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14. ABSTRACT
The goal of this project is to investigate the clinical effectiveness of temperature-controlle prosthesis liners over the long-term. To that end, outcome data are being collected at two sites over a total period of 12 months, including two 6-month intervention periods with comparable climate conditions (i.e., equal amounts of cold and warm weather). In accordance with this project plan, no results are yet available. Participant recruitment, enrollment have continued through most of the project period, with data collection starting for the first cohort in January and for the second cohort in July. The recruitment goals (25 enrollees per site) have been met and exceeded at the main site, but delays at the secondary site have necessitated ongoing efforts to meet the overall recruitment goal. The study protocol as well as preliminary results from a small sub-sample have been disseminated an abstract and manuscript form.

15. SUBJECT TERMS
Limb prosthetics; liner suspension; temperature control; phase-change material

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER O PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
REPORT	**ABSTRACT**	**THIS PAGE**			USAMRMC
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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INTRODUCTION:

The purpose of this research is to investigate the clinical effectiveness of temperature-control prosthesis liners. Such liners, which have recently become commercially available, promise to improve the micro-climate around the residual limb in users of limb prostheses. We investigate this claim in a multi-site double-blind randomized cross-over study design, intended to generate high-quality evidence.

KEYWORDS:

Artificial limbs, liner suspension, temperature control, phase change materials, clinical trial, outcome assessment, mobility, step count

ACCOMPLISHMENTS:

What were the major goals of the project?

Goals for the second year of the project were the completion of data collection for all 50 subjects (25 per site) by month 9, and the data analysis and interpretation by month 12.

What was accomplished under these goals?

(1) Pitt IRB approval was obtained on 10/17/2017 and renewed for another year on 10/28/2019. The respective HRPO approval was issued 02/01/2018. The approval at the secondary site, by Widener University IRB was obtained on 09/11/2018 and has subsequently been renewed on 03/29/2019..

At the Pittsburgh site. to date, a total of 49 potential participants were contacted and/or screened, of whom 29 were enrolled and 13 were found ineligible. While recruitment efforts are ongoing, formal enrollment of new participants will commence in the next spring to allow for a comparison of liner types around the hot days of summer. Recruitment at Widener started after the final IRB approval and has yielded 13 subjects by the reporting date. Four of those participated in the first cohort and the rest in the second cohort.

The start of the data collection period for the first cohort was in January 2019. The second cohort started the protocol in July 2019.

(2) Specific objectives of this study were not yet met at this stage, owing to the nature of the long-term protocol and the associated unavailability of data for analysis

(3) Results or key outcomes that were reported include findings from a preliminary analysis of the first month data of the first cohort. The respective conference abstract is attached.

(4) Other achievements: We have been working on publishing the protocol, which we believe may be adoptable for future randomized controlled trials in the field of prosthetics and orthotics. A respective manuscript in the journal Trials *has been accepted for publication.*

The methodology for recruitment and screening has been executed as proposed, using the Pitt+Me research registry, outreach through amputee support groups both offline and online, and disseminating information about the study at

local P&O businesses and events. An IRB approved screening script is used to determine eligibility at intake of a potential participant. Recruitment and screening materials are essentially identical between the two sites.

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

A number of graduate assistants are supported through this grant and are gathering hands-on research experience by taking on duties in the context of executing the protocol. Those students receive individual guidance and mentoring from the investigators, as well as standardized training in human subjects' protection and research ethics.

Also, the unanticipated necessity to replace part of the study team led to some activities in that domain. PI Fiedler met repeatedly with colleagues and students at Widener University, in order to convey knowledge specific to this research area, including the state of the science, typical barriers and limitations, and the importance of the goals of this project in this context.

How were the results disseminated to communities of interest?

Nothing to Report.

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

The next reporting period will be dedicated to completing the data collection and the analysis of results in accordance with the statement of work. While, due to the previous delays, a one-year-data extension of the project has become necessary, study activities are consistent with the updated timeline to eventually accomplish the goals and objectives.

IMPACT*:*

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

Nothing to Report.

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?

Nothing to Report.

