

# **VoltaFeet:**

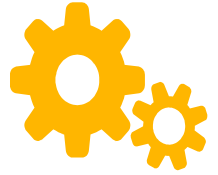


# **The Future of Sterile Foot Care**

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**In collaboration with Dr. Moran, Dr. Setton, and Dr.  
Ruppert-Stroescu**

# Presentation Overview



- 1** Commercial Need
- 2** The VoltaFeet Solution
- 3** V&V Testing Results
- 4** Future Directions

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# A Need for Sterilization

Why it is important to maintain a sterile skin surface.

# Odor, Infection, Injury

Let's examine the foot...



## Foot Odor (Bromodosis)

Affects 16% of people (NFHA, 2012)

- Caused by microbes breaking down sweat and skin debris

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- Painful, unsightly fungal infection

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## Chronic Diabetic Foot Ulcers

Affects 6.3% of people Globally, 13% in North America (Zhang et al. 2017)

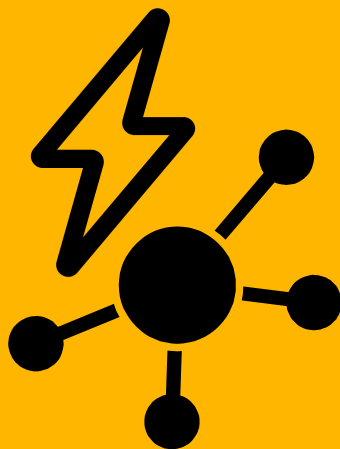
- Poor healing response, risk of infection/amputation

# Commercial Needs

**Foot Odor + Athlete's Foot + Diabetic Socks**



A **convenient, reliable, long lasting** treatment that **eliminates microbial activity** on the surface of the foot.

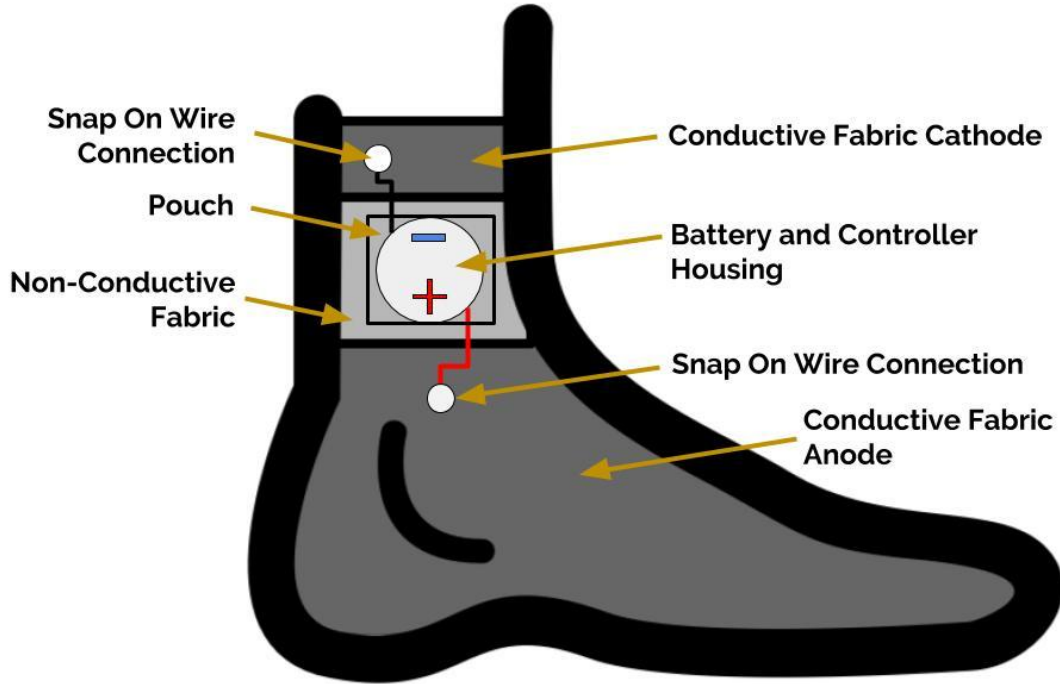
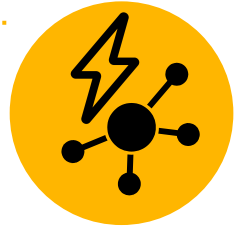


