Preliminary Report: *Electrion*

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Class: Senior Capstone Design- Group 2

Background

The greatest density of sweat glands in the human body exists on the bottom of the feet, which can perspire up to a half pint of moisture a day (CPMA). This warm and wet environment is highly productive for the growth of bacteria and fungus with waste products that often lead to malodorous and unsightly feet. According to the Institute for Preventive Foot Health, 16 percent of adults have suffered from significant foot odor; the medical term for this condition is bromodosis. Despite the complex diversity that is foot flora, Brevibacteria is identified as a major contributor to the production of foul smell (IPFH). Furthermore, the point prevalence of athlete's foot, a common fungal infection, is conservatively 3-15 percent (10-50 million people in the U.S.) (IQWiG). Widely endorsed risk factors such as diabetes and hyperhidrosis significantly increase an individual's susceptibility to preventable microbial imbalances that frequently go unreported and untreated despite recurring doctor visits. For diabetics, the poor peripheral vasculature associated with the condition amplifies the risk for runaway foot infections or ulcers that go undetected due to peripheral neuropathy-often leading to impressively foul odors and higher level medical intervention. Over 100 million people in the United States are diagnosed with diabetes or prediabetes, and that number is growing rapidly (CDC).

In conjunction with increasing costs of healthcare, the expanding diabetic population is fueling market demand for a proactive, affordable, and convenient commercial solution for bromodosis that can be implemented by the user at home. At present time, the market lacks an emergent product that is dominant in balancing longevity, convenience, and therapeutic effectiveness. Limited regulation exists in the niche of existing solutions with most focus surrounding metal toxicity considerations when relevant.

Project Scope

Considering the robust population affected by bromodosis and other related microbial maladies a simple, effective, and long-lasting treatment is needed for reliably eliminating toe/foot fungus as well as foot and shoe odor in a diverse population not solely limited to athletes. The most important specifications for a novel solution to this problem include effective anti-microbial functionality that persists for an extended period (> 6 months), reliability across a diverse range of users, cost efficiency and user safety. Secondary specifications include maximizing user comfort, quality of the design, and easy use with very few steps; these considerations are important in ensuring long-term use and market viability. These specifications are developed further in the design requirements section. We are going to deliver a daily wearable item that will eliminate existing microbial infections of the foot and prevent the growth of future ones by sterilizing the shoe environment. A functional prototype of this device will be tested and ready by April 1st, 2019. A detailed preliminary design schedule with all foreseen intermediate tasks to meet this final deadline is visualized in a Gantt chart displayed in Appendix A with the supervising group member indicated.

Design Requirements

Necessary specifications and secondary considerations of the prototype that will be designed are displayed in Table 1 and Table 2, respectively. Successfully following the necessary specifications in a prototype build will facilitate an effective product. Secondary considerations/specifications are features that are desirable, but not crucial, in a successful prototype; however, they are vital aspects in moving this product forward into a competitive market. As research into the market space continues, specifications will continue to be added.

Table 1: Necessary Specifications of Prototype

Antimicrobial Efficacy	Eliminates 99.9% of microbes/fungus of the toes and feet in 12 hours.
Diverse Sizing	Reliable for feet sized 4 through 12 men's and women's.
Long Functional Duration	Antimicrobial effects remain functional for at least 6 months and withstand at least 50 washing and drying cycles.
User Safety	Must not result in shocks or punctures after repeated loading during locomotion in any practical environment; If an electrical current is used, it must be less than 1 mA.
Affordability	Must be competitively priced to alternate solutions; less than $10 to produce.
Simple Operation	The product should be effective with minimal user effort. Less than 10 seconds should be required to turn on functionality (not including the time to put on the product).

Table 2: Secondary Specifications of Prototype

Comfortable to Wear	The design should be as comfortable as an ordinary sock, as to not discourage use, which includes the location of functional components and materials used.
Quality Design and Appearance	A sleek design that seeks to hide/camouflage the functional components. At least 60% of a randomly polled sample should say they would buy the sock just based off the appearance.

