VANDERBILT UNIVERSITY

LUMASiL

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Executive Summary

Diabetics can face serious complications if they do not take care of themselves properly, such as diabetic foot ulcers (DFUs). The main problem behind DFUs is the slow healing process. Their sluggish healing is mainly attributed to peripheral arterial diseases and a lack of blood flow. Issues like peripheral neuropathy exacerbate their conditions. Blood vessels, typically in the hands and feet, will become finer causing reduced circulation of the blood. Oxygen and nutrients are important in the healing process, but the supply to tissue and nerves is limited due to the narrow blood vessels. Diabetic patients are more susceptible to injuries because they are less sensitive to pain, temperature and touch due to damage to the nerves.[1]

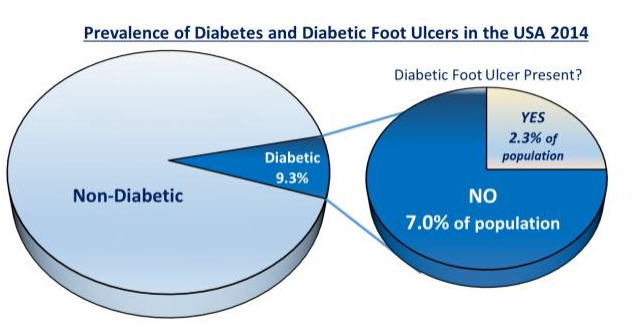
In order to expedite the wound healing process, we will develop a low-level light therapy device, LumaSil, to heal the DFUs. Previous studies have proven the efficacy of LED light exposure at wavelengths of 415 and 880 nm to help fight bacterial infections and promote wound healing respectively [2,3]. This device will use LED lights and fiber optics that will be incorporated into a patient's cast. The LEDs will transfer light from a LED module source via cabled fiber optic to a patch design. The patch design will be in close proximity with the patient's wounds, and thus progress the healing process.

There are a couple devices similar to the one we envision that use low level light therapy. However, we do not imagine them invading our market niche, but rather harmlessly possessing the same treatment method. A boot model exists that has LEDs that shine onto the injured epithelial layer. Because our technology includes the use of LEDs, this is a similar device. However, our design will be incorporated into a cast treatment rather than a removable boot. This improves patient compliance and therefore prevents the patient from tampering with the device.

While we have not treated the efficacy of low-level light therapy to heal DFUs, there are multiple journal articles that cite this as a viable solution. Specifically, blue LED treatment has been cited as a possible way to accelerate the wound healing process in addition to being an antimicrobial agent. Furthermore, there are studies that show that absorption of infrared light can ultimately result in down regulation of death-associated genes.

Addressing the Medical Need

Diabetes is an increasingly prevalent disease affecting 1 of every 11 Americans today. That's approximately 29 million Americans. With this disease comes many additional complications like heart disease, kidney disease, and nerve damage. Of these complications, a commonly overseen condition in diabetic patients is the presence of diabetic foot ulcers (DFUs). These foot ulcers, though small at first, have the potential to develop into very costly occurrences. DFUs are categorized on the severity of tissue damage and can range from superficial redness of the skin (stage I) to deep wounds that damage underlying bone, muscles, and nerves (stage IV). These more serious wounds almost always require amputation of the foot or leg, not only costing upwards of $45,000, but also costing the patient much pain and suffering.



Astonishingly, there is no active healing process or treatment for these wounds. The current standard care treatment involves using a total-contact cast to remove any load or pressure onto the wound when walking. Although this method isolates the wound to let it heal, it does not

work to actively heal the wound. There is a need for a device that directly promotes wound healing, complements current standard and procedures, and requires no patient input.

Project Objective Statement

LumaSil seeks to add an active form of healing DFUs onto the standard of care (SoC). Low-level light therapy has been previously proven to accelerate the rate of shallow-wound healing up to 50%. By incorporating this therapy into the full-contact cast used as SoC, this device has the potential to alter current standard practices. However, in order to do so, this device must meet specific needs regarding the patient, the provider, and the general healthcare system. In addition to the above, the device must be small, easily-portable, waterproof, and automated in order to assure patient compliance and be easily adopted. The provider must find application of the device simple and requiring minimal preparation time. Finally, the product should be low cost, dependable, and durable in order to it to be viable in the medical device industry. These traits should also allow the product to be adopted into various insurance plans, in order to be a practical treatment option.