# The VoltaFeet Solution

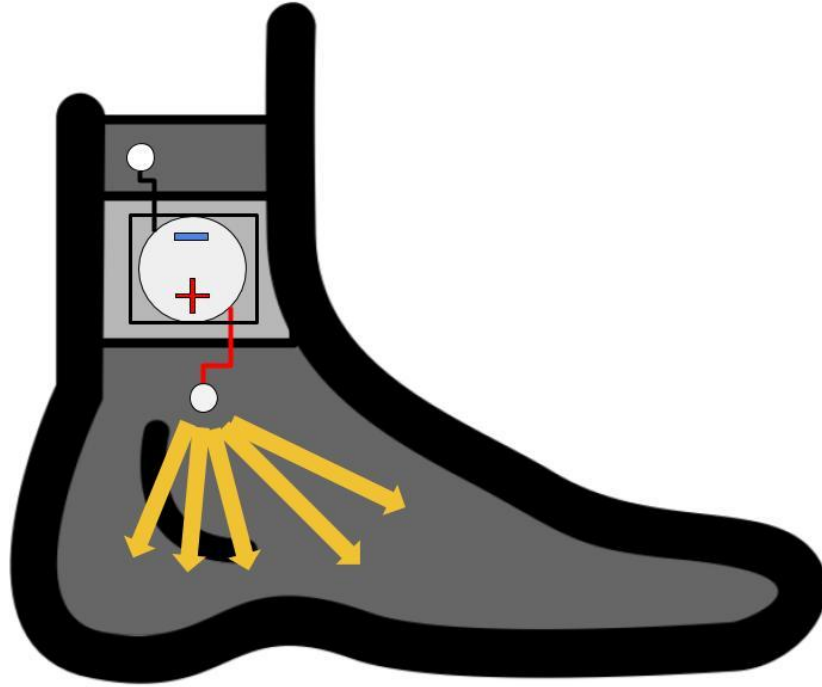
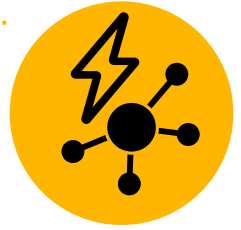
How we use electrochemical delivery of silver ions for antimicrobial foot protection.



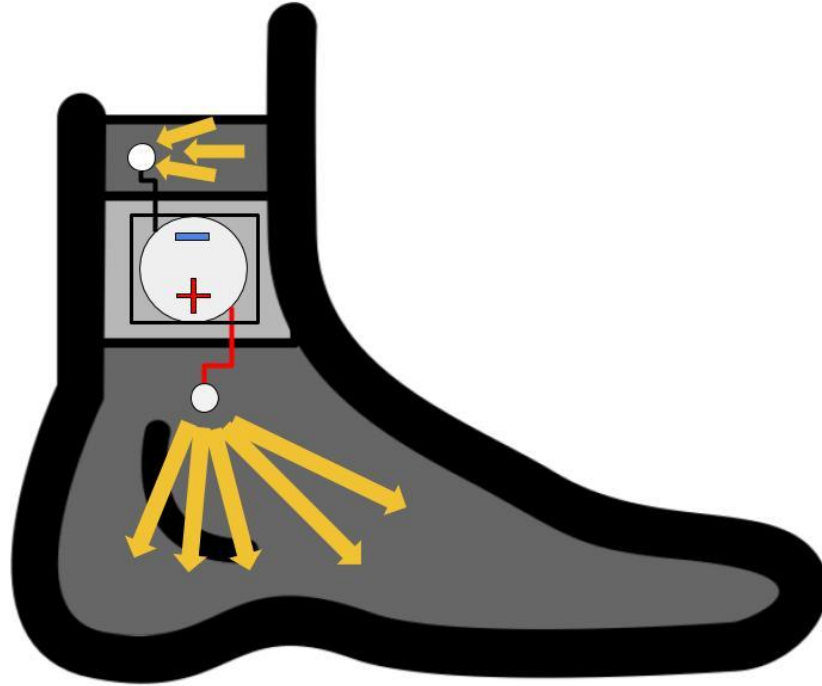
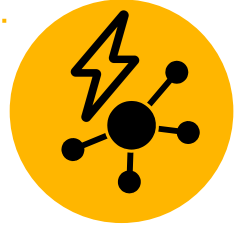
# VoltaFeet Design



