Moisture Management Liner Effectiveness Study

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1. Background and Introduction

The comfort and fit of the residual limb within a prosthetic socket are of primary concern for many amputees. The residual limb is typically covered by non-breathable and non- thermally conductive materials that can create a warm and ultimately moist environment. These layers consist of a prosthetic liner that rolls onto the limb and traps heat and occasional extra prosthetic socks. Studies found increases in socket temperature after the prosthesis was donned (0.8°C) [1] and after 30 minutes of walking (2.5°C) [2]. Temperatures were found to remain elevated long after activity cessation and even a rest period of double the duration of the preceding activity period is insufficient to return the limb to its initial temperature [3]. Peery, et al. [1] suggested that a modest temperature increase of only 2°C may be responsible for reports of thermal discomfort by amputees. Therefore, a small amount of activity can cause the socket temperature to elevate and remain at an uncomfortable level for an extended period of time, which can lead to decreased wear times. In summary, an uncomfortable socket/residual limb interface decreases prosthesis use among amputees who want to remain active in their lives.

To address this, Vivonics, Inc. and Liberating Technologies, Inc. (LTI) have developed a silicone liner approach to wick sweat from the skin and out of the socket through specially designed microchannels and to passively conduct heat from the skin using thermally conductive elastomers. This liner has been developed to work alongside a thermo-electric cooling (TEC)-based module called the Intrasocket Cooling Element (ICE) developed in a parallel project by Vivonics and LTI. The ICE device can be embedded into the prosthesis in order to cool the residual limb. A technology that can provide thermal control while retaining adequate suspension, weight, and other prosthetic characteristics would benefit many prosthesis wearers.

2. Study Rationale

This study will focus on investigating the efficacy of this novel moisture and thermal management (experimental) liner.

The rationale for this study is to determine how well the new technology can regulate the residual limb temperature, reduce the moisture generation, and remove excess moisture in a controlled laboratory environment.

3. Objectives

The primary objective of this study is to measure the effects experimental techniques of moisture and thermal management has on moisture and temperature in the socket. Moisture and thermal management of the residual limb inside the prosthetic socket could result in greater comfort while wearing the prosthesis, and ultimately could result in greater function and better quality of life (QoL).

4. Study Design

A repeated measures study will be conducted to analyze the temperature and moisture generation of the residual limb with and without the experimental liner and active cooling system within a standard prosthetic socket.

Both able-bodied research subjects, and lower limb amputee research subjects who use transfemoral or transtibial prostheses will be recruited for testing. Liners for able-bodies subjects will have the distal end removed to allow for donning. All subjects will visit Liberating Technologies, Inc. to be consented and to complete study testing.

Test conditions include:

- **Control condition.** This would be a non-modified control liner (such as commercially off the shelf (COTS) liners or ones made without any additives) for able-bodied subjects and, for amputees, a check socket (with or without an unmodified control liner, depending on whether the amputee typically wears a liner or not).
- **Experimental liner condition**. This would be a prototype liner designed to reduce and/or remove moisture and heat that builds up on the limb.
- **Active cooling condition**. This would integrate the TEC module (see Figure 1) into the socket for amputees (with the experimental liner or with a control liner), or the TEC module with the experimental or control liner for able-bodied subjects.

Figure 1. TEC Module embedded into standard prosthetic socket for active cooling condition.

Passive cooling and moisture management will be achieved from an experimental liner made of standard silicone used in COTS liner with bio-compatible thermally conductive additives. A standard check socket will be fabricated for each amputee subject if necessary to fit the experimental liner. Additional modifications, such as channels in a liner and socket, may be used to remove moisture such as ones developed under New England IRB (NEIRB) protocol NEIRB # 14-232/HRPO Log A-17885.

Active cooling will be achieved by embedding a TEC assembly into a standard prosthetic socket and liner. The TEC assembly is comprised of a thermoelectric cooling unit (TEC), heat sink, fan and heat spreader and has previously been tested under New England IRB (NEIRB) protocol NEIRB # 120160413/HRPO Log A-17885.2. An experimental socket with the integrated heat spreader will be fabricated for each amputee subject. The amputee subjects will either visit their prosthetist's office

or LTI's in-house prosthetist for measurements and the new socket will be fabricated. The subjects may return for alignment and adjustment on the new socket.

Testing will measure the temperature, humidity, socket suspension and moisture accumulation of the limb when active cooling, moisture/thermal management, and no cooling is applied in order to determine the effectiveness of the proposed technology.

Walking will be used to increase the temperature of the limb in order to measure the system's ability to cool it as well as to determine subject perception of heat and comfort with the experimental liner and active cooling system as compared to the control liners and sockets.

Research participants will have socket temperature and moisture data collected while walking on a treadmill in the different conditions throughout different site visits. The active cooling from the ICE module will be completed with the experimental liner as well as with the control liner. The order of conditions with the experimental and control liners and the active cooling on or off will be randomized for each subject.