Documentation of Final Design

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Prototype of the Final Design

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Product Validation (Experimental Design)

This feasibility study consisted of evaluating the healing rate of DFUs on the foot over the course of 2 to 4 weeks. Randomization and general collection of data and documents will occur.

- Randomization – randomization was used to ensure that patients are not chosen to participate in a specific treatment subconsciously or purposefully, thereby reducing the chance that outcomes are based on the patient, as opposed to the device.
- Surveys/Interviews/Questionnaires – During the time that wounds were being examined, patients were questioned as to the comfort and perceived success of the device.
- Document and Artifact Collection – Pictures of the diabetic foot ulcers were taken during examination both for visual documentation as well as future analysis and publication. These pictures contain no identifying information, but instead are associated with the device being used and the time at which the picture was taken.
- General Data Collection – Data was collected when patients meet with their doctor on a weekly basis.

The study design involves a matched experiment. Two groups (LumaSil, SoC) will be tested to determine the efficacy of LumaSil. Both treatment groups receive the SoC treatment which involves applying a full contact cast and offloading the wound. SoC treatment will provide a benchmark to which the LumaSil enhanced treatment can be compared to.

Patent Search

A brief patent search produced few similar technologies, but none that will interfere with the progression of our LLLT device patentability. This similar technology includes a boot model with LEDs shining directly onto the injured epithelial. Because our technology includes the use of LEDs to transfer light from a LED module source, via cabled fiber optic, to a patch design which will be in contact with the patient's wounds, all while minimizing light scatter.

Additionally, our design will be incorporated into a cast treatment rather than a removable boot, supporting patient compliance and minimizing device tampering.

Anticipated Regulatory Pathway

Our device can be classified under the following FDA device labels, each under Title 21, Subchapter H – Medical Devices:

Part 888 – Orthopedic Devices
Subpart E – Surgical Devices
Section 888.5940 – *Cast Component*
- "…a device intended for medical purposes to protect or support a cast"
- Class I (general controls)

Part 890 – Physical Medicine Devices
Subpart D – Physical Medicine Prosthetic Devices
Section 890.3025 – *Prosthetic and orthotic accessory*
- "…a device intended for medical purposes to support, protect, or aid in the use of a cast, orthotics (brace), or prosthesis"
- Class I (general controls)

Part 890 – Physical Medicine Devices
Subpart F – Physical Medicine Therapeutic Devices
Section 890.5500 – *Infrared lamp*
- "… a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating"
- Class II (performance standards)

This device would be a Class I device that would require 510(k) approval. Assuming approval, the current primary market for the device will be clinical centers administering on extremity wound healing treatments to diabetic patients, such as the Vanderbilt Orthopedic Foot & Ankle Center. Due to the treatment regimen, it is currently necessary for a provider to have weekly access to the patient during treatment, in order to replace the disposable section of the device and assure the power source will suffice until the following visit.

Reimbursement

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Estimated Manufacturing Costs

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Potential Market

Assuming approval, the current primary market for the device will be clinical centers treating diabetic patients with extremity wounds such as DFUs. Our initial market entry will start with targeting centers such as the Vanderbilt Orthopedic Foot & Ankle Center. Due to the treatment regimen, it is currently necessary for a provider to have weekly access to the patient during treatment to replace the disposable section of the device, assure the power source will suffice until the following visit, and monitor healing progress. For initial feasibility study, subjects would be recruited from Vanderbilt Orthopedics Foot and Ankle Center (recommended by Dr. Adam Hicks, DPM). After approval, future markets would expand to other specialty centers across the country. Again, because this is an adaptation of an existing standard of care, adopting this technology is expected to be swift.

Our device is estimated to cost from $60-$100 in material and labor costs. The disposable section of the device would be mass-produced and sold in bulk, while the reusable component would ideally be sold in smaller order sizes and reused. Existing treatments currently cost a minimum of $5000 per episode and are liable to failure. Further market analysis will lead to a more definitive unit price, though we estimate that a single device treatment (4 weeks) would cost anywhere from $400-$600 and is estimated to reduce the overall cost of treating DFUs by approximately 50%.

