Development of a Prosthetic Liner with Active Cooling to Enhance Amputee Comfort

Cruz, Caitlin, 12th, caitlincruz22@fsha.org, Flintridge Sacred Heart Academy;

Risha, Allison, 12th, allisonrisha22@fsha.org, Flintridge Sacred Heart Academy

Submitted for Publication: 29 May 2022

Abstract

Over 2 million people in the United States live with a prosthetic limb. Amputees typically wear liners to provide a layer of padding between the skin and hard plastic prosthetic, however these liners cause overheating. Overheating in the prosthetic interface, or area where the skin meets the prosthetic, can lead to discomfort, poor fit, and ultimately site blistering. A prosthetic liner with embedded active cooling has been developed that will provide up to 1.7°C cooling. The liner is constructed of silicone sheets and tubing, and preliminary testing confirms that 1.7°C cooling is achievable. A path is presented toward a functional cooling prototype and a validation procedure to verify cooling meets the needs of amputees.

1.0 Introduction

In the United States, 2.1 million people are living with a prosthetic device following an amputation (AccessProsthetics). While prosthetics are commonly used to give amputees greatly increased capability, they also bring comfort issues. Liners are used to help fit the prosthetic to the amputated site, as well as prevent skin irritation. And while these thick liners are useful in providing padding between the hard prosthetic and tender skin, they are the cause of overheating. Moisture from sweat pools inside the prosthetic, which can lead to slipping and sliding of the liner (A. Chavez, Personal Communication, October 22, 2021). This slipping requires the amputee to remove the prosthetic, liner, cotton sock, wipe down the different parts, and reapply.

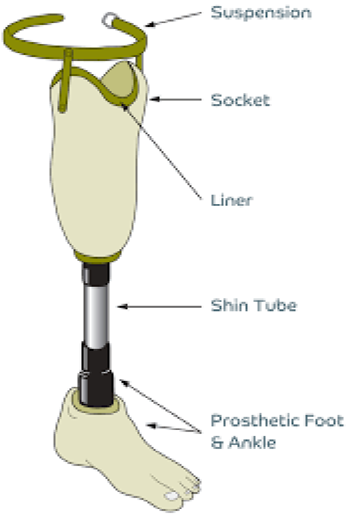
This process can become tedious if done several times a day. This paper describes a prototype cooling system integrated at the amputated site-prosthetic interface designed to improve amputees' quality of life. The liner will prioritize the top two qualities for an amputee; the need for prosthetics to be both functional and comfortable, and would be an optimal solution for an active amputee lifestyle.

1.1 Background

1.1.1 General

After an amputation has healed, the next step is to get fitted for a prosthetic, which can be a very difficult journey. To an amputee, fitting and comfort of their prosthetics are one of the most important factors throughout this process (Chavez, 2021). Conduction of heat and excess production of sweat are two of the biggest issues amputees face. Both of these factors lead to improper and uncomfortable fit.

Figure 1 - Image of prosthetic parts (Blatchford)



In Figure 1, the structure of a normal prosthetic is shown. Blisters and irritation most commonly occur at the socket part of the prosthetic where the amputated site and prosthetic meet (also known as the prosthetic interface). Movement of the prosthetic's socket against the skin is what causes blisters and irritation. (S. Grewe, personal communication, October 18, 2021). Currently, the most common way to prevent skin irritation is to utilize a silicone liner that takes away most of the friction and provides a barrier between the prosthetic and the skin. These liners are commonly made of thick, heavy silicones. The most common material for prosthetics are carbon fiber and hard-set plastics (Chavez, 2021).

It is important that liners or socks are worn between the skin and the prosthetic socket to provide a barrier between this hard exterior and the skin.