Existing Solutions

Treatment for foot odor, as well as fungal infections of the foot, rely upon several strategies to manage the microbiome of the foot. These strategies are directed toward prevention of bacterial and fungal growth or elimination of existing microbes. Preventive strategies seek to control the foot environment, making it unfavorable for the growth of bacteria and fungi. These solutions include antiperspirants, moisture elimination, and antimicrobial gear. There are also more intensive antimicrobial treatments designed to disinfect the foot environment, therefore eliminating the microbes responsible for existing odor and infections. These treatments include disinfecting ointments/sprays and foot washes. Prescription treatments for severe contamination are available for bacteria and fungi that are resistant to other strategies. A summary of the various commercially available and home remedy treatments for managing foot odor and fungal infection are listed in Table 3.

Table 3: Existing Treatments for the Management of Foot Odor and Infection

Treatment	**Description**	**Broad Examples**	**Commercial Brands**	**Cost Range***
Deodorants and Antiperspirants	Prevents sweating and masks odor	aluminum chloride, aluminum sesquichlorohydrate	Dr. Scholl's, Carpe	~ $8 - 25
Moisture Elimination	Absorbs or wicks away moisture	active carbon inserts, zinc oxide powders, wicking socks	Zorpads, Remodeez, Foot Sense Powders,	~ $4 - 20
Antimicrobial Gear	Antimicrobial materials in contact with the foot environment	Silver nanoparticle, silver, copper, and titanium thread socks	Rhone Silvertech, Balega, Tommie Copper, Tisoks	~ $12 - 45
Antifungal Ointment	Potent antifungal agent to kill an existing infection	Butenafine hydrochloride, miconazole nitrate	Activis, Lotrimin, generics	~ $2 - 10
Foot Washes	Disinfects the foot; home remedies	Vinegar baths, salt washes, tea baths	N/A	~ $2 - 15

* Cost Range estimated by list online pricing of commercial brands and competitors

Analysis of Wearable Technology Solutions

The existing options for treatment of odor and foot infection offer several advantages and disadvantages relative to each other. The most convenient of the existing solutions include preventive antimicrobial gear and moisture eliminating technologies. These products require little to no effort on behalf of the user, acting passively to create a foot environment that is unconducive to bacteria. Conversely, the more active and frequently potent interventions, including the various sprays, powders, and ointments that can be applied directly to the foot, require frequent if not daily reapplication to remain effective. To ensure maximal convenience for the user, this design project will be investigating improvements to convenient daily wearable technologies that can offer preventative as well as curative treatment that rival the more labor-intensive therapies. A pros and cons examination of the wearable odor eliminating and disinfecting technologies is therefore offered in Table 4.

Table 4: Analysis of Existing Wearable Antimicrobial Footwear Technology

Technology	**Advantages**	**Disadvantages**
Active Carbon	Absorbs moisture	Limited longevity (60 wears[1], 1 month[2]), Indirectly antimicrobial
Moisture Wicking Socks	Facilitates evaporation	Limited effectiveness, Indirectly antimicrobial
Silver Nanoparticle/Yarn Socks	Antimicrobial[3], low concentration effectiveness[3]	Rare allergy[3], Wash sensitive[4]
Copper Yarn Socks	Antimicrobial[5]	Requires high concentration Cu for effectiveness[5]
Titanium Yarn Socks	Antimicrobial under UV light[6]	Requires UV radiation[6]

[1] *Zoropads,* [2] *Remodeez,* [3] Mijnendonckx, et. al, [4] *Benn, et. al,* [5] *Vincent, et. al,* [6] *Itabashi, et. al.*

Table 4 indicates that of the commercially available technologies for eliminating foot odor and managing fungal infection, some operate indirectly by eliminating moisture while other technologies utilize bacterial and fungal sensitivity to certain oxidative metals, such as silver, copper, and titanium. In addition to the commercially available antimicrobial metal-containing socks, zinc has also been shown to be an effective antimicrobial in its oxidized state (Pasquet). Zinc oxide is frequently utilized in antiperspirant powders, such as Dr. Scholl's for this effect. Silver and Copper for example have been shown to be effective in causing lethal oxidative damage to microbial DNA, cytoplasmic membranes and proteins involved in cellular respiration. Contact with these metals can almost completely eliminate bacteria and fungi in a matter of hours (Mijnendonckx, Vincent).