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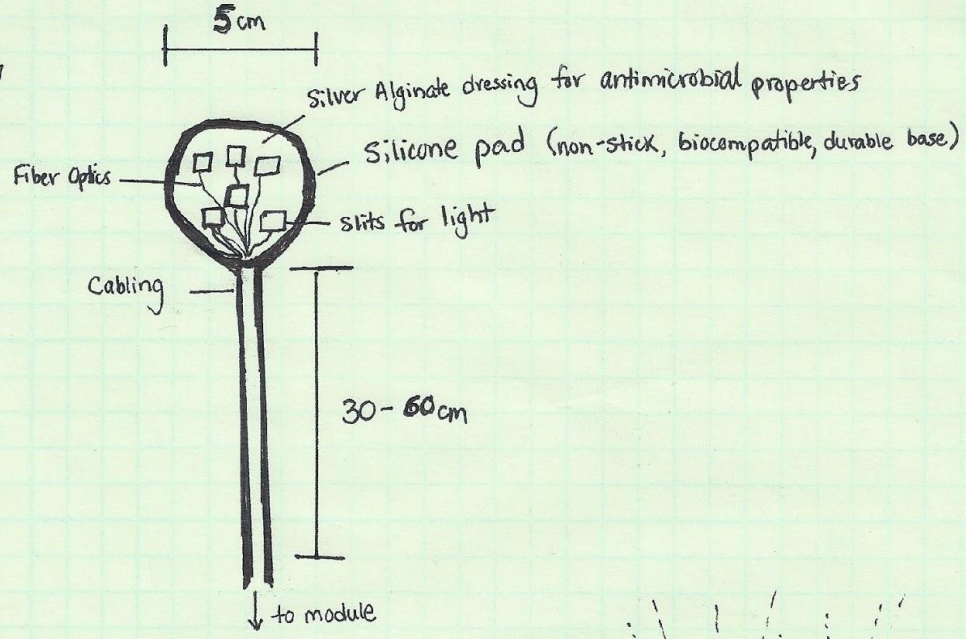
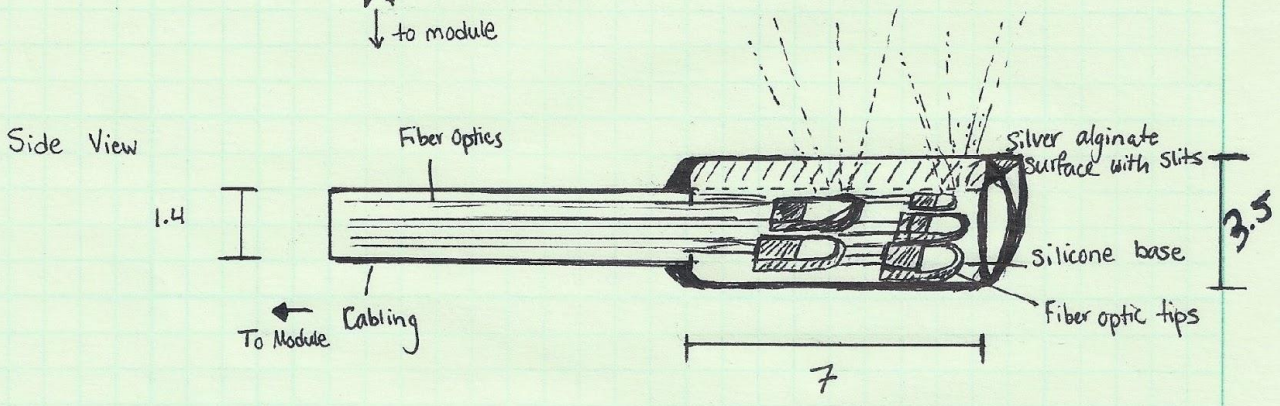
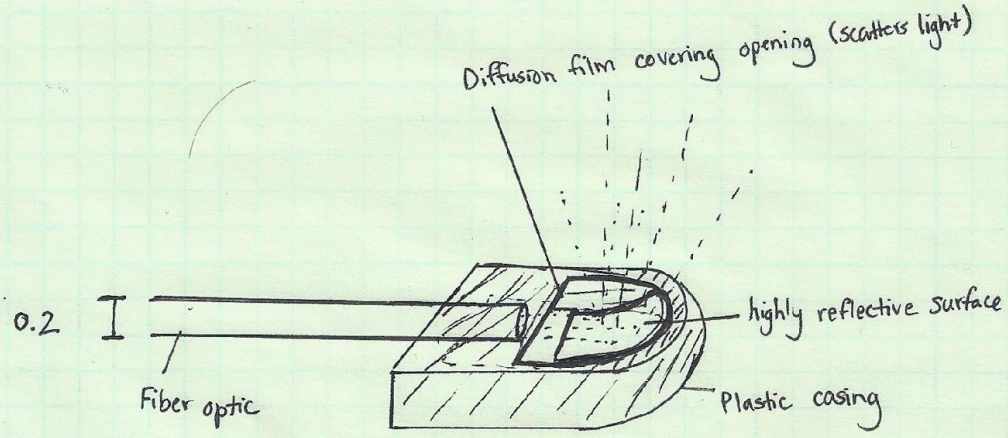
Top View