5. Study Population

Both able-bodied persons and persons with transfemoral and transtibial limb loss who are able to walk with a prosthesis will be recruited for this study. Able-bodied subjects will be recruited via word of mouth. LTI will enlist the aid of its current in-house prosthetist, Michael Amrich, CPO and its network of prosthetists including Next Step B&P, Cornell O&P, and several others, to assist in subject recruitment and will be given flyers to hand out to their patients. Additionally, flyers will be distributed online (i.e. LTI's website: LiberatingTech.com/research-studies) and in person by LTI to persons who may be within the target population. If subjects are interested in participating, they can call the number on the flyer and schedule a time to discuss the study with the investigators.

A maximum of 10 able-bodied and 20 lower-limb amputee subjects will be recruited for this study. This is increased from a target 12 subjects to account for any drop-outs, etc.

6. Participant Eligibility

Lower limb amputees will be identified who meet the following inclusion criteria: must be 18-89 years old, be willing and able to complete the tasks outlined, are at least 6 months on a definitive prosthesis, fits within an experimental liner, and can understand English in order to be properly consented and provide their feedback to the study personnel. Subjects can be excluded at the discretion of the investigator for other unforeseen disqualifying criteria (such as specific cognitive issues, etc.).

Subjects in this study will not be discriminated by sex or race.

The risks to pregnant women and fetuses are unknown and therefore pregnant women should not participate in the study and will be screened by self-disclosure.

7. Study Methodology

Visit 1: During the first visit, the subject will be consented and enrolled in the study. Measurements and molds will be taken of the residual limb so an experimental socket can be fabricated. For the purposes of this study, the prosthetic liner is being standardized and all subjects will be provided with a prosthetic liner of the proper size, such as an Iceross Comfort Liner by Ossur or the Superior Performance Liner by ALPS, that has been deemed appropriate by a certified prosthetist

and matches the thickness of the experimental liner. Similarly, if a subject typically uses prosthetic socks, they will be provided with a standardized gel sock instead, such as the Silosheath gel sock by Silipos, of the proper size that has been deemed appropriate by a certified prosthetist.

The experimental liner will be tested on the subject to ensure proper fit and comfort as determined by a certified prosthetist. The subject may be asked to wear the liner without a prosthesis while at home before the second visit to acclimate to the liner(s) as is standard care. During this visit the subject will be asked to completed standard questionnaires regarding their quality of life with their current liner. These will include questionnaires commonly used such as the Dermatology Life Quality Index [4,5], the Residual Limb Health section of the Prosthesis Evaluation Questionnaire (PEQ) [6], and the EuroQol-5D.

The experimental socket would be created to fit the subject while wearing the gel sock (if applicable) and appropriate liner using standard clinical socket fabrication techniques. As part of the standard of care when fabricating a new prosthetic socket, the prosthetist first creates a check socket with which to test the fit on the subject before fabricating the definitive socket. Check sockets are structurally sound to walk on and use but may be a littler bulkier and heavier than a definitive socket. Because all testing will be completed in-lab, the check socket will be used for all research activities. LTI will fabricate the prosthetic sockets and install the ICE units in them.

At the same time the prosthetist fabricates the socket, s/he may also create a clear, limb "template" similar to the check socket that matches the limb without accommodating any liner or socks (skin fit). This template allows the location of the sensors on the limb to be marked on the template so that the sensors can be placed in the same location on the limb for each lab test visit.

This visit will take up to 2 hours.

Visit 2: When the experimental socket has been fabricated and instrumented, the subject will return to the lab for a second visit. The subject will be asked to meet with the prosthetist to try on the check socket for fit and alignment with the control and experimental liners.

The subject will then perform in-laboratory testing to determine the effectiveness of an experimental liner to keep the limb cooler and dryer as compared to the control prosthetic liner. The order of conditions (Experimental Liner versus Control Liner, with or without the active cooling ICE unit) will be randomized.

Similar to what was done in a prior protocol under a previous effort (NEIRB # 120160413/HRPO Log A-17885.2), an array of temperature sensors will be attached to the subject's residual limb before donning the socket and/or liner to give a more complete picture of the overall temperature distribution across the residual limb. Baseline readings will be taken of the residual limb temperature, the body's core temperature via an oral thermometer, and the ambient temperature.

In addition, we will measure the amount of perspiration produced during each condition. The limb will be dried with a towel, so pre- and post-activity weight of the liner and towel will be measured and the difference in weight is attributed to the sweat produced during that condition as described by Wernke et al. [7]. Testing may also be performed in a thermal chamber that regulates the temperature of the testing area, such as that used by Klute et al. [8], to ensure that the subject will perspire.

In addition, humidity sensors will be attached to the subject's residual limb before donning the socket and/or liner similar to work completed by Cutti et al. [9]. These will allow a more complete picture of the onset of moisture on the residual limb during activity.

In addition, marks will be made with a skin safe marker on the leg where the top of liner rests before the subject begins the testing activity (such as walking on a treadmill). Once the testing activity has ended, the same mark will be made on the leg where the top of the liner rests. The distance between these lines will show any slippage that occurred during the activity which may be due to a lack of suspension.