1.1.2 Fit and Application

To ensure the most comfortable and safe prosthetic fit, numerous parameters must be considered, including stump size, weight and activity level. The two most common methods to optimize fit are 3D scanning and molding (Wang, et al, 2020), with the actual prosthetic formed out of plastic or carbon fiber. Most amputees also choose to wear liners, the majority of them made of silicone (Chavez, 2021), which is thick enough to provide padding and protection from the pressure the prosthetic puts on the skin from the weight of the amputee. While thick silicone can provide necessary padding, it is also a thermal insulator that, upon movement or exercise, causes perspiration build-up around the amputated site (Chavez, 2021). Finally, the prosthetic can be attached to the amputation site with either a harness system or suspension system and any liner designed for use in the prosthetic interface must be compatible with both.

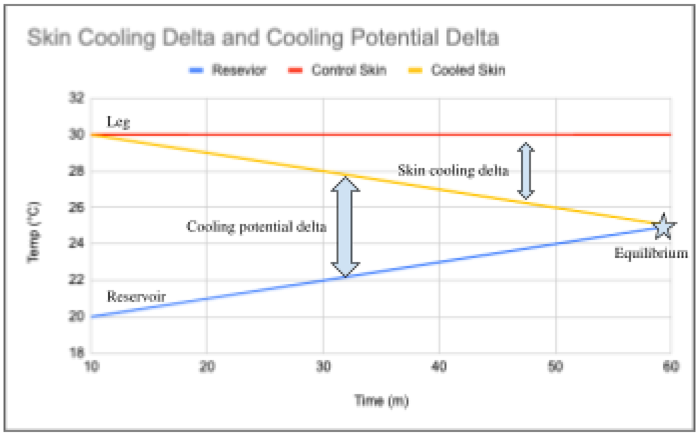
1.1.3 Cooling

There are two general types of cooling used in liners: active and passive. Active cooling describes using an outside energy source to cool the area. An example of active cooling would be the use of a fan or peltier plates. While some methods of active cooling have been tested by third party researchers, there are no active cooling products currently on the market. Passive cooling utilizes the natural phenomenons of convection, conduction, and radiation to allow better circulation of ambient air and in turn cool the area. Passive cooling material is similar to the popular Dri-Fit material, and is much more comfortable for a moving amputee than a traditional liner. Examples of passive cooling include mesh liner or sock, to cool the area/absorb perspirants. This method of cooling relies on the design and natural airflow built into the liner as opposed to an additional moving piece.

1.1.4 Energy Transfer Into and Out of Water

In a water cooled liner, energy from the skin will be transferred into the water and carried away. The comparative rates of energy production (body temperature) and energy carried away by the cool water will result in site cooling. For an idealized cooling system, temperature of skin with no cooling (control skin), temperature of skin with cooling liner on it (cooled skin) and temperature of the water circulating through the system (reservoir), are shown in Figure 2. The important temperature differences are shown as Skin cooling delta and Cooling potential delta. As the cooling potential decreases, the system approaches equilibrium.

Figure 2 - Skin Cooling Delta and Cooling Potential Delta



1.2 Literature Review

1.2.1 Key Parameters

A research group working at the University of Strathclyde in Glasgow, UK studied the thermal properties of the prosthetic interface and found that skin temperature can be accurately measured using a technique of placing sensors between the socket and liner (Mathur, 2016).

The research found that placing a sensor between the liner and socket can be used to infer skin temperature. In the current project, temperature sensors will be against the skin only during the prototype phase, while the patient is stationary and therefore comfort is not an issue. The final design will not have temperature sensors once cooling is demonstrated. However, if, in the future, the cooling rate is to be varied based on temperature, the method of placing temperature sensors between the liner and socket as discussed, could be useful.

A research group at the University of Washington, Seattle studied how to measure temperature at the prosthetic interface for an active subject. Fifteen minutes after putting on the prosthetic but before moving, amputees saw a 0.8°C rise in temperature. A 1.7°C increase in temperature was observed during a ten minute walking trial. After the one hour rest period was completed, the subject failed to return to the resting state temperature. It was found that heating occurs throughout all sides of the prosthetic, and subjects expressed that they rarely walk for more than ten minutes (Huff et al, 2004).