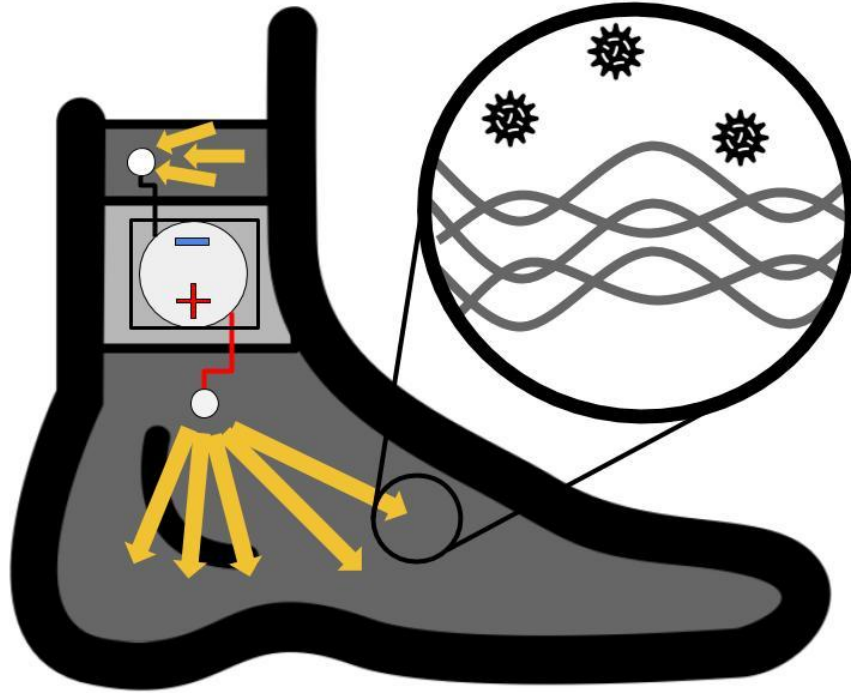
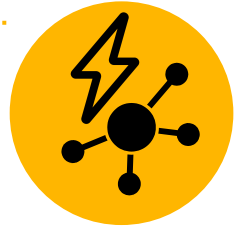
# VoltaFeet Design



