

Final Report: *VoltaFeet*



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Introduction

VoltaFeet has been developed with the goal of becoming a commercially available device that addresses the need for a simple, effective, and long-lasting treatment for reliably eliminating toe/foot fungus, as well as foot and shoe odor in a diverse user population. These foot health problems are the byproducts of the microbiome of the foot. Fungal growth, commonly known as athlete's foot, can result in flaky, itchy, inflamed and unsightly skin. The excessive growth and activity of bacteria, both on the surface of the foot and within the shoe, results in excessive foot odor known as bromodosis. In 2012, National Foot Health Assessment survey data indicated how common these problems are, with approximately 16% of the population having experienced bromodosis, 20% athlete's foot, and 11% toenail fungus (1). While several commercial solutions exist, including creams, ointments, powders, socks and inserts, the market is currently devoid of products that are both actively antimicrobial and long lasting. A product with that functionality would also find a great deal of utility for the growing population of diabetics who are prone to open ulcers on the foot. As of 2015, 9.4% of the US population, or 30.3 million americans have diabetes (2). Approximately 15% of those people will develop foot ulcers, which increase risk of infection and amputation (3). For this reason, diabetes is the leading cause of non-traumatic limb amputation (4). A device capable of decreasing bacterial load for long term ulcer protection would not only reduce the risk of infection, but could also promote healing - as higher bacterial load correlates with longer ulcer healing times (5).

Intervention - *VoltaFeet*

To meet the various needs for convenient, long lasting control of the foot microbiome, *VoltaFeet's* conductive sock like design results in electrochemical deposition of silver ions onto

the surface of the foot and into the shoe environment. Silver is one of the oldest known antimicrobial agents, with documented antimicrobial use in the treatment of foot ulcers by Hippocrates (6). By running a controlled, constant DC current through a positive silver anode, silver ions can be released in a controlled fashion at the electrode interface, where the flow of electrons is converted into ions. Silver ions are potently antimicrobial in very low concentrations, causing lethal oxidative damage to DNA as well as the proteins involved in cellular respiration for both bacteria and fungi (6,7,8,9, 10). Bactericidal levels have been cited as low as 2.5×10^{-7} M Ag^+ (11). This potency ensures that *VoltaFeet* can establish and maintain skin sterility through circuit controlled, extended release of silver.

VoltaFeet is set to cap current magnitude at approximately 60 μA , and conducts maximally when in contact with physiologically normal, moist skin. The following calculations demonstrate the theoretical amount of silver ions on the surface of the skin would be produced at a rate that is sufficient to sterilize the foot even under maximum sweat production conditions:

$$1. \frac{.25 * 10^{-6} \text{ mol } Ag^+}{1 \text{ L}} * \frac{6.022 * 10^{23} \text{ } Ag^+}{1 \text{ mol}} * \frac{1 \text{ L}}{1000 \text{ mL}} \approx 1.5 * 10^{14} \text{ } Ag^+ / \text{mL} \text{ -- Minimum bactericidal concentration (11)}$$

$$2. \frac{60 * 10^{-6} \text{ C}}{s} * \frac{1 \text{ } e^-}{1.602 * 10^{-19} \text{ C}} * \frac{1 \text{ } Ag^+}{1 \text{ } e^-} * \frac{3600 \text{ s}}{1 \text{ hr}} \approx 1.3 * 10^{18} \text{ } Ag^+ / \text{hr} \text{ -- Rate of silver release at 60 } \mu A$$

$$3. 64 \text{ in}^2 * \left(\frac{.0254 \text{ m}}{1 \text{ in}}\right)^2 * \frac{130 \text{ mL}}{\text{m}^2 * \text{hr}} * \frac{1.5055 * 10^{14} \text{ } Ag^+}{\text{mL}} \approx 8.1 * 10^{14} \text{ } Ag^+ / \text{hr} \text{ -- Required rate of silver release}$$

for ongoing sterilization for *VoltaFeet* Prototype

$$a. 64 \text{ in}^2 = \text{surface area of prototype sock foot (Figure 1)}$$

$$b. 130 \text{ mL}/\text{m}^2 * \text{hr} = \text{highest average sweat rate for a part of the foot during strenuous exercise (12)}$$

These equations assume that sterilizing the surface of the skin requires achieving the minimum bactericidal concentration of silver ions within the sweat that is in contact with the foot.

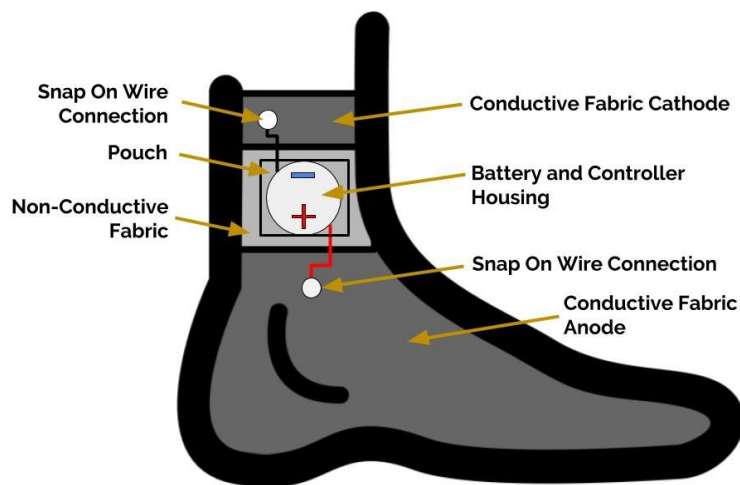
VoltaFeet operates at 60 μA , which results in a rate of silver release four orders of magnitude

higher than the theoretical minimum necessary for foot sterility. This does not take into account the loss of silver due to electrical and chemical reduction. AgCl formation is a significant concern in this case due to the presence of Cl⁻ in sweat.

Design Overview

VoltaFeet is designed to ensure consistent and long lasting electrochemical delivery of silver ions onto the surface of the foot. Figure 1 includes an overview of *VoltaFeet*'s design and major components.

Figure 1: *VoltaFeet* Design Overview



Conductive Fabric Cathode/Anode - Silver coated knitted nylon fabric in contact with the user at the lower calf for the negative cathode and at the foot for the positive anode.

Snap On Wire Connection - Metal snaps with the female half connected to the fabric via silver coated threads and the male counterpart connected to the housing leads by solder.

Non-Conductive Fabric - Polyester-spandex comprises the middle portion of the ankle, promoting electrical isolation between the anode and cathode fabrics of the sock. This prevents shorts and ensures current is driven through the user.

Pouch - A non conductive pouch made out of polyester-spandex that holds the battery and controller housing. A small hole at the bottom of the pouch allows for the anode wire to run to the foot.

Battery and Controller Housing - A 3D printed housing with a current control circuit compartment and slit for inserting a 3V lithium coin battery. A positive and negative lead are the outputs of this housing.

When the snap on wire connections are in contact, the device is ready for use, pushing a maximum current of approximately 60 μA when worn. The housing is placed inside the pouch at the ankle when in use. This housing can be disconnected and the sock washed between uses. Washing protocols remain to be tested in further development. The battery can be removed and replaced by running one's thumb up the exposed side of the battery. The final prototype is displayed in Figure 2.