The subject will be asked to do the following tasks, similar to Klute et al. [3]: (1) an initial seated rest for up to 60 minutes to obtain baseline in-socket temperature data; (2) an activity to increase their body temperature, such as walking on a treadmill [2, 3] for up to 30 minutes; (3) a seated rest for up to 60 minutes; and (4) the liner and perspiration will be collected off the limb (with a towel) and weighed for changes. The second condition will begin once baseline temperatures have been reached and the test procedure repeated in the other condition

Throughout the in-lab test sessions, photos and/or videos may be taken to document such things as the location of the sensors on the limb, the temperature gradients across the limb (with a thermal camera), etc. At the end of each condition, subjective feedback on the comfort and temperature regulation of each condition will be obtained via a questionnaire developed during this effort. The participants would fill out the questionnaire rating parameters such as perceived comfort, intra-socket temperature, potential loss of suspension, etc.

This visit will take up to 4 hours.

This visit can be repeated at the subject's volition, if more data is required or if re-testing is needed.

Visit 3: The same tasks as described in Visit 2 will be completed using the same data collection process. The order of conditions (Experimental Liner versus Control Liner, with or without the active cooling ICE unit) will be randomized. The subject will perform in-laboratory testing to determine the effectiveness the ICE unit to cool and reduce moisture generation of a residual limb with an experimental liner as compared to with a standard control prosthetic liner.

We expect to demonstrate that even if the socket doesn't reduce the temperature during walking, it can cool the socket immediately upon cessation of walking, unlike the standard socket that produces the sustained high temperatures observed by Klute, et al. [3] and Huff, et al. [2]. This benefit is expected to increase with the addition of the experimental thermally conductive liner.

This visit will take up to 4 hours.

This visit can be repeated at the subject's volition, if more data is required or if re-testing is needed.

Once all testing is completed, the research participant will complete a questionnaire to describe their opinions on the comfort, look, and functionality of the experimental liner and ICE unit.

8. Study Conduct

Subjects will be consented and screened for eligibility criteria. If they decide to participate, an experimental liner will be made that fits the size and shape of their limb and an experimental socket to fit the experimental liner will be fabricated using standard prosthetic techniques.

Subjects may withdraw at any time by simply telling the investigators they wish to stop their participation.

If a subject withdraws from the study, the data that were collected from them can still be used, and the withdrawn subjects may be replaced with a new subject. Deviations from the protocol that increase risks for subjects will be reported to Solutions IRB and HRPO for approval prior to being implemented.

The consent process and all testing will be completed at the Liberating Technologies, Inc. research facility located in Holliston, MA. Approved study staff from Vivonics, Inc. may also be present during testing visits to provide technical support or monitor testing activities. During these visits approved study staff from Vivonics, Inc. may be in contact with the subjects.

Subjects will be compensated $40 per hour for the 3 visits for the in-lab testing and prosthetist visits for an estimated total of $400 (10 hours) per subject. Travel will also be reimbursed per mile at the current IRS federal rate.

9. Study Treatment

This is not a treatment study. The purpose of the study is to evaluate the effectiveness of a moisture removal and thermally conductive liner.

10. Evaluation of Adverse Events

Based on past testing and data collection, no adverse events are expected. Adverse events could include: discomfort or dermatological reaction to experimental liner materials or sensors in the socket, tripping while walking on the treadmill, overheating or overcooling due to controller, sensor, or battery malfunction of the ICE unit. These risks have been mitigated by using biocompatible materials and/or hypoallergenic tape with the sensors, using a spotter during walking tasks for in-lab testing, and standard thermal and electrical management techniques including thermal battery management, voltage/current limiting, and monitoring temperature during testing.

All unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study and subject deaths related to participation in the study will be promptly reported to the Solutions IRB and HRPO. A written description of the adverse event will be stored in the study file maintained by the Principal Investigator. Also, the protocol will be reviewed in light of the adverse event to determine if modifications need to be made to prevent the event from occurring again. Major modifications to the research protocol and any modifications that could potentially increase risk to human subjects must be submitted to the Solutions IRB and HRPO for approval prior to implementation.

11. Ethical Considerations

There is no direct benefit to the user. Participating in this study may potentially advance the scientific community's understanding on the ability of reducing intra-socket moisture generation and cooling intra-socket temperatures to improve comfort and quality of life for lower limb amputees.

The protocol, consent form, and recruitment flyer will require IRB review and approval. The principal investigator will be in continuous communication with the IRBs and HRPO and will forward information to the co-investigators. Subjects' participation is voluntary, and they may withdraw from participation in the study at any time by simply telling any one of the investigators that they wish to stop. The investigators may choose to terminate a subject's participation if he or she experiences discomfort or injury. In addition, participants will be given any new information which is discovered during the course of the study which may influence participants' willingness to continue the study. If they desire to do so,

subjects' will also have the option to discuss any concerns regarding the study activities or the investigators with an impartial staff member of the site IRB, whose duty it is to hear and review such concerns and provide advice or take any other appropriate actions.