Patent Analysis

To evaluate this market space for protectable innovation, we first narrowed our scope to focus on wearable technologies that demonstrated antimicrobial potency. A patent search of the most promising antimicrobial footwear technologies regarding active charcoal, silver, and copper was conducted to determine pertinent prior art. These technologies are best suited as starting points for addressing our design specifications for antimicrobial potency that is long lasting and user friendly with minimal effort required.

Active Carbon

In regards to active carbon/charcoal based strategies for wearable moisture eliminating devices, several expired patents could be found that protect various designs and methods of manufacturing an odor absorbing surface. These expired patents, include the use of activated charcoal particles woven into the fabric of hunting clothes (US5678247A) and two different methods for fixing active carbon to a surface (US4517308A, US6277179B1). Currently, US20090203275A1 is active for protecting the use of active carbon or another absorbent agent in creating one way valve for transmission of moisture outside of footwear. The swelling of the absorbent layers in the device creates a seal against outside moisture. Zorpads, a product that utilizes an active carbon sheet that is stuck to the insole of a shoe, is currently patent pending according to their website. A similar international WO patent application (WO2001097867A3) was found involving an adhesive layer, absorbent layer, and moisture conducting upper layer for attachment within a shoe, garment, or fabric was found that has not yet been approved. A technological solution utilizing active charcoal, or another moisture wicking agent, would therefore have to demonstrate novelty from the diverse array of shoe pads, inserts, and coatings that currently exist.

Silver-Containing Wearables

Various active patents exist regarding antimicrobial socks/textiles that utilize silver. US6499320B1 protects an antimicrobial sock design with silver threading composing an interior layer in contact with the users skin. Other patents focus on protecting designs that more explicitly utilize silver nanoparticles attached to the thread fabrics through various means. These patents cover specific manufacturing techniques related to the construction of such a garment. US6979491B2 protects a process for reducing silver in solution followed by the soaking and drying of threads in the silver nanoparticle solution. In a slight deviation from this design, US20130178779A1 protects the use of triangularly shaped silver nanoparticles bound to a calf high sock in combination with moisture wicking natural fibers. These patents specify weights of silver, reduction/fixation processes, and largely focus on applications in wound care or odor control. Innovation in this space would need to be careful to ensure a novel method of introducing silver or silver ions into the sock design.

Copper-Containing Wearables

The patent landscape regarding copper containing socks with antimicrobial function is fairly limited in comparison to that of silver technologies. Two expired patents granted in 1980 and 1979 feature “fine particles of copper, silver, or copper silver alloy” or a copper core with copper fibers for use in footgear (US4206514A, US4151660A) respectively, otherwise, copper’s antimicrobial properties have largely been developed for use in medical bandages and the treatment of burn patients. Patents regarding this use include collagen bound silver ions dating back as far as 1974 (US3800792A) while applications for copper bandages have come more recently, including 2014 (US20150209386A1) and 2017 (WO2018160589A1). These patents cover the use of Cu^{+} or Cu^{++} ion releasing copper oxides and mixed elastic/copper fibers respectively.

Patentability Conclusions

Our initial design concepts regarding the active generation of silver and/or copper ions through the action of a continuous DC current through a fine mesh or wire is a novel departure from all of the above technologies. Controlled release of antimicrobial metal ions, as far as our search has revealed, has only been attempted through incorporating metal threading, nanoparticles, or a partially water soluble chemical, but never through the use of a driven circuit. The scope of recent patents addressing problems ranging from foot odor and fungal infection to diabetic wound healing and burn treatment suggests opportunity to develop an improved technology utilizing antimicrobial metals and/or active carbon to decrease microbial threats.

Team Organization of Responsibilities

To ensure a functional and efficient team-dynamic, responsibilities have been distributed to the team members that encompass a broad range of current and future tasks. These are shown in Table 5. A responsibility is not meant to be fulfilled solely by the member in which it is assigned, but that member is expected to take the lead in the area and facilitate the communication of the team in areas surrounding the responsibility.