Figure 2: VoltaFeet Prototype

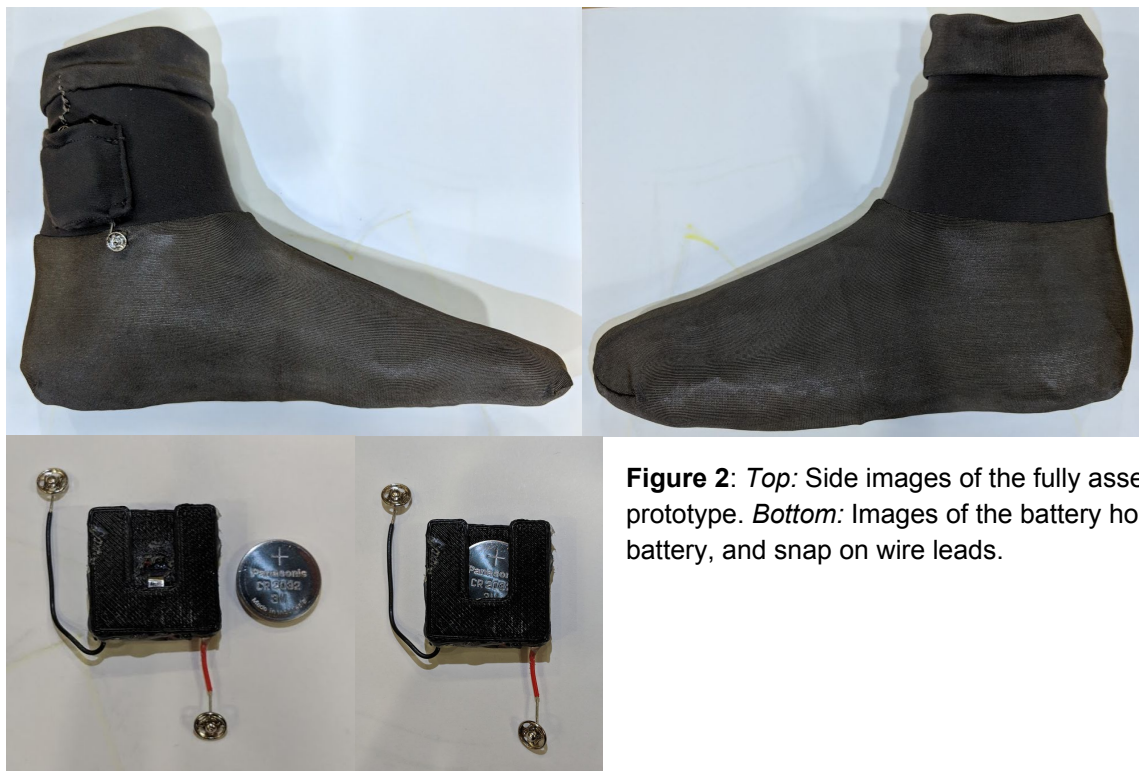


Figure 2: *Top:* Side images of the fully assembled prototype. *Bottom:* Images of the battery housing, battery, and snap on wire leads.

Within the back compartment of the battery housing is the current regulator chip for the circuit, powered when the 3V lithium coin cell is inserted into the housing slot, as seen in the

bottom right image of Figure 2. Figure 3 illustrates the circuit housed in the pocket of the prototype which is responsible for current regulation and power supply.

Figure 3: VoltaFeet Circuit Diagram

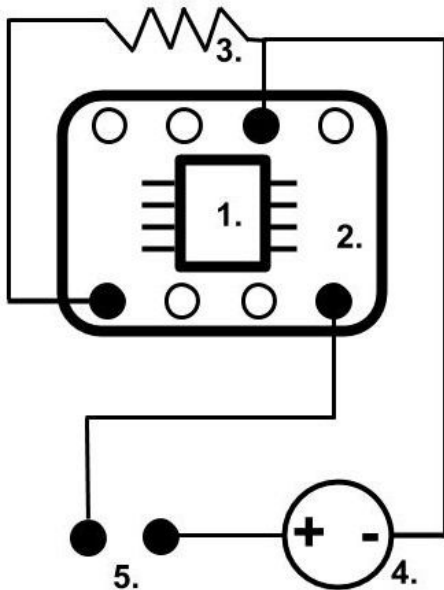


Figure 3: The configuration and components for the current regulating chip powering *VoltaFeet*. The LM 334 3-Terminal Adjustable Current Source (1) is soldered onto an 8 pin breakout PCB board (2) with connections made at pins 1,4, and 6. To cap the output current at approximately 60 μ A current, a 1.2 kOhm must be connected (3). A 3V CR2032 Battery powers the ship as shown (4). The load for this circuit, which for *VoltaFeet* is skin impedance, is driven at (5) - between the two output leads from the battery and controller housing.

Prototype Production

Prototype production involved two distinct elements: the textile and the control circuit. The control circuit was assembled by the group and soldered by hand with the housing elements developed in CAD outlined in Appendix A. The textile was produced in collaboration with the fashion department at WashU, specifically through the talents and wisdom of Professor Mary Ruppert-Stroescu. She provided the team a 3D rendering software that constructs detailed digital representation such as one of the group member's feet. A live action photo of the data acquisition process is shown in Appendix B. The rendering was then processed using a software called MeshMixer to create an easily printable 3D foot model. Professor Ruppert-Stroescu then created the final prototype around this model which will be on display at BME day. Appendix C provides a professional step by step guide, known as an "Order of Operations" for creating the textile component. The following serves as a more thorough discussion of the production process.

Parts List

A total of 11 parts were necessary for completion of the final prototype. The most expensive component by a significant margin is the “Stretch Conductive Fabric” supplied by LessEMF, which costs around \$6.00-\$9.00 per sock, depending on the size of the sock. This price could be minimized in later iterations by localizing the conductive fabrics use to certain target areas, instead of making it compose the entire bottom part of the sock. The total cost of the parts in the prototype is \$11.38. The pricing breakdown and additional information for each part can be found in Appendix D. It is important to note that none of the parts were ordered in bulks, so listed prices are larger than they would be in a large scale manufacturing operation.

Design Specifications Met

To establish the efficacy of *VoltaFeet*, several experiments were conducted to isolate key functionalities outlined by our design specifications. A comprehensive list of these features is depicted in Table 1. The fields indicated in green represent design specifications that we have verified with confidence either through iterative experimentation or literature from relevant fields. Our efforts to verify the unmarked specifications were inconclusive and serve as grounds for future investigations and prototypes. Taken together, *VoltaFeet* satisfies our aims in antimicrobial efficacy, safety, user satisfaction, and longevity which are paramount elements of a successful commercial product in this space which are supported by key studies in the discussion to follow.