The investigators will ensure the anonymity of all participants in this study. After completing the consenting process, subjects will be assigned a random identification number. The number will be used on all test data associated with the subject. No personal identifiers will be associated with the data collected from the subjects during the various tests. The PI will have a master document linking the subject name with ID number, and it will be stored on a password protected computer, with only the PI and approved study staff having access to the master list. All collected test data will be kept at Liberating Technologies, Inc. and stored in a secure manner depending on the media: either a password protected computer with access limited to the co-investigators, or in a locked filing cabinet in the investigator's office. A copy of the test data will also be retained by the PI in the program folder, also stored in a secured manner. Deidentified test data may also be stored at Vivonics, Inc. using the random identification numbers assigned to subjects.

12. Study Monitoring and Oversight

The oversight of the study falls on the PI and co-investigators. They will be responsible for ensuring the study follows the approved protocol and for reporting any deviations or adverse events that occur during the study to Solutions IRB and HRPO. De-identified data, photos, and videos will be kept indefinitely to show in scientific presentations and publications. Photos will not contain any identifying information about the subject. The photographs will not include the subject's face or any identifying marks such as tattoos. If identifying photographs happen to be received from a subject, they will be de-identified by either cropping or blurring using photo-editing software.

Additionally, representatives of the United States Army Medical Research Acquisition Activity (USAMRAA) are eligible to review research records as a function of their responsibility to protect subjects in research.

13. Investigational Product Management

The experimental liners tested in this study are modified to increase the thermal conductivity and remove moisture from the limb to regulate intra-socket temperature and reduce moisture accumulation. The ICE technology tested in this study is a cooling device for the residual limb that is an add-on system to a standard prosthetic socket. Additionally, commercially-available temperature and humidity sensors may also be used in the instrumented sockets.

EXPERIMENTAL LINER

The experimental liner is a product of mixing thermally conductive additive to a base silicone material. The base material is a medical grade room temperature curing silicone rubber (RTV-2) from Wacker Chemie AG with characteristics of biocompatibility, low surface tension, thermal and chemical stability. This silicone can be sterilized easily for single as well as repeated use. The nature of the silicone is hydrophobic which prevents microbial growth. Additives such as boron nitride, carbon and graphene nanoparticles are added to enhance the thermal conductivity of the liner. These nanomaterials are skin safe and are currently being used in other skin contacting applications such as cosmetics and wearable electronics [10, 11, 12, 13].

The experimental liner will be manufactured and packaged at a manufacturing facility that makes COTS liners using the standard procedures.

INTRASOCKET COOLING ELEMENT

The ICE active cooling module is comprised of a combination of: 1) an inner Heat Spreader (isothermal) layer designed to maintain approximately constant temperature along a section of the inner wall of the socket and 2) a Heat Extractor

providing a heat channeling pathway utilizing: a) a Thermo-Electric Cooling (TEC) module, b) a heat radiator (heat sink) structure and c) an air circulating system (fan) to discharge the heat to the surrounding air.

The heat spreader functions to collect heat from around the circumference of the limb and then route it to a much smaller and more focal point where it is expelled from the socket by the heat extractor. Additionally, the system has been developed to work in conjunction with commercially-available prosthetic liners where the heat spreader is in contact with the liner, not the skin, and pulls the excess heat through the liner to extract it.

The active heat pumping mechanism that is used in these devices is a thermoelectric cooler (TEC). TECs are semiconductor devices that use electrical current to pump heat from one side of the device to the other based on the Peltier effect. As an active system, a TEC can chill the heat source (residual limb) to a temperature lower than its surroundings. In the ICE system, the TEC is used to pump heat from the heat spreader to a heat sink acting as a radiator. The TEC raises the heat sink to a temperature above ambient. A fan then facilitates removal of heat from the heat sink. The TEC heat pumping action is particularly useful in high ambient temperature situations where the heat sink and fan alone would not be able to sufficiently cool the hot side of the heat spreader.

The ICE unit is powered by a standard, commercially-available 2 cell Li-ion rechargeable battery pack, such as the Tenergy 18650 7.2V 3500mAh battery, and is housed in a case to protect against damage. This battery has protection circuitry, including over-charge, over-discharge and short-circuit protection, and is being charged with the recommended charger externally, off the subjects. Control of the device is based on a push button where the user engages the button when he/she feels that cooling in necessary and turns off the system when he/she no longer needs cooling. When the device is on, the system will to regulate cooling to the limb based on feedback from multiple sensors in the device, including the hot and cold side temperatures of the TEC. As long as the cold side of the TEC is above the minimum threshold, the TEC will be powered to reduce the limb temperature while taking into account battery life. As the cold side temperature approaches the threshold temperature, the voltage to the TEC will be reduced to maintain a TEC cold side temperature above the threshold. Prior studies have shown that applying cooling at a temperature of 22°C (72°F) is the lowest temperature that is uniformly well-tolerated [5]. Because we will have a prosthetic liner between the ICE cooling element and the skin, we will use a cold side threshold temperature that takes into account the thermal properties of the standardized liner to ensure a residual limb temperature of no less than 22°C. Our testing has shown that the cold side threshold can be as low as 11.5°C (53°F) and still maintain a skin temperature of greater than 22°C. Therefore, based on this data, we will use 11.5°C as our minimum cold side temperature threshold; however, we may iterate the control algorithm and adjust the threshold as needed as more data is collected that can inform the algorithm.