This research shows that even without movement, the prosthetic leg insulates enough to produce almost a full degree of temperature increase. This, along with the large time frame it takes for amputees to cool down post-activity, is rationale for this project. Second, the mean-residual limb temperature climbed 1.7°C after ten minutes of walking. This 1.7°C is used as the target value for skin cooling in the prosthetic interface. This metric is important as it acts as a guide to determine whether or not the device is able to be deemed successful or not based on how much cooling it provides.

1.2.2 Market and Competition

Both passive and active cooling methods are being investigated by liner manufacturers, but none seem to be proving practical for an everyday amputee. Currently, there are no effective active cooling liners on the market as evidenced by extensive research and discussion with prosthetic specialists. Not one active or passive cooling system seems to be practical for an everyday amputee (Chavez, 2021).

A specific method being tested for the market is an attached fan and peltier plates to provide cooling against the limb and within the socket (Dupnik, 2018). This device uses a method of active cooling to cool skin. It is still in testing and is not currently available for purchase. The method of attaching a fan was considered for this project, but was later ruled out due to size, weight, and effectiveness. Another device on the market is a liner made of sweat absorbing material, however it does not actively cool. As the liner absorbs the sweat, it dissipates through the material, removing it from the surface of the skin. This may feel similar to wearing a Dri-Fit material, making it more comfortable with cooling coming from evaporation of the sweat. While traditional liners tend to work more efficiently in comfort and sweat absorption than any newer device, no active cooling or combination active/passive cooling methods are currently on the market and available for amputees (Williams, et al. 2018). A current passive cooling method that is on the market, known as SmartTemp, uses a phase changing material to improve thermal properties (Wernke, 2015). The SmartTemp liner uses Outlast, a phase-changing material that keeps skin cool by absorbing heat and “melting” (Heidenheim, 2013). SmartTemp tested the temperature after exercise as well, and it seemed to be effective. This is a passive cooling method as it uses static components to cool.

1.3 Problem Statement

Amputees need a comfortable and cost-effective method to actively cool the prosthetic interface to avoid discomfort and skin irritation while maintaining the proper fit of their prosthetic. An effective water-cooled liner is needed that will produce at least 1.7°C of cooling.

2.0 Methods

2.1 Concept Design

An active cooling, silicone prosthetic liner is produced that can achieve 1.7°C site cooling via water circulation. A pump will circulate water through tubes that are part of the liner. In Figure 3 heat is being transferred from the body to the liner, however, the liner does not hold a high heat capacity like water so the heat is reflected back to the skin causing overheating. In Figure 4, tubes will be adjacent to skin, allowing the transfer of heat from the skin into the water, where the water can remove this heat from the skin area out.

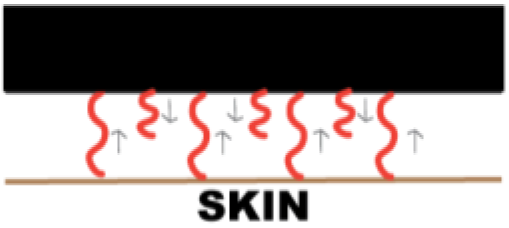


Figure 3 - Heat transfer in typical liner

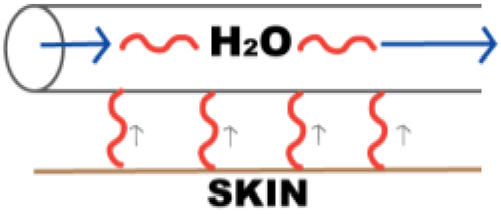


Figure 4 - Heat transfer in liner with water

Silicone materials were chosen for liners and tubing since they are common materials used in liner production. The thickness of the liner and tubing will affect the comfort where thicker is better and thermal transfer rates where thinner is better. Additional variables include the water circulation rate and radiator design (how fast energy can be transferred from water into the surrounding room temperature). The silicone components used are 0.5mm thick liner and 3mm inner diameter, -0.5mm wall thickness tubing. Two different radiator designs are tested (high flow rate and low flow rate). The pump is a Gikfun Mini water cooled water Pump Air Diaphragm Pump, made of silicone. It has a maximum flow rate of 0.04 Gallons Per Minute.