Table 1: Design Specifications

Design Specification	Conclusion
99.9% Antimicrobial Efficacy	All zones of inhibition with E. coli resulted in negative stick and streak tests
Broad Range Efficacy against gram (+/-) bacteria and fungi	Our results on gram negative E. coli will likely translate to other microbes such as gram positive staph aureus and fungi based on Spadaro et. al and other literature
Sizing Options	Using silver coated knitted nylon provides a flexible, stretchable material that can accommodate a few foot sizes with one sock
Works with 99.9% efficacy on Skin Surface	It is reasonable to believe our results in agar media can translate to skin surfaces after adjusting to impedance changes
Cost Effective (\$10-\$30)	The final cost for the prototype without labor or accounting for bulk material discounts is \$11.38
User Safety (safety risks are at most low-moderate by Design Safe standards)	Satisfactory design safe analysis and functional currents (5-150 μ A) far below the threshold of feeling for DC current (~5 mA). Silver is a hypoallergenic metal with little to no risk of immune response.
Comfort	Fell 1.39 points behind the average score for the normal sock. This is well out of the 0.5 range that was desired
Appearance	Fell 0.08 points behind the average score for the normal sock, within acceptable range
Quality	Scored 0.54 points higher on average than the normal sock
Weight (< 180 g)	Complete prototype with battery and housing collectively weighed 45 grams
Silver Ion Skin Penetration (\geq .1 mm)	Although we were not able to conduct skin studies due to regulations, we were able to achieve depth penetrations in agar against gravity of at least 5.5 mm
Longevity (> 1 month functional use)	Device remains functional for at least one month of use. Battery life is estimated to last > 1 month based on manufacturer data. Silver release maintained at higher than required current density (1.2 μA/cm²) for 14 days of continuous use
Simple Operation (< 10 s)	Circuit activation via battery insertion and snap connection required fewer than 10 seconds on average in ergonomics testing (~8.3 seconds)

Table 1: A complete list of *VoltaFeet* design specifications and the rationale behind why or why not the current prototype meets those feature requirements.

Antimicrobial Efficacy

VoltaFeet's design at a fundamental level is the creation of a reliably sterile surface. The skin naturally hosts and collects a plethora of microorganisms such as bacteria and fungi that may lead to odorous scents and infections for at risk demographics. To be a novel solution, *VoltaFeet* must not only demonstrate antimicrobial activity, but also show that the active electrochemical deposition of silver via a current-controlled circuit is worth the added complexity compared to a passive silver textile. In this spirit, the vast majority of our senior design capstone was dedicated to experimental design, scientific inquiry and critical interpretation of results surround this design specification. From these anti-microbial related experiments, we support the following design choices and claims shown in Table 2.

Table 2: Antimicrobial Design Choices and Claims of *VoltaFeet*

Antimicrobial Feature	Design Choice or Claim
Electrode Placement	The anode and cathode must be separated by the user interface as well as positioned on the foot and high ankle regions respectively
Advantages of Current	Electrochemical deposition creates zones of inhibition above and beyond that from diffusion
Silver and Silver Ions in Fabrics	Silver and silver ions are passively antimicrobial in wires as well as fabrics
Added Sterile Protection	The current-driven ion deposition in the fabric prevents the growth of microbe colonies and kills existing ones beyond control values

Regarding overarching methods, our group created an IBC protocol amendment with the supervision of the Setton lab to work with the bacterial strains of E. Coli (gram-negative), Staph Aureus (gram-positive), and Pseudomonas Aeruginosa (gram-negative). E. Coli was chosen on

account of availability from the Setton lab's present research while the other two were out of ecological relevance to the foot. Due to a prohibitively high cost pseudomonas was declared outside the scope of inquiry. The results from staph are still pending as the plates culture; the results are expected by the presentation and by extent BME day. Thus, this body of evidence is limited to E. coli.

Across all studies, we utilized 9.5 cm tissue culture plates filled with 20 mL of agar. The bacterial load was 100 uL of maximally confluent E. coli in LB broth spread evenly across the surface of the plate after the agar was sufficiently cooled. The plates were incubated at 37.5°C for 16 hours after which they were imaged and discarded appropriately in biohazard waste. Notably, all setup was done in a sterile fume hood equipped with UV light capabilities with ample 70% dilution ethanol on hand for transferring items into the hood. When applying current to the cultures, analogous breadboard circuit configurations to that of Figure 3 were used with a single 3V battery as a power source. Current outputs were continuously monitored by a multimeter placed in series with the circuit. Current levels were modulated via removable resistors. Initial and final battery potentials were assessed for every run. Any further study-specific details are included when necessary in their sections.

Electrode Placement and Advantages of Current

Expanding on the prior work of Spadaro et al., we had the expectation that for the low currents we wanted to implement, ~5.0 μA , activity at a silver anode would be most antimicrobial (13). On the other hand, the cathode should have minimal activity. Notably, the conventions for anode and cathode are for an electrolytic cell in this paradigm. We replicated Spadaro's low current study with silver wire to serve as a proof of concept by not only verifying the design's

electrode placement, but also showing that current creates zones of inhibition above and beyond what a silver wire control can achieve by diffusion with no current.

Currents of 0 μA (control), 4.9 μA , 57.6 μA , and 158.0 μA were applied to the cultures immediately after seeding with *E. coli*. Clouded areas on the plate are regions where *E. coli* has flourished. Figure 4 shows the findings for 4.9 μA and control in conjunction with Spadaro's findings for 4.0 μA which jointly reinforce that antimicrobial action occurs at the positive anode with the absence of efficacy at the negative cathode. The control provides the additional insight that for silver wire, a current facilitates a marked zone of inhibition that is 2.0 mm perpendicular to the wire. It can be seen that without the current, the zone of inhibition is restricted to only the wire itself (0.0 mm). Notably, Spadaro's group found zones ranging from 3-5 mm, but this can likely be explained by the fact that figure was from a plate of staph aureus rather than *E. coli*.

Figure 4: Antimicrobial Action at the Anode and Current Advantages

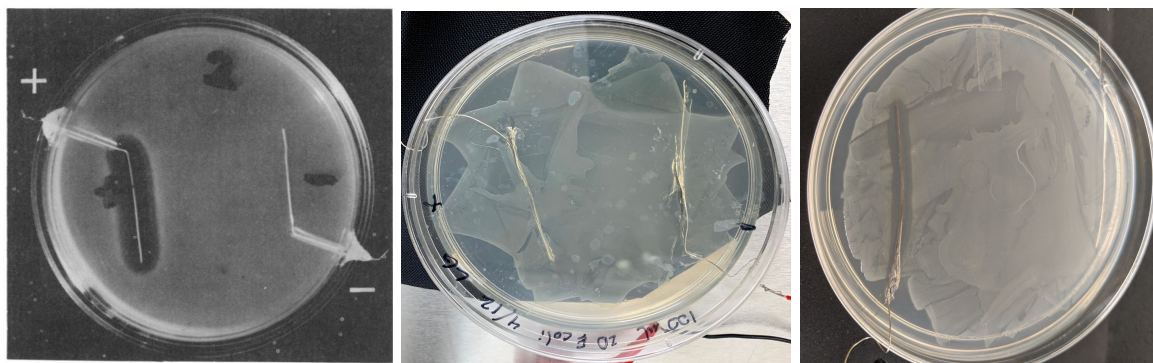


Figure 4: *Left:* Spadaro et. al-- Culture plate of *S. aureus* after 24 h of incubation with a 0.4 μA current and silver electrodes. Note the inhibition (clear zone) at the anode. *Middle:* Culture plate of *E. coli* after 16 h incubation with a (control) 0.0 μA current and silver electrodes. *Right:* Same as middle with current of 4.9 μA . Note the anode inhibition matched to the left plate with no cathodic effects.

The zones of inhibition were confirmed through standard stick and streak tests where multiple points on the incubated plate within the cleared space were probed and placed on a fresh medium. All stick tests in the cleared regions were negative which attests that the zones represent regions of antimicrobial efficacy with high fidelity. Figure 5 depicts one example of the

stick and streak tests. Notably, the same results were attained when the current controlled configuration was used on a farmed over plate of *E. coli* despite a lack of turbidity clearing which implies the bacteria were either killed or deactivated. This is further evidence towards the prototypes potential in sterilizing surfaces.