Table 5 - Team Organization of Responsibilities

Team Member	Responsibilities
Matt Heiken	● Researching the antimicrobial properties of different metals and metal compounds to find the best combination to ensure effective and safe use over a long period of time. ● Leading the search of materials for a prototype, which includes online research and reaching out to distributors in the St. Louis area. ● Designing the cosmetic aspects (including logo and color scheme) of the prototype to make it appealing to consumers. ● Taking the lead on creating powerpoints for future presentations.
Logan Groneck	● Exploring current solutions to the problem, and finding landmarks of their antimicrobial properties and long-term functionality. ● Reaching out to suppliers of existing products in the market to discover consumer preferences in material and design. ● Heading our group's communications with our client, Dr. Dan Moran. ● Leading the functional construction of multiple prototype designs, which includes considerations in safety and diverse sizing.
Ashton Naumann	● Investigating and devising different delivery methods of antimicrobial functionality. ● Contacting WashU faculty who specialize in the foot microbiome to better understand the common species of flora that colonize in different patient populations. ● Leading experimental testing of prototypes on antimicrobial functionality and duration. ● Having the Engineering Communication Center review our technical documents. ● Ensure that the weekly reports are submitted on time.

References

Benn, Troy M., and Paul Westerhoff. “Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics.” *Environmental Science and Technology*, vol. 42, no. 11, 2008, pp. 4133–4139., https://pubs.acs.org/doi/pdf/10.1021/es7032718.

“General Questions.” *CPMA*, California Podiatric Medical Association, www.podiatrists.org/visitors/foothealth/faqs/general.

Institute for Quality and Efficiency in Health Care. “Athlete's Foot: Overview.” *Informed Health Online*, U.S. National Library of Medicine, 14 June 2018, www.ncbi.nlm.nih.gov/pubmedhealth/PMH0072733/.

Itabashi, T., et al. “Bactericidal and Antimicrobial Effects of Pure Titanium and Titanium Alloy Treated with Short-Term, Low-Energy UV Irradiation.” *Bone and Joint Research*, vol. 6, no. 2, 1 Mar. 2017, pp. 108–112., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5331176/.

Mijnendonckx, Kristel, et al. “Antimicrobial Silver: Uses, Toxicity and Potential for Resistance.” *BioMetals*, vol. 26, no. 4, Aug. 2013, pp. 609–621., https://link.springer.com/article/10.1007%2Fs10534-013-9645-z.

“National Foot Health Assessment 2012.” *Foot Odor* | *Institute for Preventive Foothealth (IPFH)*, Institute for Preventive Foot Health, June 2012, www.ipfh.org/resources/surveys/national-foot-health-assessment-2012.

“New CDC Report: More than 100 Million Americans Have Diabetes or Prediabetes.” *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention Media Relations, 18 July 2017, www.cdc.gov/media/releases/2017/p0718-diabetes-report.html.

Pasquet, Julia, et al. “The Contribution of Zinc Ions to the Antimicrobial Activity of Zinc Oxide.” *Colloids and Surfaces A: Physicochemical and Engineering Aspects*, vol. 457, 5 Sept. 2014, pp. 263–274., https://www.sciencedirect.com/science/article/pii/S0927775714005172.

Vincent, M., et al. “Contact Killing and Antimicrobial Properties of Copper.” *Journal of Applied Microbiology*, vol. 124, 20 Dec. 2017, pp. 1032–1046., https://onlinelibrary.wiley.com/doi/epdf/10.1111/jam.13681.

Patent References

Bernhardt, Frederick. (US6499320B1) *Garment having antimicrobial properties and its associated method of manufacture.* 31 December 2002.

Dehn, Michael. (US20090203275A1) *Self-Closing Ventilation Insert and Method of Producing it.* 13 December 2016.

Dudaa, Marcus. (US20130178779A1) *Sock for treatment of foot and leg wounds, methods of use and manufacture.* 29 December 2015.

Ehlenz, Peter, and Lutz Irgel. (US451730A) *Method of Producing a Sorptive Body, Particularly for Eliminating Odors, Air Freshening, Etc. and the Resultant Product*. 14 May 1985.

Gabbay, Jeffrey. (US20150209386A1) *Copper Containing Materials for Treating Wounds, Burns and Other Skin Conditions.* 24 October 2014. *Application Only

Knight, Mc, and Guldalian, J. (US3800792A) *Laminated collagen film dressing.* 2 April 1974.

Pole, Robert. (WO2001097867A2) *Perspiration absorbing items.* 16 June 2000 *Application Only

Reymonet, Jean-Louis. (US6277179B1) *Agglomerates based on active charcoal, their process of preparation and their use as adsorption agents.* 21 August 2001.