2.2 - Radiator Construction

Two radiators were designed to accelerate energy transfer from water to air: a low flow rate and high flow rate design.

The low flow rate design (Figure 5) includes 4 – 0.16cm ID brass tubes, 7.5cm in length. Each tube is connected to aluminum heat sinks with thermally conductive tape.

Figure 5, front side of Radiator 1

The high flow rate design (Figure 6) consists of a single 0.635 cm OD copper tube 24 cm in length with. Heat sinks were spaced to maximize heat transfer and attached with thermally conductive tape.

Figure 6 - Radiator 2

2.3 - Prototype Construction

The same configuration was used on both component and system prototypes. System prototype 1 (referred to as P1), shown in Figures 7 and 9, includes a five tube configuration

Figure 7 - System Prototype 1

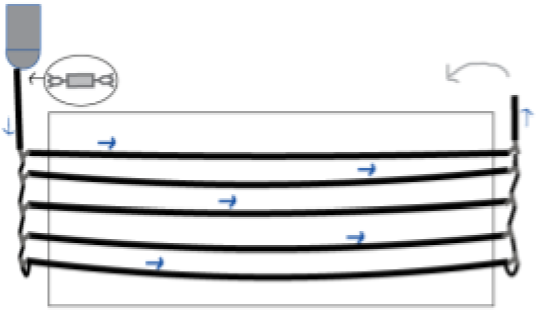


Figure 9 - Multipath sleeve design

connected to the pump. This five tube configuration was connected by ¼ to ⅛ mm silicone connectors with care taken to avoid kinks (which can restrict flow). An 0.5mm thick silicone liner was placed between the water tubes and skin.

Prototype 2 (referred to as P2), shown in Figures 8 and 10, used a silicone liner. The tube configuration was altered to be a one tube path with no connectors, meaning there was no kinking in the connections. This tube path increased the water flow resistance as it was a single path and took a longer amount of time for the water to flow through. The 0.5mm silicone liner was again used between the tubes and the skin. In prototype 3 (referred to as P3) the final sleeve design incorporates the five-tube configuration as seen in P1. This prototype, however, is within the silicone sleeve now and is placed beneath a silicone layer to be in contact with the skin, similarly to P2.

Figure 8 - Prototype 2

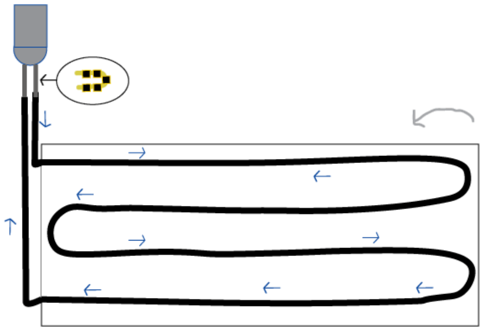


Figure 10 - Single path sleeve design

In all prototypes the sleeve was secured with velcro and the reservoir is the water contained in the circulation tubes.

2.4 - Validation and Methods of Testing with Radiator and Liner Versions

To show that the prototype device can achieve the required 1.7°C cooling, a testing setup shown in Figure 11, was consistently used to collect data.

The subject was seated and stationary during testing. Temperature sensor one measures the water running through the tubes near the pump (labeled reservoir, Figure 11, colored blue, Figure 12) and is insulated from room air. Temperature sensor two was placed on the opposite leg of the liner and wrapped in silicone to measure the temperature of skin with no cooling (labeled control skin, Figure 11, colored red, Figure 12), and sensor three was slid inside the liner against a tube and the skin to measure the temperature of the skin with cooling (labeled cooled skin, Figure 11, colored yellow, Figure 12). Data recording started once sensors were placed and continued for around one hour. This procedure allowed recording of an equilibrium temperature (i.e. 30°C) prior to turning on the cooling pump. In addition, temperature data was recorded for an average of ten minutes after the pump was turned off in order to observe expected warming

