beginning of the exercise bout and have it remain on until the completion of the second rest period. After the completion of the rest-walk-rest sequence, the subject's prosthesis and the inside of the liner were wiped down with paper towels and weighed along with all com-

ponents that could accumulate moisture. The change in residual-limb skin temperature, maximum minus minimum observed during each 30 min period (rest, walk, rest), was calculated for each sensor site for both study prostheses.

Subjective experiences were assessed with two questionnaires at the end of each laboratory assessment. The first questionnaire was the Prosthesis Evaluation Questionnaire (PEQ) [19]. This standardized, self-report instrument is specific to persons with lower-limb amputations and is used to evaluate prosthetic care with regard to prescription and prosthesis-related quality of life. Three scales measuring ambulation, frustration, and residual-limb health were scored. The ambulation questions queried ability to walk in general, in close spaces, on stairs and ramps, in urban environments, and on slippery surfaces. Frustration was assessed by frequency of occurrence and rating. Residual-limb health questions examined sweat, smell, volume changes, rashes, ingrown hairs, and blisters. All three scales were scored so that



Figure 2. Moisture-wicking sock shown with proximal elastomeric airflow seal.

100 indicated the best outcome (i.e., most healthful, easiest to walk on, least frustrating). The questions were modified from the original, which uses a 1 mo period of experiences upon which to base subjective answers, to a 1 wk period of experiences.

The second questionnaire was a custom, self-report questionnaire consisting of five questions to assess the prostheses' thermal and moisture management acceptability. The questions were scored from strongly disagree (0) to strongly agree (10) and included (1) "My residual limb gets too hot and sweaty when I am active in this socket system," (2) "I find this socket system keeps my residual limb at a very comfortable temperature," (3) "My prosthesis feels like it is sliding up and down or falling off when I am active," (4) "I have been more active than normal as a result of this prosthesis," and (5) "I have to stop and dry my residual limb when wearing this prosthesis."

A paired *t*-test was used to determine whether differences in step activity levels were statistically significant ($p < 0.05$) between the DAE and Suction prostheses. A linear mixed model was used to assess whether differences in residual-limb skin temperatures were statistically significant ($p < 0.05$) by prosthesis and sensor site. Exact *p*-values are reported for each test. The analysis was conducted using SPSS version 19 (IBM Corporation; Armonk, New York). Accumulation of perspiration, expulsion of perspiration (DAE prosthesis only), and subjective experiences were not statistically analyzed because of large expected variances.



Figure 3. Prosthetic liner with proximal and distal (through the hollow locking pin) air flow ports.

RESULTS

The sample population of this study consisted of moderately active community ambulators who might benefit from improved perspiration management. Seven males with transtibial, unilateral amputation provided informed consent. Two subjects were withdrawn after providing informed consent but before completing any study procedures: one who became unreachable and one because of concerns about obesity and structural safety margins of the novel prosthesis. Four completed the protocol as planned, and one completed the protocol with a minor deviation. The subject who deviated experienced a weight gain and had fit issues half way through the protocol. This subject was fit with a larger prosthesis and then completed the remainder of the protocol. The five participants who completed the protocol were 44 ± 15 yr old (mean \pm standard deviation), 14 ± 15 yr postamputation (3 traumatic etiology and 2 secondary to infection), with a height of 1.83 ± 0.05 m and a body mass of 89 ± 18 kg.

Observations of their activity levels over the 1 wk acclimation period found subjects were not significantly more active ($p = 0.22$) while wearing the Suction prosthesis ($3,649 \pm 2,411$ prosthetic leg steps/d) than while wearing the DAE prosthesis ($2,607 \pm 2,308$ prosthetic leg steps/d).

There were no differences in residual-limb skin temperature across study prosthesis ($p = 0.37$) or sensor site ($p = 0.68$) during the rest-walk-rest protocol while wearing

thermally insulative clothing. The residual-limb skin temperature generally stayed constant during the first 30 min rest period, increased ($\sim 3^{\circ}\text{C}$) during the 30 min walk at self-selected speed, and fell gradually ($\sim 1^{\circ}\text{C}$) during the final 30 min rest period (**Table**).

After the rest-walk-rest protocol when subjects were wearing thermally insulative clothing, our observations found that the DAE prosthesis accumulated 1.09 ± 0.90 g and expelled 0.67 ± 0.38 g perspiration, while the Suction prosthesis accumulated 0.97 ± 0.75 g. Neither limb lost adherence during the test, nor did any of the subjects stop walking because of adherence (or any other) concerns.

As measured by the PEQ, subjects opined that their residual limb was healthier while wearing the DAE (89 ± 15) than with the Suction (66 ± 30); it was easier to ambulate while wearing the DAE (76 ± 25) than with the Suction (65 ± 32), but wearing the DAE (49 ± 32) was more frustrating than the Suction (58 ± 40).