SOCKETS

The prosthetic interface used in this study will be fabricated by a Board-Certified Prosthetist, following conventional standardized methods. The "ICE System" is to be incorporated into the socket design with manufacturing techniques similar to those used to integrate commercially-available prosthetic components and add-ons, such as suction valves, shuttle locks, elevated vacuum systems (e.g. Ohio Willow Wood ONE system), etc and used in a prior approved protocol (NEIRB # 120160413/ HRPO Log A-17885.2). The inclusion of the "ICE System" will be such that the structural integrity and functionality of the socket will not be compromised. The socket characteristics will be similar to the subject's usual socket, monitoring and maintaining acceptable mobility and comfort throughout the testing procedure.

CONTROL LINERS

The control liners tested in this study will either be commercial-off-the-shelf (COTS) products that are approved for the general population or made with only the base silicone of the experimental liners. We have standardized the control liner used for this study in order to eliminate confounding factors of liner material and thickness.

PROSTHETIC SOCKS

The prosthetic socks in this study will be commercial-off-the-shelf (COTS) products that have been identified to work well with the ICE system, for example, the Silosheath gel sock by Silipose.

TEMPERATURE SENSORS

Commercially available temperature sensors, such as thermistors, thermocouples and iButtons, may be used to monitor the temperature of the ICE device as well as the temperature of the residual limb inside the prosthetic socket. The thermistors and thermocouples have been used in the approved protocols for the previous and current studies (NEIRB # 120160413/ HRPO Log A-17885.2). The iButton has been used in O&P clinical practice and research studies to monitor temperatures within O&P devices [15].

HUMIDITY SENSORS

Commercially available humidity sensors, such Sensirion SHT21S, may be used to monitor the humidity of the residual limb inside the prosthetic socket. This humidity sensor has been used in another research study on prosthetic sockets following a similar protocol by Cutti et al. [9].

14. Data Analysis

The data collected in the laboratory will include limb temperature, ambient temperature, limb humidity, ambient humidity, and moisture generation on the limb. Standard outcomes measures will include: Dermatology Life Quality Index, Modified Dermatology Life Quality Index, the Residual Limb Health section of the Prosthesis Evaluation Questionnaire (PEQ), and the EuroQol-5D). Custom questionnaires that were developed to assess the experimental liner and ICE system will also be used.

The primary outcome of this study will assess the effect of the experimental liners on the temperature of the residual limb; however secondary measures include moisture generation and humidity on the residual limb as well as satisfaction with the prosthesis using the above measures. Measures during the experimental liner conditions will be compared to the control conditions both with and without the ICE system being active.

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APPENDIX A – QUESTIONNAIRES EXPLANATION

Surveys and Questionnaires

During the human subjects testing we will be collecting subjective feedback on the comfort and temperature of the experimental liner as well as quality of life with their current liner. These will include the Dermatology Life Quality Index, the Residual Limb Health section of the Prosthesis Evaluation Questionnaire (PEQ), the EuroQol-5D, and custom questionnaires specific to the experimental liner. Some will be administered before any testing, such as the quality of life surveys regarding their current liner, others will be administered immediately upon the conclusion of each test session such as the custom questionnaires.

Visit #1 – Part #1 – Dermatology Life Quality Index

The Dermatology Life Quality Index (DLQI) is a simple, self-administered, validated questionnaire developed by Finlay and Khan [1] that is designed to measure the health-related quality of life of patients suffering from skin issues.

Visit #1 – Part #2 – Modified Dermatology Life Quality Index

Meulenbelt et. al. [2] has modified the DLQI (mDLQI) to apply on a monthly basis and applied it to amputees. The results of this questionnaire will be compared to the validated DLQI. The questionnaire was modified slightly from Meulenbelt et al. for grammatical errors and to change “amputation stump” to “residual limb” to use more commonly accepted terminology.

Visit #1 – Part #3 – EuroQoL-5D

Another questionnaire we will be using is the EuroQoL-5D (EQ-5D) survey. The EQ-5D is a well-known and widely used health status instrument that was developed by the EuroQol Group and has remained fundamentally unchanged since it was introduced in the 1990s. The number of studies using the EQ-5D suite of instruments, registered with the EuroQol Group, totaled over 17,000 by 2015. EQ-5D is designed for self-completion by respondents and is ideally suited for use in surveys, in clinics, and in face-to-face interviews. It is cognitively undemanding and takes only a few minutes to complete. We will be using the EQ-5D as a validated measure of quality of life.