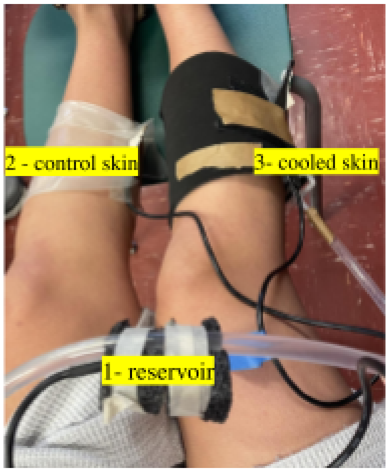


Figure 11 - Validation Test Setup

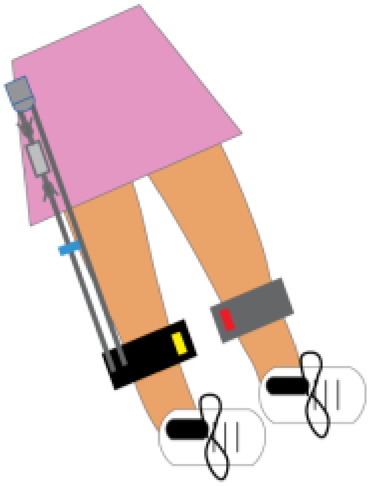


Figure 12 - Color-coded testbed setup sketch

after the pump is powered off.

The device needs to produce a 1.7°C delta to be deemed successful (Huff et al, 2004). Since the accuracy of the temperature sensors is $\pm\ 0.5°C$ (Adafruit), a skin cooling measurement of 1.7°C ± 0.5 would show that the target could be met.

Figure 13 - Fanny Pack Testbed

The final validation step would be a field test using a more compact design where the subject could be active. The design would hold the pump, batteries, and switch in the fanny pack shown in Figure 13 with the tubes running down the subject's leg. The liner would wrap around the leg in a similar fashion as the stationary test. By allowing the product to be mobile, more tests could be run to simulate the true environment the liner would be placed in; one of someone who is active and in motion.

3.0 Results

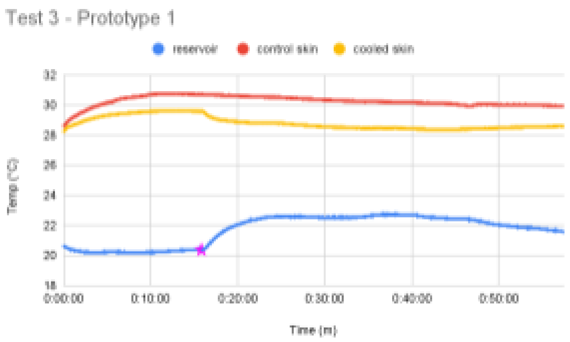
Component testing showed the following design factors to be optimal: 3 mm inner diameter tubing and 0.5mm thick silicone.

For each test, temperature data was recorded at the reservoir (blue), the baseline skin temp (red) and for the cooled skin (yellow) as described in 2.4. The star on the graphs indicates the turning on of the pump to begin water circulation.

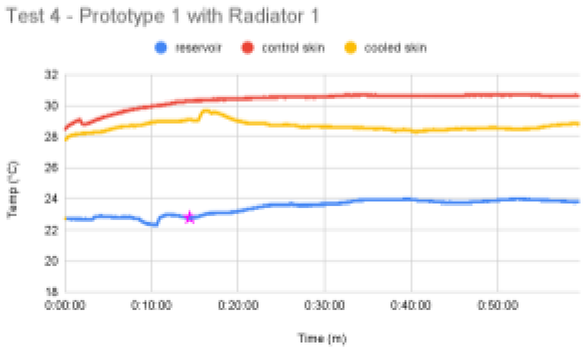
Test 3 (seen in Graph 1) demonstrated a 1.7°C cooling between the baseline skin temperature and the cooled skin temperature using prototype 1. Based on test length, the 1.7° cooling was consistent for thirty minutes until the test was ended. It is important to note that the reservoir temperature (blue line) did increase significantly in the first 10 minutes, but then reached equilibrium, and the decrease of the cooling potential delta (temperature between cooled skin and reservoir) after the pump was turned on limits the heat transfer available to cool the skin.