Figure 5: Example Stick and Streak Test

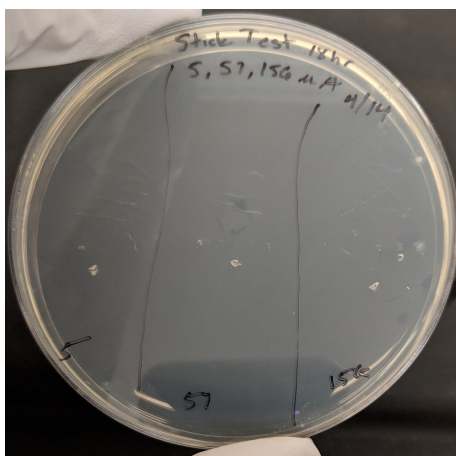


Figure 5: A sample of the repeated negative stick and streak tests taken from the cleared zone of inhibitions. This particular plate demonstrates antimicrobial efficacy for 5 μA , 57 μA , and 156 μA trials.

Taken together, these findings attest to the placement of the anode surrounding the surface of the foot, since that is the site of antimicrobial inhibition via silver ion deposition. Moreover, the anode and cathode are separated to avoid any short circuiting that could prevent the electrochemistry necessary at the electrode-electrolyte interface to elicit these effects. These findings suggest that electrochemical deposition via a controlled current augment antimicrobial qualities of silver wires.

Silver Ions in Fabrics

The electrochemical deposition in pure silver wire is well studied, however prior to this project there has not been much exploration into whether silver textiles that may be plated,

nanocoated or woven with silver, usually integrated with nylon for flexibility, can produce the same antimicrobial effects when current is applied. Two commercially available silver textiles called Technicot and Stretch were identified. Technicot is a woven fine silver wire mesh fabric with only one direction of flexibility while Stretch is a knitted silver plated fabric with multidirectional flexibility. Therefore, it is expected that Technicot would have greater therapeutic effect on microbes than Stretch; however, in the context of a sock prototype Technicot's rigidity proved to be difficult to navigate.

To investigate whether these fabrics replicate the promising electrochemical deposition findings from the silver wire, two of each fabric 2.5 mm were embedded in separate plates under the agar surface with one as a no current control and the other with 57.6 μA during the 16 hours of incubation. We chose 57.6 μA as the current level of interest to maintain a current density of similar magnitude to the wire experiments ran with 4.9 μA . The resulting current density was 0.73 $\mu\text{A}/\text{cm}^2$. It is current density rather than current that dictates the antimicrobial active effect. Spadaro et al. found that current densities of approximately 1 $\mu\text{A}/\text{cm}^2$ were effective on staph aureus at the silver anode so we expected a similarly robust finding with E. coli (13).

Figure 6 illustrates the passive antimicrobial activity from the fabric silver ions exceeding that of the silver wires. Since there is no current running through the control fabrics, the inhibition zone is directly due to diffusion of the silver ions that are leaching from the fabric due to looser bonds to the fabric when compared to the pure silver wire. Thus it can be said with confidence that the diffusion limit of these fabrics in agar is larger than 2.5 mm. Notably, the ring of inhibition spreading radially from the electrodes running current is marginally larger than that of the control with an average distance of 2 mm compared to .5 mm in Technicot versus the 2 mm compared to 1.5 mm in Stretch fabric. It appears that the diffusion is more pronounced in

the vertical direction than the lateral direction relative to the electrode. This is sensible considering the distance from the silver ion source to diffuse laterally at the surface exceeds that of the vertical diffusion at all points according to right triangle approximation. Taken together, Technicot and Stretch fabric exhibit similar antimicrobial impact at the passive level which reinforces the choice of Stretch for the prototype.

Figure 6 : Passive Antimicrobial Properties Between Technicot and Stretch

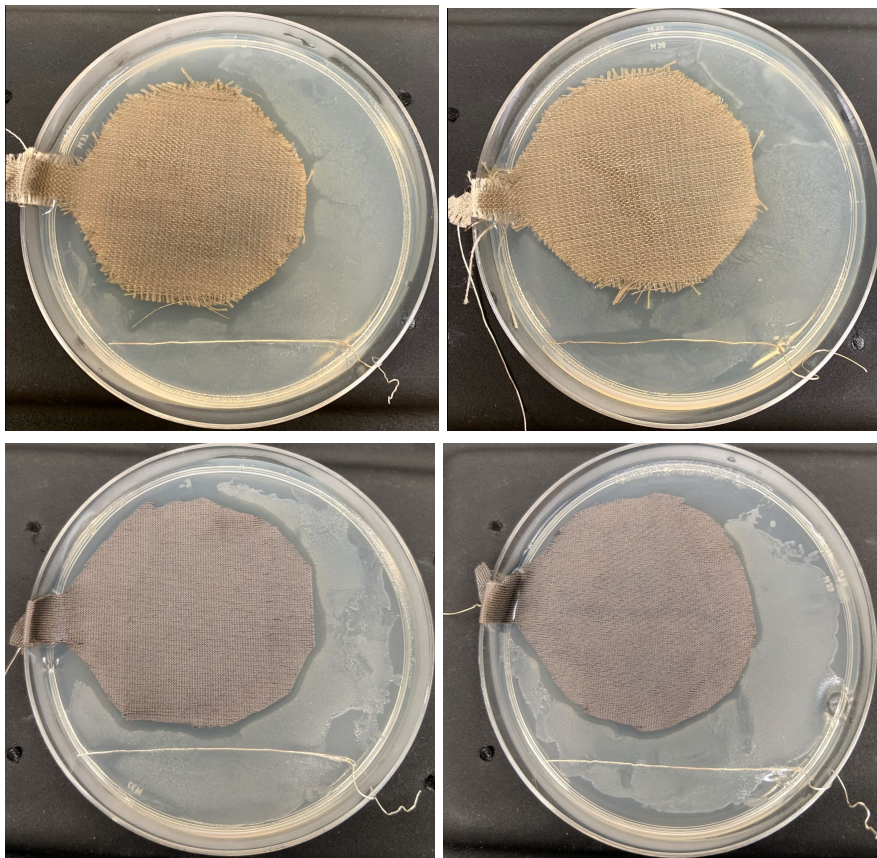


Figure 6: *Top Left:* Technicot fabric at 57.6 μA , current density 0.76 $\mu\text{A}/\text{cm}^2$. *Top Right:* Technicot control. Notice the diminished lateral zone of inhibition (clear) on the surface. *Bottom Left:* Stretch at 57.6 μA , current density 0.76 $\mu\text{A}/\text{cm}^2$. *Bottom Right:* Stretch control. Notice the slightly diminished lateral zone of inhibition in the control when compared to the current manipulation.