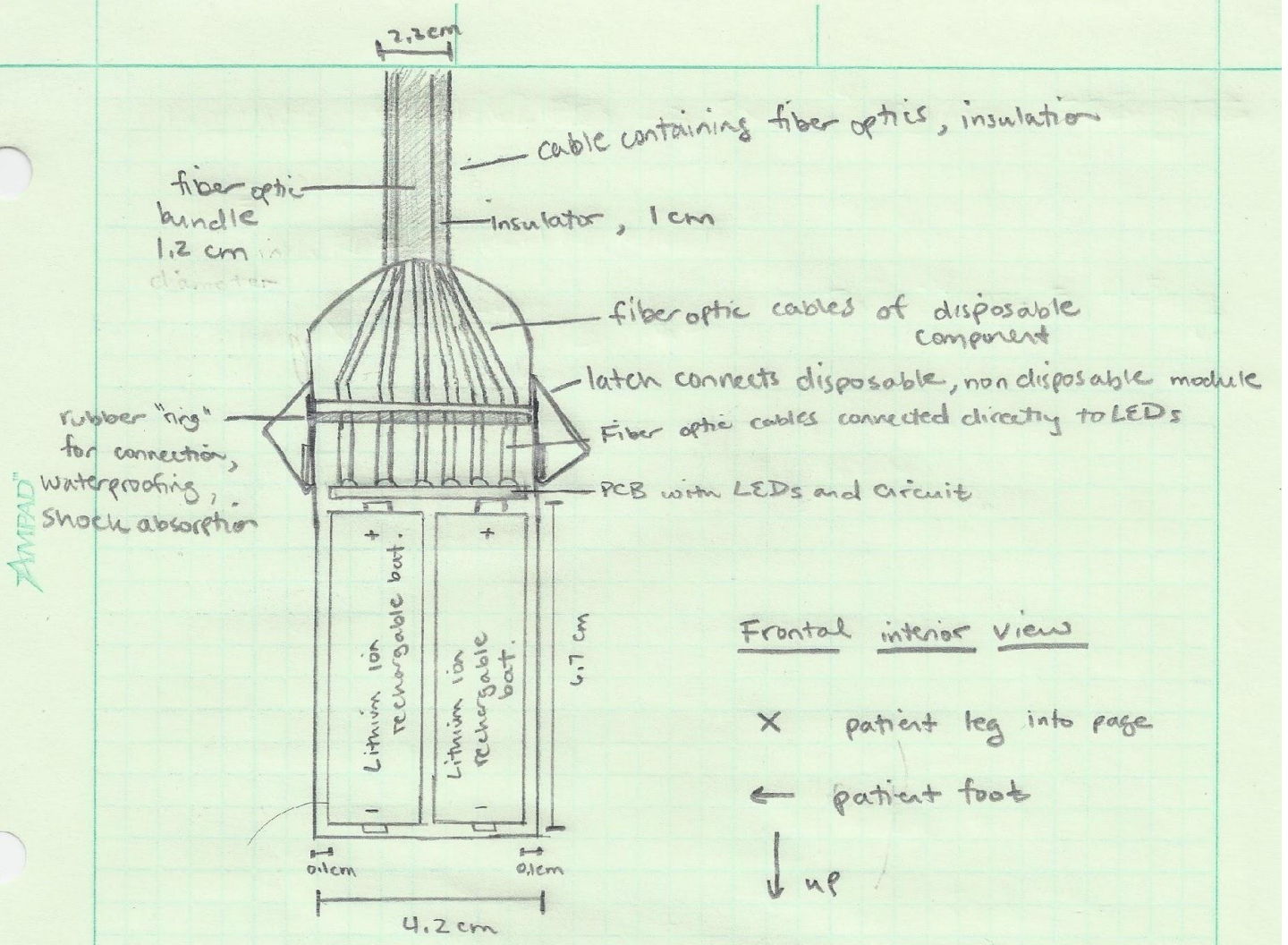


Side View



Fiber Optic Tips





External side view