Visit #1 – Part #4 – Residual Limb Health Scale

The fourth measure we will be using is a subscale of the validated Prosthesis Evaluation Questionnaire (PEQ) [3]. The PEQ consists of 82 items grouped into nine subscales, each addressing a different aspect of prosthesis wear (pain, satisfaction, comfort, etc.). The PEQ scales are not dependent on each other, so it is reasonable to use only those scales of interest. We will be using the Residual Limb Health section which rates qualities such as in-socket perspiration and skin breakdown of the residual limb. For each scale used, all of the individual questions that make up that scale must be included. The questions refer to the prior 4 weeks and are scored using a visual analog scale (100mm line). There is no total score. A guide gives coding instructions for all questions and groups the questions under different subscales. Each subscale score is computed by excluding any unanswered questions and averaging the answers within each subscale.

Visit #2 & Visit #3 – Part #1 & Part #2 – Individual Liner Questionnaire

The custom individual liner questionnaire was developed to rate the different aspects of the experimental and control liner. This questionnaire will be completed immediately after each activity to rate the liner that was used during that activity.

Visit #2 & Visit #3 – Part #3 – Liner Comparison Questionnaire

The custom liner comparison questionnaire was developed to measure the subject’s preference for different criteria between the experimental and standard liner. This questionnaire will be completed at the end of Visit #2 and Visit #3 after the subject has completed both sets of activities.

References

[1] A. Finlay and G. Khan, “Dermatology Life Quality Index (DLQI)-a simple practical measure for routine clinical use,” Clinical and Experimental Dermatology, vol. 19, no. 3, pp. 210–216, 1994.

[2] H. Meulenbelt, J. Geertzen, M. Jonkman, and P. Dijkstra, “Skin Problems of the Stump in Lower-limb Amputees: 2. Influence on Functioning in Daily Life,” Acta Dermato Venereologica, vol. 91, no. 2, pp. 178–182, 2011.

[3] D. A. Boone and K. L. Coleman, “Use of the Prosthesis Evaluation Questionnaire (PEQ),” JPO Journal of Prosthetics and Orthotics, vol. 18, no. Proceedings, 2006.

APPENDIX B – QUESTIONNAIRES

Moisture Management Liner Effectiveness Questionnaire

Version 1.0

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Sponsor	U.S. ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY (USAMRAA)
Sponsor Protocol #	
Solutions IRB #	

Subject ID:	

Visit #1 – Part 1 – Dermatology Life Quality Index

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please fill in once circle for each question.

Over the last week:	Not Relevant	Not at all	A Little	A lot	Very Much
1. how itchy, sore, painful or stinging has your skin been?		○	○	○	○
2. how embarrassed or self-conscious have you been because of your skin?		○	○	○	○
3. how much has your skin interfered with you going shopping or looking after your home or garden?	○	○	○	○	○
4. how much has your skin influenced the clothes you wear?	○	○	○	○	○
5. how much has your skin affected any social or leisure activities?	○	○	○	○	○
6. how much has your skin made it difficult for you to do any sport?	○	○	○	○	○
7. has your skin prevented you from working or studying?	**No** ○	**Yes** ○			
	Not Relevant	**Not at all**	**A Little**	**A lot**	**Very Much**
-If "No", over the last week how much has your skin been a problem at work or studying?	○	○	○	○	○
8. how much has your skin created problems with your partner or any of your close friends or relatives?	○	○	○	○	○
9. how much has your skin caused any sexual difficulties?	○	○	○	○	○
10. how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	○	○	○	○	○

Visit #1 – Part 2 – Modified Dermatology Life Quality Index

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST MONTH. Please fill in once circle for each question.

Over the last month:	Not Relevant	Not at all	A Little	A lot	Very Much
1. how itchy, sore, painful, or stinging has the skin been on your residual limb?		○	○	○	○
2. how embarrassed or self-conscious have you been because of the skin on your residual limb?		○	○	○	○
3. how much has the skin on your residual limb interfered with you going shopping or looking after your home or garden?	○	○	○	○	○
4. how much has the skin on your residual limb interfered with the time you wear your prosthesis usually?	○	○	○	○	○
5. how much has the skin on your residual limb affected any social or leisure activities?	○	○	○	○	○
6. how much has the skin on your residual limb made it difficult for you to do any sport?	○	○	○	○	○
7. how much has the skin on your residual limb been a problem at work or studying?	○	○	○	○	○
8. how much has the skin on your residual limb created problems with your partner or any of your close friends or relatives?	○	○	○	○	○
9. how much has the skin on your residual limb caused any sexual difficulties?	○	○	○	○	○
10. how much of a problem has the treatment for the skin on your residual limb been, for example by making your home messy, or by taking up time?	○	○	○	○	○

Visit #1 – Part 3 – EuroQoL-5D

By placing a tick in one box in each group below, please indicate which statements best describe your health today.