CHANGES/PROBLEMS:

Changes in approach and reasons for change

We have not seen the necessity to change our approach to recruitment and data collection in the reporting period.

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

The main problem that affected the timeline of this project was the unexpected passing of Dr. Akins early on in the project period. This has, among other things, affected recruitment at the Widener site and resulted in a shortfall of participants. We are continuing our recruitment efforts in order to reach the targeted sample size eventually. A third

cohort can be included, albeit with an abbreviated protocol (only covering the summer months when temperature control materials may have the greatest effect) before the end of the project period.

Changes that had a significant impact on expenditures

Expenditures have been lower than anticipated, reflecting the delays in staffing for this study. Since an extension of the study period has been granted, it is expected that these funds will be eventually expended as planned.

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

No changes to report.

Significant changes in use or care of human subjects

No changes to report.

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

Not applicable

PRODUCTS:

Publications, conference papers, and presentations

Journal publications. *Nothing to report.*

Books or other non-periodical, one-time publications. *Nothing to report.*
Other publications, conference papers, and presentations. *Fiedler, G., Singh, A., McKernan, G., Zhang, X. (2019). "Effect of Liner Material on Prosthesis User Activity – Preliminary Data", American Orthotic and Prosthetic Association (AOPA) Assembly, San Diego, CA, Sep 25-28*

Website(s) or other Internet site(s)

Pitt+Me study page: https://pittplusme.org/studyarms/publicdetails?guid=321eea6d-40c0-4cae-87f2-2e6a7e4ae34b

Clinicaltrials.gov page: https://clinicaltrials.gov/ct2/show/NCT03428815

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	*Goeran Fiedler*
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	*Gfiedler*
Nearest person month worked:	*3*
Contribution to Project:	*IRB compliance, recruitment/ enrollment of subjects, visit/training c at Widener site, data interpretation/dissemination, reporting*
Funding Support:	

Name:	*Anita Singh (from Aug 2018)*
Project Role:	*Co-PI*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*2*
Contribution to Project:	*IRB compliance, recruitment, GSR hiring and training, supervision of data collection, dissemination*
Funding Support:	

Name:	*James Peters*
Project Role:	*Co-invesitigator*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*1*
Contribution to Project:	*data collection, recruitment and screening, scheduling, supervision c student assistants*
Funding Support:	

Name:	*Xueyi Zhang*
Project Role:	*Graduate research assistant*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*8*
Contribution to Project:	*Training, participant scheduling, data collection, post-processing, dissemination*
Funding Support:	

Name:	*Kevin Quinn*
Project Role:	*Student research assistant*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*2*
Contribution to Project:	*Training, protocol review, manuscript development, assistance with recruitment, screening, and material ordering*
Funding Support:	

Name:	*Robert Johnston*
Project Role:	*Student research assistant*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*4*
Contribution to Project:	*Data collection, assistance with recruitment, screening, scheduling*
Funding Support:	

Name:	*Danielle Sell*
Project Role:	*Student research assistant*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*4*
Contribution to Project:	*Data collection, assistance with recruitment, screening, scheduling*
Funding Support:	

Name:	*Gina McKernan*
Project Role:	*Statistician*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	*0*
Contribution to Project:	*Executing the blinding protocol, processing and analysis of preliminary data*
Funding Support:	

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

No.

What other organizations were involved as partners?

Organization Name: *Widener University*

Location of Organization: *Chester, PA*

Partner's contribution to the project *(identify one or more)*

Collaboration *(external site for this multi-site study)*

SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS: *An updated Quad Chart is inluded with attachments.*

APPENDIX: *Conference abstract presented at AOPA 2019*

EFFECT OF LINER MATERIAL ON PROSTHESIS USER ACTIVITY – PRELIMINARY DATA

Goeran Fiedler[1], Anita Singh[2], Gina McKernan[1], Xueyi Zhang[1],

[1]University of Pittsburgh, [2]Widener University

INTRODUCTION

The advent and subsequent widespread use of elastic liners for prosthesis suspension in the past decades, has helped address a number of important clinical problems, including the safe connection between residual limb and prosthesis, wearing comfort, and ease of prosthesis donning and doffing. However, the circumstance that the elastic liners are in such close contact with the skin that they prevent heat and moisture exchange with the environment has also lead to undesirable side effects in many users, most notably excessive sweat accumulation. Among the various approaches to combating this issue is the use of phase-change materials in prosthesis liners. These materials are capable of absorbing thermal energy and thereby stabilizing the surface temperature of the limb better than comparable conventional liners.[1] However, it is yet unknown whether this more steady temperature has clinical effects, for instance, if it contributes to a difference in prosthesis users' activity levels.