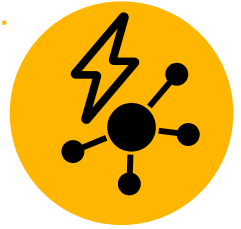
# VoltaFeet Design



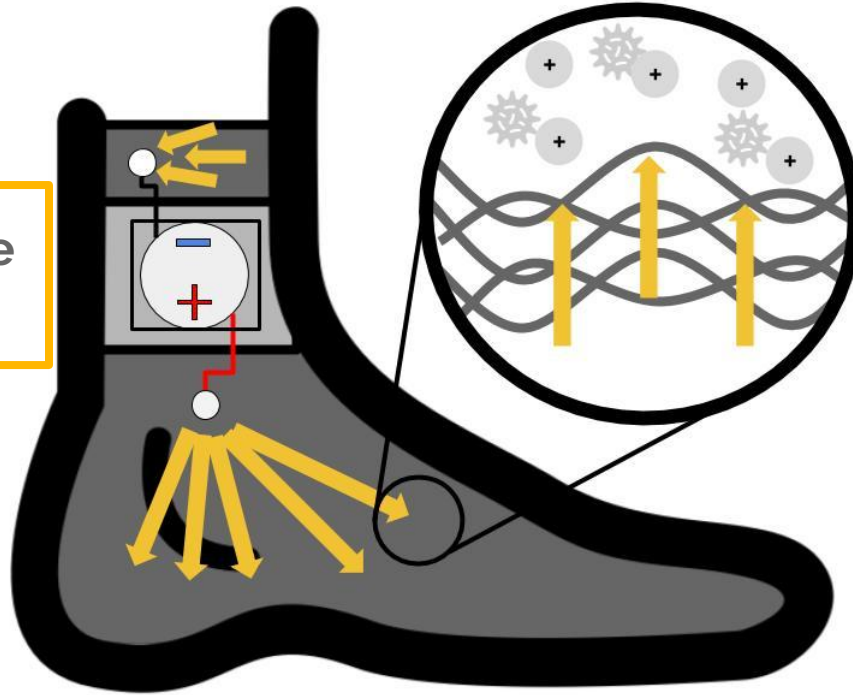
# VoltaFeet Design



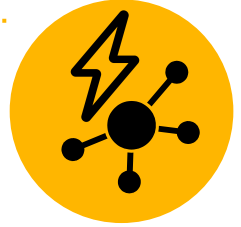
# VoltaFeet Design



Electrode/Electrolyte  
Interface



# VoltaFeet Prototype



# Verification Criteria

Design Specification	Conclusion
<b>99.9% Antimicrobial Efficacy</b>	<b>All zones of inhibition with E. coli resulted in negative stick and streak tests</b>
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 accomodate 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 $\mu$ 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
<b>Longevity (&gt; 1 month functional use)</b>	<b>Device remains functional for at least one month of use. Battery life is estimated to last &gt; 1 month based on manufacturer data. Silver release maintained at higher than required current density (<math>1.2 \mu\text{A}/\text{cm}^2</math>) for 14 days of continuous use</b>
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)



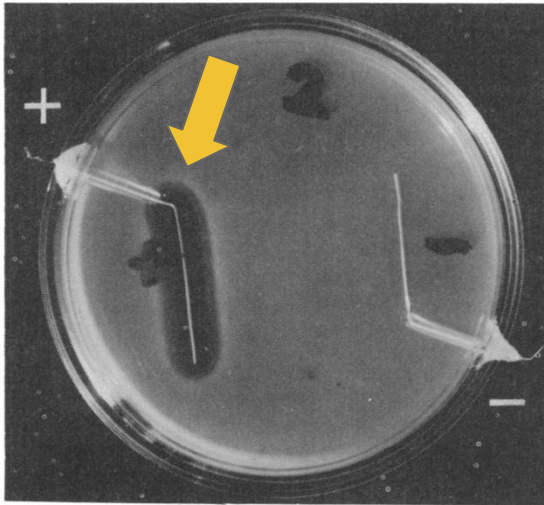
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## V&V Testing Results

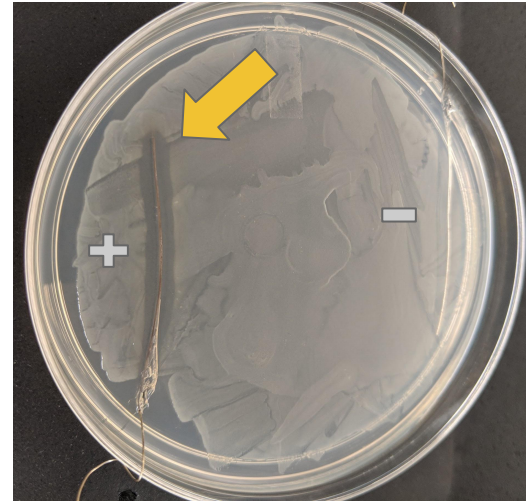
Does VoltaFeet satisfy the design specifications and user needs?

# Applied Current Boosts Silver's Antimicrobial Nature at Anode



**Left:** 0.4  $\mu\text{A}$ , Silver electrodes,  
*S. aureus* (Spadaro et. al).

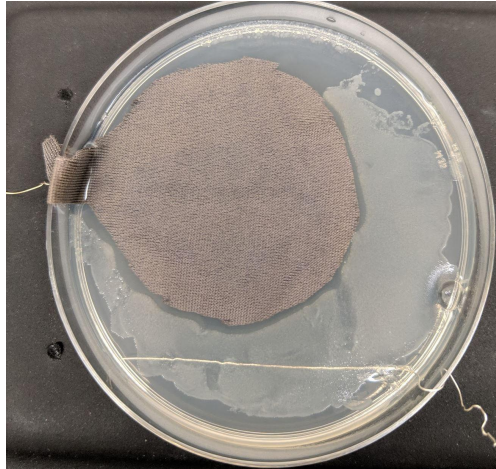
4 mm clear inhibition zone.