Added Sterile Protection

From the antimicrobial studies thus far, the remaining question is if current-controlled electrochemical deposition lends a benefit analogous to the silver wire results or if it is negligible when compared to diffusion. To explore this question, the limits of the diffusive effects were tested by embedding the electrodes 5.5 mm below the surface of the agar and placed the grounding wire at the surface to direct the electromotive force more vertical. Past study iterations may have stunted the emergent active effects by directing the current density horizontally in the plane of the electrode via a grounding wire lying in the plane. As the material of choice for the prototype, the Stretch fabric was ran with a current 57.6 μA corresponding to a current density of 0.76 $\mu\text{A}/\text{cm}^2$ and a control at identical depth with no current. Figure 7 shows an upper bound for the diffusion limit of the Stretch electrode at 5.5 mm via the completely farmed over control plate. The *most vital* finding of all the antimicrobial studies thus far is the fact that the 57.6 μA current resulted in significant, but not complete, inhibition above the fabric electrode. The fabrics were confirmed to be at the same depth, therefore this study is strong evidence that the applied current confers added sterility protection for surfaces above and beyond that offered by diffusion. Since bacteria can find refuge below superficial layers of skin, this finding is critical.

Figure 7: Controlled Current in Stretch Fabric Provides Added Sterility Protection

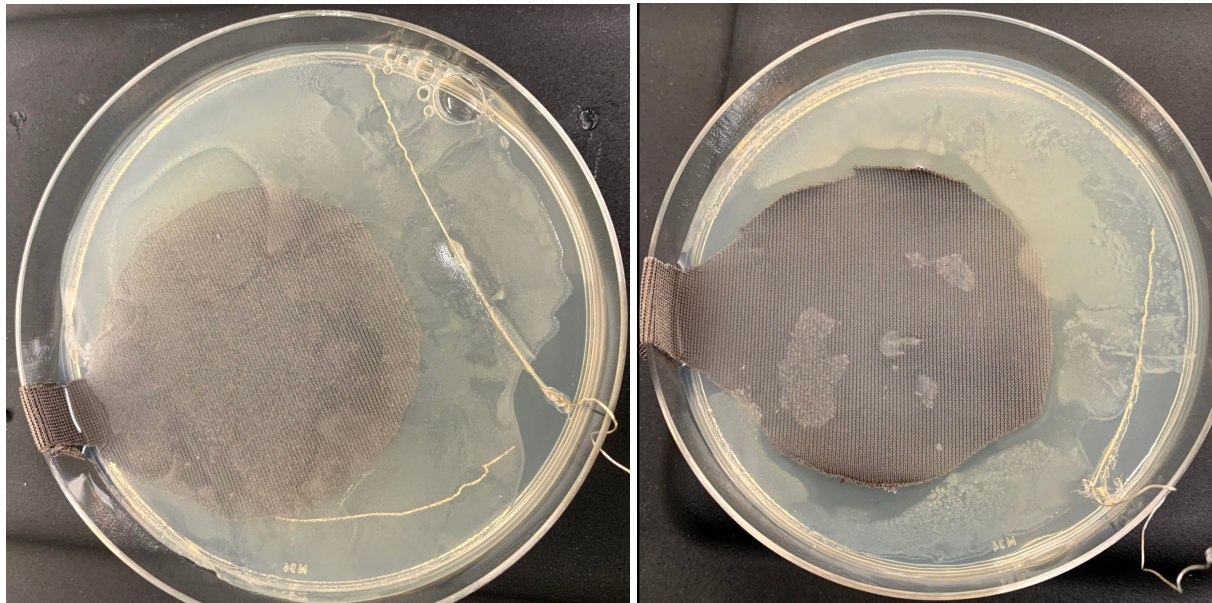


Figure 7: *Left:* Stretch control. Notice the plate is completely farmed over the anodic electrode. *Right:* Stretch with 57.6 μA and current density of 0.76 $\mu\text{A}/\text{cm}^2$. Notice the significant clearing.

From these iterative antimicrobial efficacy studies, it is evident that the Stretch fabric electrode demonstrates significant passive antimicrobial properties with a diffusive limit between 2.5 mm and 5.5 mm from the embedded studies. Moreover, the active antimicrobial properties are significant compared to those of diffusion which supports the need for *VoltaFeet*. A few limitations of our understanding of this antimicrobial efficacy is what the exact magnitude of this active effect is with regard to penetration depth and how the agar medium translates to the skin. The skin is undoubtedly of higher impedance which will reduce both the passive and active impact of the silver ions. This hindrance impedance is reduced when the skin is wet and luckily the areas of the foot that tend to be the most vulnerable to bacteria are also those that are moist. It turns out that agar is a good analog for tissue, so the collected data is fairly compelling for the diabetic foot ulcer application as well as other open wound treatments. It is expected that a current density close to the effective 0.76 $\mu\text{A}/\text{cm}^2$ demonstrated in these studies should also be therapeutic to the foot.

The final limitation encountered was that of experimental regulations. Of course, the most compelling data set would be derived using the prototype on participants' feet over an extended period of time with a bilateral control for comparison via swab onto culture plates before and after the socks are worn. However, the fact that the individual's foot microbiome is unknown and offers the slight possibility of fostering microbes such as MRSA make getting IBC approval for such experimentation remarkably difficult. The study would have to be conducted on a clinical scale or outside the laboratory setting--outside of this investigation's reach. Immediate efforts are now focused on expanding these findings to staph aureus (gram positive).

Safety

In designing a prototypes, the safety of the user is the first and foremost consideration when doing tradeoff analyses of design choices. The primary vehicle for evaluating this prototypes safety was through a class provided software called Design Safe; the considerations it brings forth are discussed in the following section.

Design Safe Analysis

A thorough analysis of the risks to users presented by the prototype found that although multiple hazards do exist, they are all qualified as being low risk or on the lower end of moderate risk. The user groups identified to be at risk were athletes, diabetic patients with foot ulcers, users with bromodosis, engineers, manufacturers, and small children. The risks to athletes, diabetic patients, and users with bromodosis are all very similar since the device will be used in almost identical ways by each group.

Although electrical hazards are commonly dangerous in other settings and devices, most of the electrical risks are minimized and effectively negligible in this product since it makes use

of microcurrents way below the threshold of feeling powered by a very small power source (3V lithium ion coin battery). Nevertheless, 3V coin batteries have been known to cause internal damage if ingested since the internal resistance of the gut is significantly less than the resistance of the skin (14). As a result, there is a sizeable risk present to small children who are likely to put random objects in their mouths, because it is not improbable to imagine a user leaving a pair of socks laying on the ground where it would be accessible to children. Since it is very unlikely that a child would be able to ingest the entire sock, a way to minimize this risk would be to child-proof the battery housing so that the battery cannot be easily accessed.

Another moderate level risk that is present is the risk of battery combustion. Although it is tremendously unlikely that a certified 3V coin battery explodes, our current prototype design allows for the user to replace the battery. This means that if the user were to replace the original certified battery with an uncertified battery, combustion might become more likely. However, the few cases of coin batteries exploding that exist are due to them being placed in settings with much higher temperatures than the circuit could produce on its own or that a user could even tolerate. As a result, the probability of combustion is remote, but since the severity of the resulting injury could be serious, it is still a moderate risk for all user groups. A possible method for reducing the risk of combustion, and other risks including burns, is to build an on/off switch into the prototype that allows the battery to not constantly run, giving it a chance to cool down. However, the current of our circuit is regulated at such a low current (60 μ A) neither burns nor combustion are anticipated under normal use conditions.