MOBILITY

I have no problems in walking about	☐
I have slight problems in walking about	☐
I have moderate problems in walking about	☐
I have severe problems in walking about	☐
I am unable to walk about	☐

SELF-CARE

I have no problems washing or dressing myself	☐
I have slight problems washing or dressing myself	☐
I have moderate problems washing or dressing myself	☐
I have severe problems washing or dressing myself	☐
I am unable to wash or dress myself	☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities	☐
I have slight problems doing my usual activities	☐
I have moderate problems doing my usual activities	☐
I have severe problems doing my usual activities	☐
I am unable to do my usual activities	☐

PAIN / DISCOMFORT

I have no pain or discomfort	☐
I have slight pain or discomfort	☐
I have moderate pain or discomfort	☐
I have severe pain or discomfort	☐
I have extreme pain or discomfort	☐

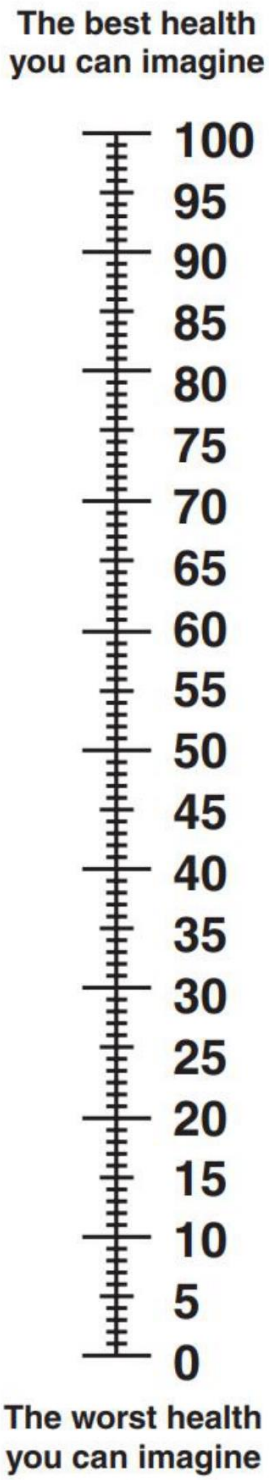
ANXIETY / DEPRESSION

I am not anxious or depressed	☐
I am slightly anxious or depressed	☐
I am moderately anxious or depressed	☐
I am severely anxious or depressed	☐
I am extremely anxious or depressed	☐

Visit #1 – Part 3 – EuroQoL-5D

1. We like to know how is your health today.
2. This scale is marked from 0 to 100.
3. 100 means the best health you can imagine.
   0 means the worst health you can imagine.
4. Mark an X on the scale to indicate how is your health today.
5. Now, please note the number you marked on the scale in the box below.

Your Health Today = ☐



Visit #1 – Part 4 – Residual Limb Health Scale

Instructions

As you read each question, remember there is no right or wrong answer. Just think of YOUR OWN OPINION on the topic and make a mark THROUGH the line anywhere along the line from one end to the other to show us your opinion.

If you use different prostheses for different activities, please choose the ONE you use more often and answer all the questions as though you were using that prosthesis.

Example

How important is it to you to have coffee in the morning?

NOT AT ALL EXTREMELY IMPORTANT

Over the past four weeks, rate your morning coffee.

TERRIBLE **EXCELLENT**

OR check __I haven't drunk coffee in the morning in the past four weeks.

This example shows that the person who answered these questions feels that having coffee in the morning is important to him. He also thinks the coffee he has had lately has not been very good.

If he hadn't drunk any coffee in the last four weeks, he would have put a check by that statement instead of putting a mark on the line between TERRIBLE and EXCELLENT.

As in this example, make a mark across the line rather than using an X or an O.

Please answer all the questions.

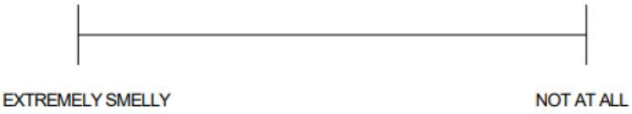
Support for development of the PEQ was provided by the U.S. Department of Veterans Affairs.

Visit #1 – Part 4 – Residual Limb Health Scale

These questions are about YOUR PROSTHESIS

Q. **Over the past four weeks, rate how much you sweat inside your prosthesis (in the sock, liner, socket).**

R. **Over the past four weeks, rate how smelly your prosthesis was at its worst.**



S. **Over the past four weeks, rate how much of the time your residual limb was swollen to the point of changing the fit of your prosthesis.**

T. **Over the past four weeks, rate any rash(es) that you got on your residual limb.**

OR check __ I had no rashes on my residual limb in the last month.

U. **Over the past four weeks, rate any ingrown hairs (pimples) that were on your residual limb.**

OR check __ I had no ingrown hairs on my residual limb in the last month.

V. **Over the past four weeks, rate any blisters or sores that you got on your residual limb.**

OR check __ I had no blisters or sores on my residual limb in the last month.