A currently ongoing research study has the goal of investigating this question by comparing the effects of different liners over a one-year period.[2] We are presenting preliminary data of the first sub-sample.

METHOD

People with lower limb loss who are using a prosthesis with liner suspension for ambulation were recruited for participation in this IRB approved study. They received a new set of two liners (to alternate daily for cleaning and drying) which they were instructed to use instead of their original liner(s). Whether they received interventional liners (made from phase-change material) or identical looking placebo liners for this first intervention period was randomized and both participants and study personnel were blinded to the group allocation. Upon verifying the fit of the study liners, participants were asked to continue with their usual activities of daily living while using the new liners and wearing a StepWatch activity monitor on their prosthetic leg. The StepWatch monitor data is read out by study personnel approximately every two weeks. Average daily step counts were statistically compared between participants using the intervention or the placebo liners.

RESULTS

A total of 18 participants has started the protocol, of which 10 have participated at least one month and were included in this preliminary analysis (Table 1).

Table 1: Participant demographics (n=10; 70% Male)

	Min	Max	Mean	Std. Dev
Age/years	32	77	56.5	13.2
Weight/kg	61.23	129.27	93.80	19.84
Height/cm	157.48	195.58	175.86	10.61
Plus-M/%ile	47.1	64.5	56.1	5.6

Average daily step counts were 2,681 for the intervention group (n=4) and 1,920 for the control group (n=6). The distribution was approximately normal (Figure 1), so a comparison of means is appropriate. The effect of treatment condition on average daily steps was not significant: $F(1,8) = 1.58$, $p=0.244$.

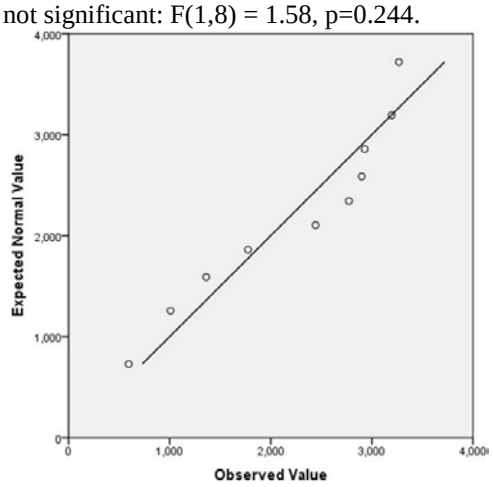

Figure 1: Normal Q-Q plot of Average

CONCLUSION

The presented preliminary analysis offers the first findings of this ongoing long-term intervention study. In this small sub-sample and over a very limited period of assessment time, the group differences in daily step counts were not significant.

Limitations of this study, some of which will be overcome by increasing the sample size and assessment period in the context of the larger work, include the data collection only during the months of January, February and March in the U.S. Midwest. With an average daily high temperature of 6.2 degrees C, it is likely that the problem of sweat accumulation was not as pronounced as it would be expected in warmer months of the year. It must also be noted that three of the participants had socket fitting problems during parts of the data collection period, preventing them from wearing their prosthesis for several days (those days were disregarded for step count averages) and potentially skewing the results.

SIGNIFICANCE

This ongoing randomized control trial will generate evidence on the effectiveness of different liner materials that may inform clinical decision making in the future.

REFERENCES

1. Wernke et al. *JPO.* 2015;27(4):134-139.
2. Fiedler et al. 45th AAOP Meeting; Mar 6-9, 2019; Orlando, FL.
3. 12-item Short Form (v 1.2). http://www.plus-m.org. Accessed on 7/30/2016.

ACKNOWLEDGEMENT

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