Test 4 (seen in Graph 2) integrated the Radiator 1 with Prototype 1. At its greatest the skin cooling delta was 2.31°C. A slower flow rate was measured in component testing because of the radiator, and overall cooling was more gradual during the forty minute test. The reservoir warmed up fairly slowly which allowed the cooling potential delta to stay fairly large, indicating that the radiator radiated heat from the water into the air.

Graph 1 - Prototype 1 Cooling Data



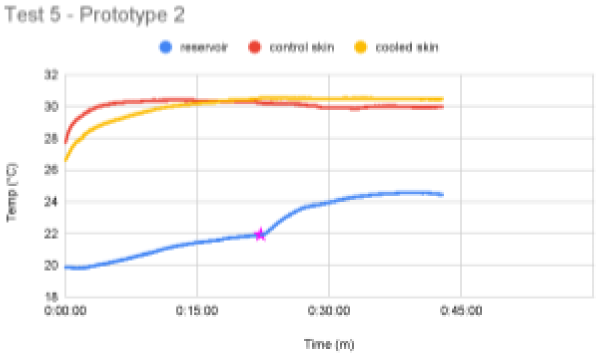
Graph 2 - Prototype 1 with Radiator 1 Cooling Data



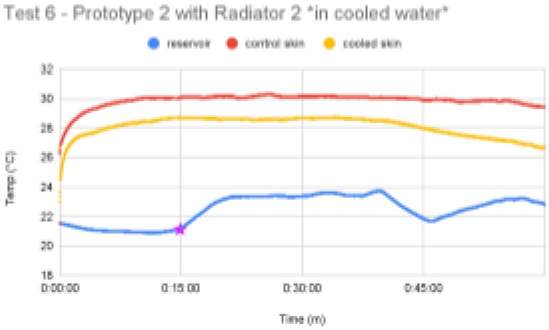
Tests with prototype 2 demonstrated that a single path cooling tube could not meet the design requirements of 1.7° cooling. As seen in Graph 3, the reservoir warms quickly (diminishing cooling potential) with no measurable skin cooling.

One interesting result from a Prototype 2 test is shown in Graph 4. After confirming "no measurable cooling", the radiator was submerged into a beaker full of cold water. This change is seen at minute 36. At this point, the reservoir temperature quickly drops 2°C and the skin begins to cool. This result opened the discussion of the possible addition of an ice pack/cold source to

Graph 3 - Prototype 2 Cooling Data



Graph 4 - Prototype 2 with Radiator 2 - with cooled water Cooling Data



the radiator that the consumer could replace to elicit maximum cooling and a large cooling potential delta.

4.0 Discussion

Due to the two components of functionality and comfortability, materials needed to be chosen carefully to both cool the overheating that current prosthetics and liners are producing and accommodate the comfort component that this new product needs to provide. Thinner materials were chosen for the tubing and the liner to increase energy transfer rates between skin and water. The tradeoff between liner thinness (for thermal conductivity) and thickness (for padding) cannot be investigated until a device is ready for testing with human subjects and padding (comfort) can be measured.

The device showed that the target of 1.7°C cooling could be achieved with the multiple cooling pathway design.

While the radiator was not necessary to achieve target cooling with P1, P2 could not reach the target without the radiator. The radiator did increase the cooling a small amount, however, and could be furthered if submerged with an ice pack/cooling source for rapid cooling or extension of time with constant temperature. Using this result, it is clear that tube configuration is the main element of a successful liner since both prototypes used the same tubing and silicone

Tube configuration is extremely important in gaining a significant cooling delta. The greater cooling delta was observed in the multipath prototype (P1) as opposed to the single path prototype (P2) because of the flow rate.