Another risk that applies to all user groups is the possibility of being cut or scraped by the silver wire in the sock. This would be caused by a fracture of the silver wire, which could result from overuse or overstretching of the fabric that the wire runs through. Currently, our prototype has two wires that exit the battery casing; one that goes to the conductive fabric at the

bottom of the foot, and one that goes to the conductive fabric at the ankle. Both of these wires are susceptible to fracture but are coated in rubber in hopes to prevent sharp edges from being exposed if it were to happen. The other risks that are not mentioned in this discussion are shown and qualified in Appendix E. It is noteworthy that the metal of choice for this fabric being silver virtually eliminates concerns of skin allergy or reaction.

User Satisfaction

A survey on the comfort, quality, and appearance of the prototype was given to a non-randomized group of 13 athletes. Participants were asked to rank each of the three qualities of a normal sock and the prototype on a Likert scale (1-5 scoring). Despite best efforts to gather a random sample that spanned all user groups, it proved to be a difficult task due to a lack of an ability to amass and poll strangers. The results of the survey are shown in Table 3. This survey included timing how long it took participants to activate the circuit by inserting the battery and connecting the housing. On average, participants ranked the appearance of the prototype 0.08 points less than the normal sock, and the quality 0.54 points greater. Both of these differentials fall well within the 0.5 point difference that was defined as being the desired outcome in the verification and validation report. However, the average rating of comfort was more than a whole point less for the prototype than for the normal sock. Most participants complained that the seam located right on the toes of the prototype was uncomfortable. Looking forward, other designs will be explored to prevent a seam from resting on the toes so that comfort can be improved. Utilizing more advanced manufacturing equipment would allow for seamless design. Stretchable knitted fabric provides some moderate comfort, while also accommodating a variety of user foot sizes per sock size.

Table 3: Comfort, Appearance and Quality Likert Ratings & Operation Time

	Average Response	Standard Deviation
Normal- Comfort	4.23	0.44
Prototype- Comfort	2.84	1.14
Normal- Appearance	3.62	1.33
Prototype- Appearance	3.54	1.20
Normal- Quality	3.46	1.27
Prototype- Quality	4.00	0.91
Functional- Operation Time	8.33 seconds	2.14 seconds

Table 3: Comparison of the rankings of comfort, appearance, and quality on a Likert scale (a ranking from 1-5) of a Normal sock and the Prototype sock. Functional operation time indicates how long it took users to insert the battery and connect the housing to the sock for operation.

Longevity

An important design specification to ensure product viability is device longevity. A key strength behind the concept of electrochemical release of silver is the sustainability of constant antimicrobial action in a compact design. To verify longevity there are two failure points that must be addressed, battery life and supply of silver ions.

Battery Life

A short battery life can limit the overall convenience and cost effectiveness of the device, as well as its efficacy if rapid battery failure is a risk. Following 72 hours of powering a constant current circuit at approximately 160 μA , there was no appreciable drop in the maximum voltage of any tested lithium cell batteries. Manufacturer data from Energizer suggests that under optimal operating conditions driving a relatively small resistive load (such as sufficiently moist skin), a CR2032 Lithium coin cell battery should last for at least 900 hours, or 37.5 days of continuous use (15). This manufacturer data can be seen in Figure 8.

Figure 8: Battery Longevity Manufacturer Data

Continuous Discharge Characteristics

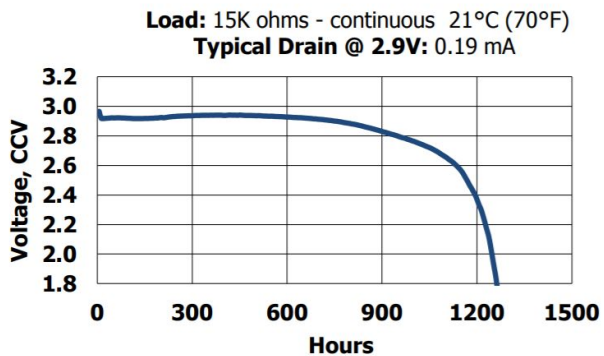


Figure 8: CR2032 Battery longevity data for driving a small resistive load from the Energizer Product Datasheet.

This longevity on a single battery is optimal for meeting our design specification of a functional duration lasting at least one month. One month of functional use would likely require less power than one month of continuous use (24 hr/day), suggesting that a single battery charge exceeds our specification for longevity.

Silver Ion Supply

Another risk to the longevity of this device is a limited supply of silver contained within the fabric of the device. As the device is run, silver will be diminished from the anode foot of the sock. To determine if this loss of silver was appreciable over time and would threaten longevity, a constant current was injected through a sample of Stretch conductive fabric continuously over the course of two weeks while periodic measurements of impedance were recorded. An image of this experimental set up can be seen in Figure 9.

Figure 9: Experimental Monitor for Impedance Changes

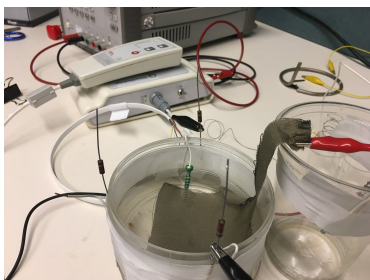


Figure 9: 10 cm² of fabric were submerged in phosphate buffered saline while 120 μ A of DC current was run between the fabric solution interface. This produced a current density of 1.2 μ A/cm². The fabric was the anode.

If significant portions of the silver were released over the course of study, one would expect to observe an increase in the impedance of the fabric electrode as its conductive coating was diminished. The data summary in Table 4 indicates the finding of no significant increase in impedance.

Table 4: Impedance Change Over Time for Stretch Fabric

Initial Impedance Measurement	Final Impedance Measurement
8 kOhms	8 kOhms

Table 4: Data indicates that 120 μ A run continuously for two full weeks does not deplete the chosen fabrics silver reserves an appreciable amount, as indicated by consistent electrode impedance.

Further study will be necessary to eliminate other risks to silver longevity and product viability, including corrosion and mechanical wear of the fabric. Longer electrical runs at higher currents will be necessary to find the limit of silver release for this device.

Conclusions

Through verification testing, the potency and viability of electrochemical silver deposition has been established for sterilizing the skin surface through a long lasting and convenient wearable. Whether for consumers looking for relief from malodorous feet or patients interested in protecting vulnerable diabetic ulcers, *VoltaFeet* has promising results worth investigating further. The dataset contained in this report indicates that at very achievable current densities, far below the threshold of perception, antimicrobial concentrations of silver can be produced in a way that is cost effective, maintainable, and elegant in its simplicity.

Future Directions & Ethics

There are several short term and long term objectives for *VoltaFeet*. In the short term, we have just received our order of Staph Aureus and will begin repeating fabric electrodes tests with this new, gram positive species to demonstrate broad spectrum lethality found in literature. Additionally, it is a priority to better elucidate the longevity of the Stretch Conductive Fabric by subjecting it to more rigorous chemical and physical washing processes that would better capture consumer maintenance. Subjecting the design to several controlled stress tests, such as a laundry cycle, and evaluating impedance change could provide a valuable data set regarding the loss of silver from wear as well as chemical interactions that occur in physiologically more relevant testing.

With the appropriate approval, there are many tests utilizing user skin interfaces that would provide valuable knowledge about differences from the in vitro culture conditions previously mentioned. While agar is a suitable material to electrically approximate exposed flesh, the skin interface has differences in impedance, charge, microbiome and chemical composition that are challenging to recreate in vitro. It is very likely that requirements for current density will vary between the two types of experiments, and more research must be done to experimentally determine an effective minimum current for *VoltaFeet*. To reduce the battery draw, future prototypes will maximize current density by reducing the surface area of silver fabrics in the foot of the design, therefore concentrating silver ions at the most susceptible areas.