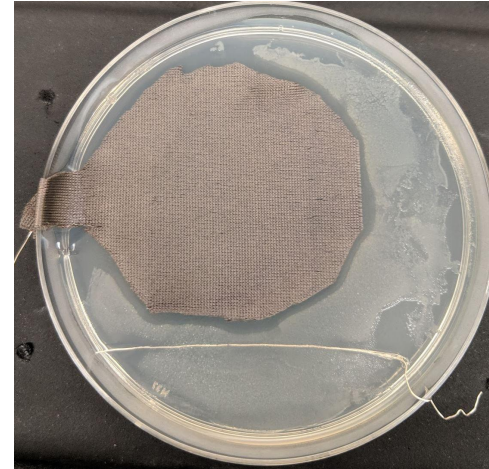
**Right:** 4.9  $\mu\text{A}$ , Silver electrodes,  
*E. coli*.

2 mm clear inhibition zone.

# Our Silver Fabric is Passively Antimicrobial Beyond its Surface



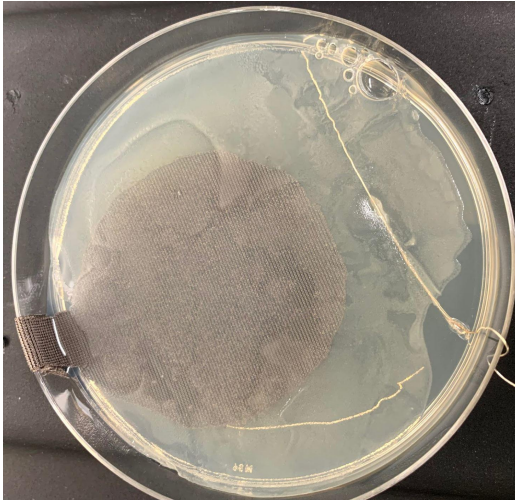
**Left:** 0.0  $\mu\text{A}$  (Control), *E. coli*,  
Electrode depth 2.0 mm



**Right:** 57.6  $\mu\text{A}$ , 0.76  $\mu\text{A}/\text{cm}^2$  *E. coli*,  
Electrode depth 2.0 mm.

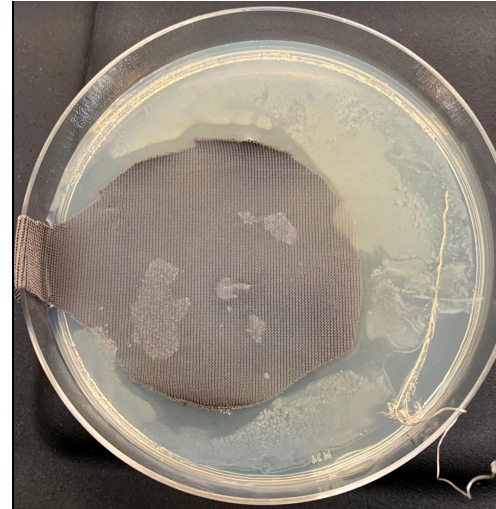
Notice increase in lateral inhibition on the surface. 0.5 mm average radial increase

# Active Deposition Provides Benefits Above and Beyond Diffusion



**Left:** 0.0  $\mu\text{A}$  (Control), *E. coli*,  
Electrode depth 5.5 mm

No surface inhibition.