As measured by the custom questionnaire, subjects agreed (7.6 ± 1.8) that the Suction prosthesis got too hot and sweaty during activity but strongly disagreed (0.8 ± 1.0) when wearing the DAE prosthesis. Subjects slightly disagreed (4.0 ± 3.2) that the Suction prosthesis kept their residual limb at a very comfortable temperature, but they strongly agreed (8.8 ± 0.6) with the statement when wearing the DAE prosthesis. With regard to adherence, subjects somewhat disagreed that both the Suction prosthesis and the DAE prosthesis (3.0 ± 3.7 vs 3.0 ± 2.4 , respectively) felt insecure during activity. Subjects slightly disagreed (3.7 ± 3.4) that they were more active than normal when wearing the Suction prosthesis, and slightly agreed (5.6 ± 2.1) that they were more active

when wearing the DAE prosthesis. Finally, subjects agreed (6.4 ± 3.1) that they had to stop and dry their residual limb when wearing the Suction prosthesis, but strongly disagreed (0.8 ± 0.7) with that statement when wearing the DAE prosthesis.

DISCUSSION

Accumulation of sweat inside the prosthetic socket of people with lower-limb amputation can lead to the prosthesis and liner sliding off or the users significantly reducing their activities so their prosthesis will stay on. The usual way to solve this problem is to simply doff the prosthesis, pour out the accumulated sweat, towel off the residual limb, and resume activity. The purpose of this study was to compare the performance of a novel prosthesis that can expel accumulating perspiration with a standard-of-care while participants performed a repeatable, laboratory-based protocol.

A limitation of this study was the small sample size ($n = 5$) of persons with transtibial amputation who were moderate community ambulators. Applying these results to the broader amputee population who have higher or lower mobility, different etiologies, or different amputation levels (e.g., transfemoral) should be done with caution.

The activity level of individuals while wearing the study prostheses was not statistically different, but this may be due to the large variation in activity levels. Importantly, the activity levels while wearing either prosthesis remained above the 1,100 to 1,450 prosthetic leg steps/d threshold for remaining a community ambulatory [20–21], suggesting that either study prosthesis would enable individuals to live independently. Unsolicited posttest comments by the subjects provide some insight regarding the large variability in the observed differences. One subject had difficulty aligning the locking pin while donning the DAE prosthesis and bruised the distal end of his residual limb. His frustration and discomfort may account for the observation that his daily step count while wearing the Suction prosthesis was more than three times the amount when wearing the DAE prosthesis. Another subject was moving to a new residence while wearing the Suction prosthesis and injured himself (not study related), which may explain why his activity level was more than four times the amount while wearing the DAE prosthesis as opposed to the Suction prosthesis.

Table.

Change in residual-limb skin temperature (mean \pm standard deviation) while wearing study prostheses during first rest period, exercise period, and second rest period.

Time Period	DAE ($^{\circ}\text{C}$)	Suction ($^{\circ}\text{C}$)
First Rest		
Medial Gastrocnemius	0.0 ± 0.4	0.0 ± 0.3
Lateral Gastrocnemius	0.0 ± 0.3	0.5 ± 0.3
Exercise		
Medial Gastrocnemius	3.1 ± 0.8	3.4 ± 0.7
Lateral Gastrocnemius	2.8 ± 0.4	2.9 ± 0.8
Second Rest		
Medial Gastrocnemius	-1.1 ± 0.2	-1.1 ± 0.1
Lateral Gastrocnemius	-0.9 ± 0.5	-0.8 ± 0.3

DAE = dynamic air exchange.

Another subject inquired about wearing the DAE prosthesis while running during the initial fitting. As we had not performed any standardized load tests (e.g., [22]), we asked the subject to only use the DAE prosthesis during low-impact athletic activities like walking and biking. Upon completion of the protocol, this subject admitted that he did not wear it to work because he worried it would not hold up to the rigors of his job, which may explain his very low activity level (<200 prosthetic steps/d) while wearing the DAE prosthesis in comparison to his activity level while wearing the Suction prosthesis (>4,000 prosthetic steps/d).

The DAE prosthesis had negligible effects on residual-limb skin temperatures when compared with the Suction prosthesis. Despite the air flow produced by the small differential pressure between the proximal and distal ports of the DAE prosthesis, it was insufficient to reduce local skin temperatures. However, it is possible that operation of the DAE system produced some convective cooling that countered additional heat sourced by local vasodilation of the gastrocnemius muscle. Such a scenario might result in a lower core temperature while the local skin temperature remained constant. Heat sourced by friction from residual-limb pistoning may have also countered any convective cooling by the DAE, but this scenario would likely have no effect on core temperature. Skin temperatures could also have been influenced by the thicknesses and materials of socks worn between the liner and the socket on both study prostheses. Subjects were free to don socks during acclimation and prior to testing to achieve a satisfactory fit. The sockets for this study were fabricated following our clinical practice of between a 0- and 2-ply fit. While in situ sock thickness is difficult to measure, we suggest the sock thickness, if present, was thin.