There are no pressing ethical considerations with the development of this technology. Further study is necessary to ensure ethical marketing of this device's limitations - particularly regarding the ability to reduce or prevent infection. Claims involving antimicrobial capabilities pertaining to infection risks are heavily scrutinized by the FDA.

IP Considerations

VoltaFeet has potentially valuable IP in its design. Electrochemical deposition of silver as a mechanism of promoting sterility in textiles is a completely novel space without predicate designs. There is a strong argument to be made that this is a nonobvious departure from existing technology, including conductive silver garments, silver nanoparticle impregnated garments, and silver containing bandages, largely due to the originality of electrochemical release of silver as the mechanism of sustained antimicrobial efficacy. The usefulness of this technology is readily apparent as there are significant and established markets in the space of foot hygiene, diabetic foot care garments, and foot odor control solutions.

Lessons Learned

In the testing and production of VoltaFeet, this design team learned the importance of quality experimental design with appropriate controls to back one's claims. The process of verifying the antimicrobial efficacy of current based release of silver required gradually modifying of experimental protocols, each time hypothesizing sources of error and designing ways to test for them. The freedom to design, modify, and iterate through experimental designs rapidly proved to be crucial for collecting the compelling figures found throughout this paper.

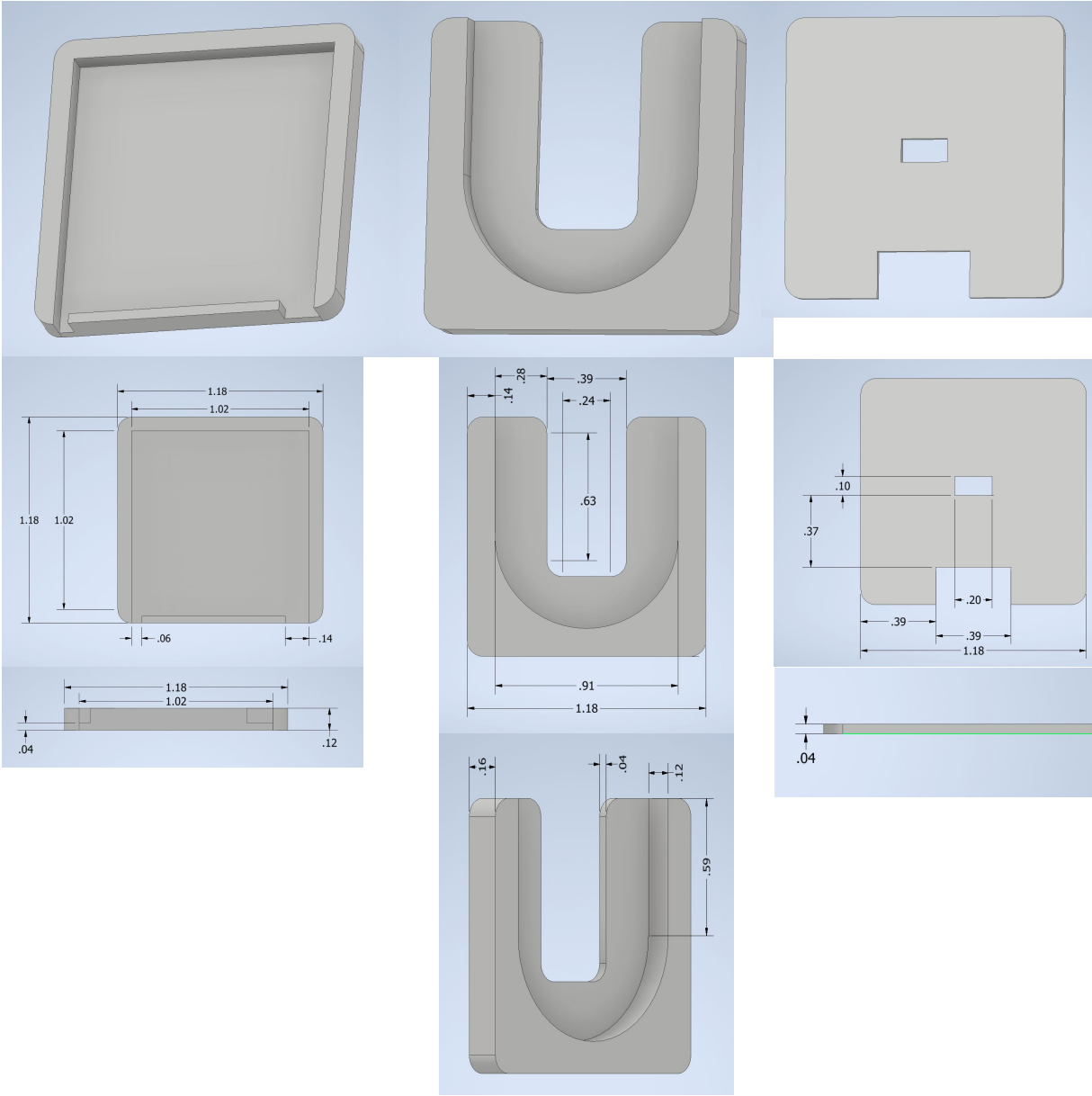
Additionally this project resoundingly proved the importance of cross disciplinary collaboration. Consultation with Dr. Ruppert-Stroescu provided valuable skills and insight outside of this design team's experience that proved vital for the creation of a successful prototype. With the added expertise of Dr. Setton and Dr. Moran, we were able to prepare relevant culture experiments as well as circuit parameters as well.

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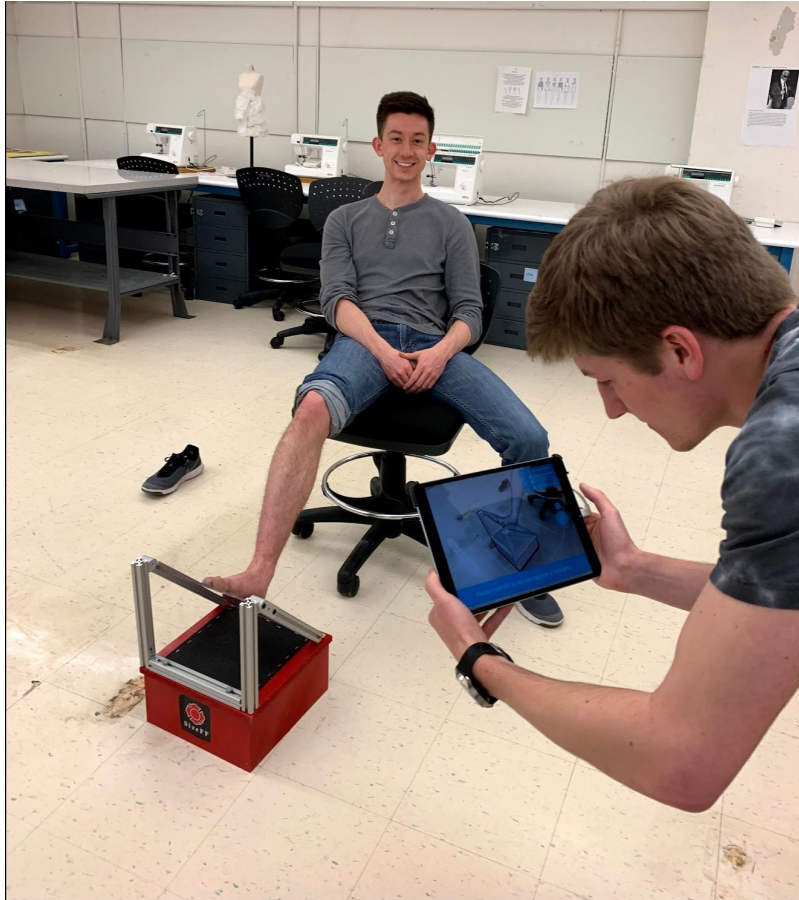
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Appendix A: CAD Diagrams for Battery Housing