Visit #2 – Part 1 – Individual Questionnaire

Liner: **Control / Experimental**	ICE Unit: **Off / ON**

Fill in the circle that best describes the liner you just walked with:

On a scale from 1-5 please rate:					
1. your comfort while **standing** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
2. your ability to **stand** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
3. your comfort while **walking** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
4. your ability to **walk** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
5. how warm your leg felt while **wearing** this liner	(1) **Cold**	(2)	(3)	(4)	(5) **Extremely Hot**
6. how much you sweat while **wearing** this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Extreme Amount**
7. how socket suspension felt while **walking** with this liner	(1) **Leg Came Out**	(2)	(3)	(4)	(5) **No Movement**
8. how confident you felt that you **would not slip** out of this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Confident**
9. how you would want a **product** like this for daily use	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Much**

10. Please provide any additional comments you feel might be useful to note:

_____

_____

_____

Visit #2 – Part 2 – Individual Questionnaire

Liner: **Control / Experimental**	ICE Unit: **Off / ON**

Fill in the circle that best describes the liner you just walked with:

On a scale from 1-5 please rate:					
1. your comfort while **standing** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
2. your ability to **stand** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
3. your comfort while **walking** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
4. your ability to **walk** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
5. how warm your leg felt while **wearing** this liner	(1) **Cold**	(2)	(3)	(4)	(5) **Extremely Hot**
6. how much you sweat while **wearing** this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Extreme Amount**
7. how socket suspension felt while **walking** with this liner	(1) **Leg Came Out**	(2)	(3)	(4)	(5) **No Movement**
8. how confident you felt that you **would not slip** out of this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Confident**
9. how you would want a **product** like this for daily use	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Much**

10. Please provide any additional comments you feel might be useful to note:

_____

_____

_____

Visit #2 – Part 3 – Comparison Questionnaire

	ICE Unit: **Off / ON**

As you read through each question, remember there is no right or wrong answer. Just check off which prosthetic liner, if any, you prefer for each criterion listed below. It will be most helpful if you are completely truthful with your answers.

Criteria	Experimental	Control	No Preference
1. Ease of donning and doffing			
2. Ability to stand/walk			
3. Comfort while sitting			
4. Comfort while walking			
5. Comfort while standing			
6. Limb sweating			
7. Overall temperature in the socket			
8. Friction/Skin Comfort			
9. Slipping in socket			
10. Overall comfort			
11. Overall preference			

12. What did you **like** about the experimental liner and/or protocol?

13. What did you **dislike** about the experimental liner and/or protocol?

14. Other comments.

Visit #3 – Part 1 – Individual Questionnaire

Liner: **Control / Experimental**	ICE Unit: **Off / ON**

Fill in the circle that best describes the liner you just walked with:

On a scale from 1-5 please rate:					
1. your comfort while **standing** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
2. your ability to **stand** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
3. your comfort while **walking** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
4. your ability to **walk** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
5. how warm your leg felt while **wearing** this liner	(1) **Cold**	(2)	(3)	(4)	(5) **Extremely Hot**
6. how much you sweat while **wearing** this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Extreme Amount**
7. how socket suspension felt while **walking** with this liner	(1) **Leg Came Out**	(2)	(3)	(4)	(5) **No Movement**
8. how confident you felt that you **would not slip** out of this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Confident**
9. how you would want a **product** like this for daily use	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Much**

10. Please provide any additional comments you feel might be useful to note:

_____

_____

_____

Visit #3 – Part 2 – Individual Questionnaire

Liner: **Control / Experimental**	ICE Unit: **Off / ON**

Fill in the circle that best describes the liner you just walked with:

On a scale from 1-5 please rate:					
1. your comfort while **standing** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
2. your ability to **stand** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
3. your comfort while **walking** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
4. your ability to **walk** with this liner	(1) **Terrible**	(2)	(3)	(4)	(5) **Excellent**
5. how warm your leg felt while **wearing** this liner	(1) **Cold**	(2)	(3)	(4)	(5) **Extremely Hot**
6. how much you sweat while **wearing** this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Extreme Amount**
7. how socket suspension felt while **walking** with this liner	(1) **Leg Came Out**	(2)	(3)	(4)	(5) **No Movement**
8. how confident you felt that you **would not slip** out of this liner	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Confident**
9. how you would want a **product** like this for daily use	(1) **Not at All**	(2)	(3)	(4)	(5) **Very Much**

10. Please provide any additional comments you feel might be useful to note:

_____

_____

_____

Visit #3 – Part 3 – Comparison Questionnaire

	ICE Unit: **Off / ON**

As you read through each question, remember there is no right or wrong answer. Just check off which prosthetic liner, if any, you prefer for each criterion listed below. It will be most helpful if you are completely truthful with your answers.

Criteria	Experimental	Control	No Preference
1. Ease of donning and doffing			
2. Ability to stand/walk			
3. Comfort while sitting			
4. Comfort while walking			
5. Comfort while standing			
6. Limb sweating			
7. Overall temperature in the socket			
8. Friction/Skin Comfort			
9. Slipping in socket			
10. Overall comfort			
11. Overall preference			

12. What did you **like** about the experimental liner and/or protocol?

13. What did you **dislike** about the experimental liner and/or protocol?

14. Other comments.