One test that was not able to be completed was the duration test, a test that would show how long a system would take to reach full equilibrium. Current tests suggest that for the cooling potential delta to equal 0 would take several hours. However, it would be helpful to have a concrete time to note how long the subject can wear the device before no cooling is experienced.

5.0 Conclusion

An active-cooling liner was made that could provide amputees more comfort while wearing their lower extremity prosthetic. After finding no effective cooling devices on the market, a prototype using silicone sheets and silicone tubing was created. This prototype is effective in cooling more than 1.7°C on inactive subjects, which was the target for cooling in the prosthetic interface..

Future scope for this project includes investigation of the effects of reservoir cooling (via ice pack or thermoelectric device), determining the system equilibrium time, investigating the efficacy on an active subject (along with system recovery time after activity), and developing a miniaturized/mobile prototype.

6.0 Acknowledgements

We would like to thank and acknowledge the support of the Computer Science Engineering Department at Flintridge Sacred Heart, as well as our advisor Mr. Ty Buxman and our external consultant Mr. Bruce Waggoner. We would also like to thank Same Grewe and Alex Chavez for their insightful and helpful interviews.

Work Cited

Artlimb. (2015, September 26). *Liners: Part3. Liner Care and General Tips*. The Art of Prosthetics. http://www.artlimb.com/more-details/lower-limb-articles/liners-part3-liner-care-and-general-tips/

Blatchford. (2020, December 15). *Below Knee Prosthesis*. Blatchford US & Canada - Mobility Made Possible. https://www.blatchfordus.com/prosthetics/information-for-amputees/advice-guides/below-knee-prosthesis/

Chavez, A. (2021, October 22). Personal Communication. [Personal Interview].

Dupnik, M. (2020, July 7). *Intrasocket Cooling Element (ICE)*. Vivonics Inc. https://www.vivonics.com/technologies/ice

Grewe, S. (2021, October 18).Personal Communication. [Personal Interview].

Huff, Elizabeth A., et al. "Measuring Residual Limb SkinTemperatures at the Skin-Prosthesis Interface." *JPO Journal of Prosthetics and Orthotics*, vol. 20, no. 4, Oct. 2008, pp. 170–173, journals.lww.com/jpojournal/fulltext/2008/10000/measuring_residual_limb_skin_temperatures_at_the.9.aspx, 10.1097/jpo.0b013e3181875b17. Accessed 8 Oct. 2021.

Mathur, Neha, et al. "Skin Temperature Prediction in Lower Limb Prostheses." *IEEE Journal of*

Biomedical and Health Informatics, vol. 20, no. 1, Jan. 2016, pp. 158–165, ieeexplore.ieee.org/abstract/document/6949596, 10.1109/jbhi.2014.2368774. Accessed 8 Oct. 2021.

Ruiz, E. (2005). *User Needs And Requirments For The Development Of A Moisture Permeable Prosthetic Interface*. RESNA ANNUAL CONFERENCE - 2015. https://www.resna.org/sites/default/files/conference/2015/other/student_scientific/ruiz.html

Wang, Y., Tan, Q., Pu, F., Boone, D., & Zhang, M. (2020). A Review of the Application of Additive Manufacturing in Prosthetic and Orthotic Clinics from a Biomechanical Perspective. *Engineering*, *6*(11), 1258–1266. https://doi.org/10.1016/j.eng.2020.07.019

Wernke, Matthew M., et al. "SmartTemp Prosthetic Liner Significantly Reduces Residual Limb Temperature and Perspiration." *JPO Journal of Prosthetics and Orthotics*, vol. 27, no. 4, Oct. 2015, pp. 134–139, journals.lww.com/jpojournal/Fulltext/2015/10000/SmartTemp_Prosthetic_Liner_Significantly_Reduces.6.aspx, 10.1097/jpo.0000000000000070. Accessed 8 Oct. 2021.

Williams, R. J., Washington, E. D., Miodownik, M., & Holloway, C. (2018). The effect of liner design and materials selection on prosthesis interface heat dissipation. *Prosthetics & Orthotics International*, *42*(3), 275–279. https://doi.org/10.1177/0309364617729923