Appendix B: 3D Foot Rendering Process



Appendix B: A 3D mesh model of design group 2 member, Ashton Naumann's foot was captured using commercially available Structure Sensor by Occipital. The entire surface of the foot was scanned in 360 degrees while the foot was pressed against a plexiglass pane at a 90 degree angle relative to the shin.

Appendix C: Order of Operations for the Textile Components

Note: A reference diagram of the finished product (oriented as pocket-facing) and pattern stencils for the constituent parts of the total textile are provided with pertinent dimensions. The cut line is highlighted and stencil dots are partitioned by 1 inch increments.

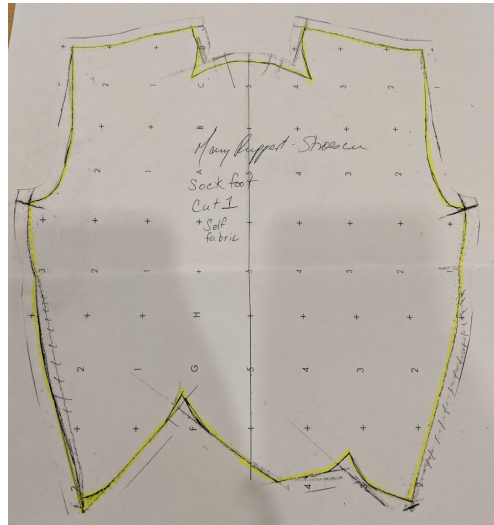
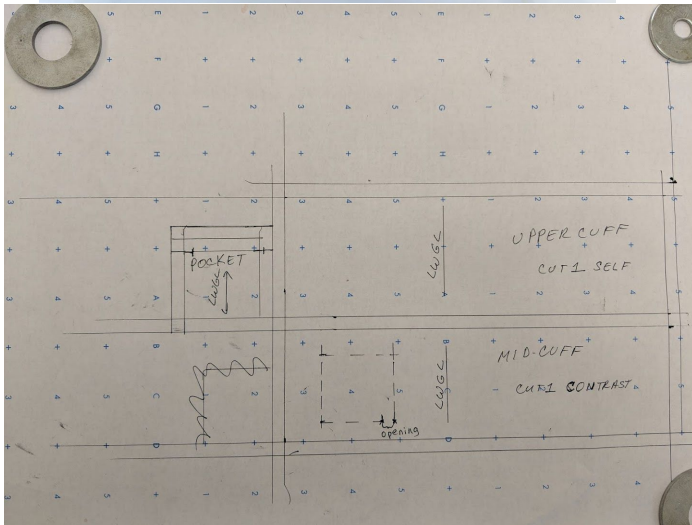
- 1) **Align** the lengthwise grain line on the pattern piece with the selvage of the conductive ("self") fabric
- 2) **Cut** on the cut line (outside line) of the upper-cuff and the sock foot
- 3) **Cut** the pocket out of the non-conductive ("contrast") material as well
- 4) **Cut** the mid-cuff out of the non-conductive material (polyester/spandex compression knit)
- 5) **Assemble/stitch** the center seam with a 301 lock-stitch
- 6) **Assemble/stitch** the heel shape
- 7) **Assemble/stitch** center back
- 8) **Assemble/stitch** toe folding according to the notches
- 9) **Finish** the upper edge of the pocket by turning it under 1/4" and stitching
- 10) **Fold** under the other three edges of the pocket and top stitch to the marked location on the mid-cuff, leaving 1/4" at the bottom right corner of the pocket for the wire
- 11) **Assemble** the center back mid-cuff seam. Put mid-cuff to foot opening and sew together
- 12) For the cuff area, **assemble** the mid-cuff (battery housing location) to the foot opening
- 13) **Assemble** the center stitch of the upper-cuff
- 14) **Fold** the upper-cuff (ground)
- 15) **Assemble** the upper-cuff to the mid-cuff in the round
- 16) **Hand stitch** the button snaps with the conductive thread onto the marked locations

Note: Mid-cuff is polyester and spandex (compression knit)

Appendix C cont. : Order of Operations for the Textile Components



Appendix C: Reference diagram of finished product along with pattern stencils for preparing the sock subcomponents, including pouch, mid cuff, and upper cuff



Appendix D: Complete Part Information

Part	Source	Part Number	Purchase Price	Per Unit Price	Datasheet URL	Lead Time
Stretch Conductive Fabric	lessemf	Cat. #A321	\$29.95 per lin ft (52in. Wide)	\$6.93	http://lessemf.com/321.pdf	5 days
ENERGIZER CR2032	walgreens	n/a	\$0.82 per unit	\$0.82	http://data.energizer.com/pdfs/cr2032.pdf	1 day
Pure silver wire	Changzhou DLX Alloy Co., Ltd.	flat silver alloy wire	\$600.00 / kg	\$0.60	https://www.alibaba.com/product-detail/Pure-Flat-Silver-Alloy-Wire-999_60607426021.html?spm=a2700.7724857.normallist.18.d16c98ecgSZPT&s=p	2 weeks
Pure Nickel Strip	U.S. Solid (Amazon)	8.88E+11	\$9.99 - 0.1x8x100 mm 100 count	\$0.10	https://ussolid.com/0-1x8x100-mm-100-count-pure-nickel-strip-solder-tabs-for-high-capacity-18650-lithium-battery-packs.html	3 days
PLA 3D Printer Filament	Hatchback	n/a	\$19.99 /1kg spool	\$0.20	https://www.hatchbox3d.com/collections/pla/products/3d-pla-1kg1-75-blk	3 days
12 kOhm resistor	E-Projects	EP51412K0	\$0.60/ unit	\$0.60	https://www.amazon.com/dp/B0185FFURE/ref=biss_dp_t_asn	3 days
Nano Shield NS085 Hook-up Stranded Wire	Nano Shield	WiredLine001	\$15.99/138ft	\$0.20	https://www.amazon.com/Stranded-Flexible-Silicone-Insulated-Electrical/dp/B07BWC596B/ref=sr_1_3?keywords=rubber+coated+wire&qid=1555551161&s=industrial&sr=1-3	3 days
LM 334 3-Terminal Adjustable Current Source	Texas Instruments	LM334M/N OPB	\$0.85/unit (10-25 units)	\$0.85	http://www.ti.com/lit/ds/sym-link/lm334.pdf	5 days
Adafruit SMT Breakout PCB for SOIC-8	Adafruit (Amazon)	1212	\$6.46/6 pack	\$1.08	https://www.adafruit.com/product/1212	7 days
			Total Cost of Unit:	\$11.38		