Song, Edward, and Wilmink, Michael. (WO2018160589A1) *Antimicrobial elastic support bandages.* 28 February 2017.

Vickers, Thomas W. (US5678247A) *Odor-Absorbing Clothing Article*. 21 Oct. 1997.

Yamauchi, Akira. (US4206514A) *Sanitary footgear articles*. 10 June 1980.

Yan, Jixiong, and Cheng, Jiachong. (US6979491B2) *Antimicrobial yarn having nanosilver particles and methods of manufacturing the same.* 27 December 2005.

Yoshimi, Hiroyuki, and Itoh, Yoshio. (US4151660A) *Socks for use with footgear.* 1 May 1979.

Product References

Product	Link
Dr. Scholl's Odor X Spray	https://www.drscholls.com/products/comfort-and-energy/odor-x-odor-fighting-spray/
Carpe Foot Lotion	https://www.carpelotion.com/index.html
Zorpads - Active Charcoal Insert	http://www.zorpads.com/
Remodeez - Active Charcoal	https://www.remodeez.com/
Foot Sense All Natural Foot and Shoe Powder	https://www.amazon.com/gp/product/B00O2DQO4C/?tag=menshealth-auto-20&ascsubtag=%5bartid|2139.a.19538343%5bsrc|%5bch|
Rhone - Silvertech socks	https://www.rhone.com/collections/running-socks-for-men
Balega - Silver	https://balega-socks.implus.com/products/silver-running-socks/
Balega - Moisture wicking	https://balega-socks.implus.com/products/hidden-running-socks/
Tommie Copper	https://www.tommiecopper.com/men/compression-sock
Tisoks	https://www.amazon.com/Tisoks-Titanium-Antifungal-Antibacterial-Athletes/dp/B078GBZBHX/ref=sr_1_13?ie=UTF8&qid=1538337716&sr=8-13&keywords=antimicrobial+socks
Lotrimin	https://www.lotrimin.com/our-products/athlete-antifungal-cream.php
Activis	https://www.healthwarehouse.com/miconazole-nitrate-2-cream-actavis-1-5-oz.html?gclid=Cj0KCQjw0dHdBRDEARIsAHjZYYCGWxIc1bTn0AMaBdd5acKb5_AECMiUHnA1JUq0Oj5ot3L2GApzFxwaAmphEALw_wcB

Appendix A: Gantt Chart

PROJECT TITLE	Senior Design (2018-2019)	**COMPANY NAME**	Group 2
CLIENT	Dr. Dan Moran	**DATE**	10/05/2018

TASK TITLE	TASK OWNER	START DATE	DUE DATE	DURATION	PCT OF TASK COMPLETE
First Semester					
Weekly Reports	Ashton	10/1/18	4/12/19	191	18%
Preliminary Report	Ashton	10/1/18	10/5/18	4	30%
Research Material Properties	Logan	10/1/18	10/15/18	14	0%
Refine Design Specifications	Matt	10/15/18	10/19/18	4	0%
Web Page URL	Matt	10/22/18	10/22/18	0	0%
Initial Design Brainstorming	Group	10/22/18	10/26/18	4	0%
Contact Industry Representatives	Ashton	10/29/18	11/2/18	3	0%
Consult Wash U Faculty	Logan	10/29/2018	11/2/18	3	0%
Pugh Chart with Design Analysis	Logan	11/5/18	11/16/18	11	0%
Budget Analysis	Matt	11/19/18	11/23/18	4	0%
Progress Report	Logan?	11/26/18	11/30/18	4	0%
Second Semester					
Prototyping	Logan	1/14/19	2/28/19	44	0%
Experimental Design	Ashton	1/23/19	2/28/19	35	0%
Experimental Testing	All	3/1/19	3/29/19	28	0%
Cosmetic and Human Factor Analysis	Matt	3/11/19	3/29/19	18	0%
Design Safe Analysis	All	4/1/19	4/19/19	18	0%
Prepare Final Prototype Demo and Report	All	4/15/19	4/19/19	4	0%
Practice Presentation	All	4/22/19	4/24/19	2	0%
Note Book Turn In + Peer Evaluation	All	4/22/19	4/24/19	2	0%
BME Poster Day	All	4/30/19	4/30/19	0	0%