The DAE prosthesis was able to expel perspiration while maintaining secure adherence during the rest-walk-rest protocol. Interestingly, the total amount of perspiration (accumulated plus expelled) while wearing the DAE was 80 percent more than the Suction prosthesis. If the approximately 0.66 g of perspiration expelled by the DAE had remained between the skin and liner, it is unknown whether that amount would have resulted in an insecure adherence. While a little moisture may increase the skin coefficient of friction [11–12], if sufficient perspiration accumulates to produce a thin film of moisture, the coefficient of friction can become greatly reduced. The time to loss of adherence under controlled conditions

(e.g., activity intensity, environment temperature and humidity) would aid in defining perspiration thresholds for secure adherence.

The user experience was measured by the PEQ, modified such that subjects reported their experiences over a 1 wk rather than a 4 wk period. The shorter duration may have weakened its psychometric properties by making it more difficult to distinguish effects between the subject's current prosthetic prescription and the study prostheses. The results suggest less frustration while wearing the Suction prosthesis but better residual-limb health and ambulation while wearing the DAE prosthesis. Subjects consistently reported less sweat inside their prosthesis, and over half reported less odor while wearing the DAE prosthesis. Two subjects were particularly displeased with the amount of sweat and odor inside their Suction prosthesis. In general, subjects reported maintaining good skin health with both systems. Unfortunately, one subject bruised the distal end of his residual limb while donning the DAE prosthesis and another developed a quarter-sized blister while wearing the Suction prosthesis during each subject's acclimation week. One subject experienced an abrasion from a thermistor while testing his first study prosthesis (DAE) and subsequently reported low scores regarding skin health while wearing the Suction prosthesis. It is unclear whether those scores reflect the prior existence of the abrasion or not. The results regarding frustration with the system were highly variable (large standard deviations), but in general the subjects thought the Suction prosthesis was less frustrating than the DAE prosthesis. The most frustrated user of the DAE prosthesis was the first subject, who found it difficult to align the pin with the locking mechanism. The pin and lock housing were modified, and we notified the subsequent subjects to be mindful of alignment and to be patient when donning the socket. Ambulation scores were similar for all questions except the ability to walk up stairs, on the street or sidewalk, and on surfaces, in which subjects generally had more confidence in the DAE prosthesis than the Suction prosthesis. One subject noted that the bulk of the suspension sleeve worn over the Suction prosthesis made ascending stairs difficult because of a limited range of knee motion.

The user experience was also measured by a custom questionnaire. The results suggest that the subjects generally perceived the DAE as more effective at providing thermal comfort and managing moisture accumulation than the Suction prosthesis. The subjects felt their residual

limb was too hot and sweaty during activity while wearing the Suction compared with the DAE prosthesis, with over a six-point difference in scores. They also felt a greater need to stop and dry their residual limb while wearing the Suction than with the DAE, with a five-point difference in scores. This suggests the subjects perceived that the DAE prosthesis managed heat and moisture more effectively than the Suction prosthesis, a proposition supported by the subjects' opinion by a difference of over four points that the DAE kept the residual limb at a very comfortable temperature. The perception of adherence was highly variable (large standard deviations), but on average scored moderately low for both study prostheses. Interestingly, subjects opined they were more active than normal while wearing the DAE than the Suction prosthesis. This opinion is in contrast to the step activity results, but their positive perception suggests that they found the DAE prosthesis to be able to provide desirable benefits with an acceptable burden. A limitation of the custom questionnaire was that it only explored a few of the many domains related to satisfaction with a prosthesis.

CONCLUSIONS

This study found that a novel prosthesis was able to expel accumulating perspiration when people with lower-limb amputation participated in a perspiration-inducing activity. In comparison with a standard-of-care prosthesis, the activity levels of the participants during a week-long acclimation period were the same regardless of which prosthesis was worn, though the lack of statistical difference may have been due to circumstances and behavioral modifications that emerged from the sample population ($n = 5$). Residual-limb skin temperatures were also the same over the duration of a rest-walk-rest protocol that included a 30 min treadmill walk at self-selected speed while wearing thermally insulative garments. While no subject lost adherence during the laboratory test (both study prostheses retained ~ 1 g of perspiration), the novel prosthesis expelled 38 percent of the total perspiration, suggesting it may improve adherence under more demanding conditions. Questionnaire results suggest the participants were receptive to both prostheses.

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Author Contributions:

Study concept and design: G. K. Klute, C. King.

Acquisition of data: K. J. Bates, J. S. Berge.

Analysis and interpretation of data: G. K. Klute, K. J. Bates, J. S. Berge, W. Biggs, C. King.

Drafting of manuscript: G. K. Klute.

Critical revision of manuscript for important intellectual content:

G. K. Klute, K. J. Bates, J. S. Berge, W. Biggs, C. King.

Statistical analysis: K. J. Bates, J. S. Berge.

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