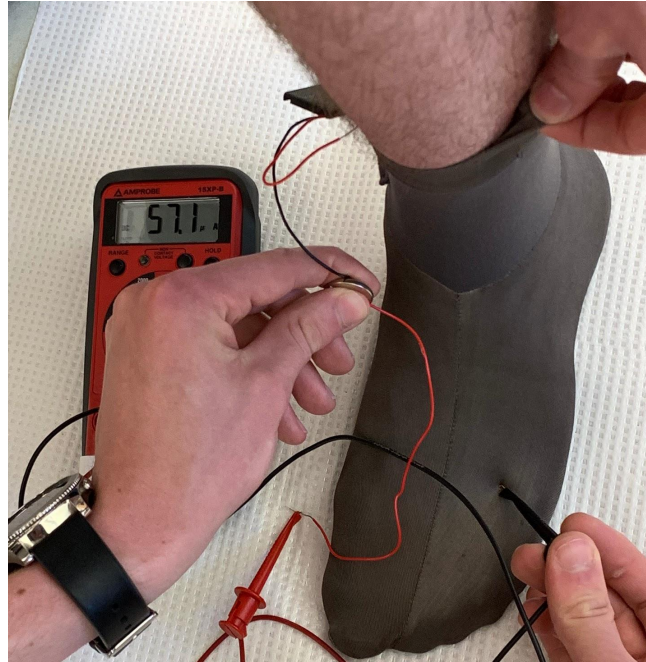


**Right:** 57.6  $\mu\text{A}$ , 0.76  $\mu\text{A}/\text{cm}^2$ , *E. coli*,  
Electrode depth 5.5 mm

Marked clearing.



# VoltaFeet Effectively Conducts Thru User Despite Skin Impedance





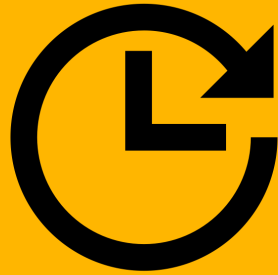
# VoltaFeet is a Valid Foot Sterility Intervention



A **convenient<sup>1</sup>**, **reliable<sup>2</sup>**, **long lasting<sup>3</sup>** treatment that **eliminates microbial activity<sup>4</sup>** on the surface of the foot.



- 1: User Satisfaction Survey + Ashton's Testimonial**
- 2: Elastic material ensures quality conducting thru user and further improves with sweat**
- 3: Limited by removable battery at 38 days continuous use, not silver content of fabric**
- 4: Bacterial culture studies supported antimicrobial activity at anode**



# Future Directions

How will we proceed with future V&V testing and protect our IP?



# Future Testing



## In-Vivo Efficacy

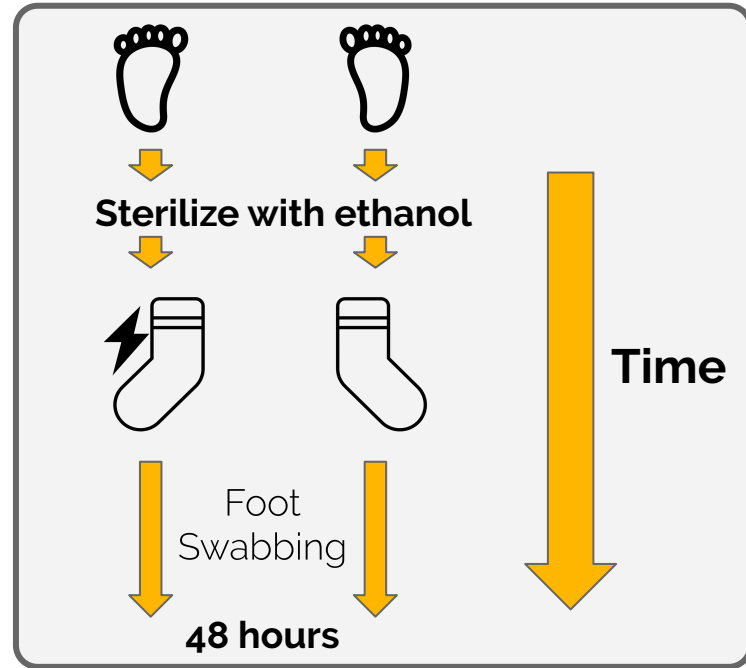
### Bilateral control experiment

- Ensure in-vivo efficacy
- Current density optimization

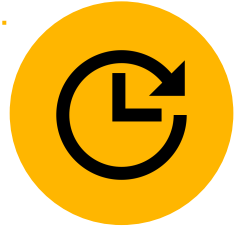
## Longevity

### Stress testing

- Washing/Drying cycles
- Amount of available silver



# Future Testing



## In-Vivo Efficacy

### Bilateral control experiment

- Ensure in-vivo efficacy
- Current optimization

## Longevity

### Stress testing

- Washing/Drying cycles
- Amount of available silver



How does **washing the prototype** multiple times affect its performance?



How do normal user conditions impact **battery life**?



How does the prototype react to **prolonged stress**?



*Thank you!*

**Questions?**

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