SmartSole: Foot Ulcer Detection

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Executive summary

A serious complication that results from diabetes is the potential to develop foot infections resulting from ulceration, the leading cause of diabetes-related hospitalizations. As a result diabetic foot ulcers cause 56% to 83% of the estimated 125,000 lower-extremity amputations performed annually and accounts for a total annual cost of $85 billion in direct cost and $400 million in indirect cost. Despite the substantial morbidity, due to diabetic neuropathy, ulcers are often not diagnosed and treated until after they have formed. Repeated surgical debridement, proper local wound care, appropriate antimicrobial therapy, and control of hyperglycemia can aid in controlling spread of infection once an ulcer has formed but these treatments and primary care physician visits are expensive, time consuming, and often not a regular practice for those patients at greatest risk. The purpose of this proposal was therefore to develop a low cost, early diagnostic method for diabetic foot ulcers. This will be done by capitalizing on the phenomenon known as capillary refill to detect pre-ulcer chronic inflammation in the foot. An inflamed part of the foot would have blood in interstitial spaces, due to increased permeability of inflamed blood vessels, unable to be displaced by an external pressure and would remain reddish while healthy surrounding tissue will blanch. This color change can be monitored in susceptible areas of the foot such at the toe, heel, and ball of foot to detect any persistent inflammation that could be an ulcer precursor. We have developed a method of monitoring this color change by a retrofitted glass scale model. The retrofitted glass scale model is designed to be an at-home, daily monitoring device which can image the sole of the foot and subsequently send those images to a third party for analysis. This device is compelling as an effective method in the care of diabetic foot ulcers because it encourages daily monitoring and by using the idea of capillary refill and the detection of color changes, it can remain low cost while acting as a preventative measure by focusing on early stage inflammation rather than the current mode of post-ulceration care.

Clinical Needs

- Nearly 171 million people worldwide suffered from diabetes in 2000; approximately 18.3% of Americans over the age of 60
- Diabetes prevalence is increasing with 789,000 new cases diagnosed; estimated that the incidence number will double by 2030
- Neuropathy is present in nearly 82% of diabetic patients with foot wounds
- Diabetic foot ulcers develop from excess pressure, abnormal loading, or trauma, and can go unnoticed for days.
- Treated post-formation with continuous debridement, wound dressings, and supplanted with off-loading devices to prevent recurrence. Infected or late stage ulcers often have no options except for amputation ; 85% of all amputations

Early diagnosis of ulceration is of an extreme importance in addressing the severity complications. Currently, no early pre-formation ulcer diagnosis for diabetic foot patients exists other than routine foot examinations.

Estimation of product costs

Materials	Budget Cost	Production Cost
Base	$10.00	$6.50
Batteries	$5.00	$0.30
LED	$0.67	$0.30
Fisheye	$6.00	$0.22
Data Analysis	$5.00	$5.00
Total	$26.67	$12.32
Percent Savings		53.8%

Figure 1. Costs for prototype were estimated by their materials costs as well as an estimated price for data analysis.

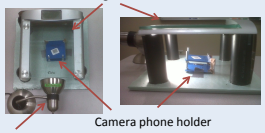
- Cost of base encompassed costs for cutting and forming the base of the device
- Data analysis costs were estimations on how much the costs of third-party analysis would require for diagnosis of patients
- Quality assurance costs for initial testing by 3rd party were estimated as $3-$7Total

- Production Cost / Unit = $15.32-$19.32
- Desired retail Price = $22-$25
- Estimated Profit /Unit = $2.68-$9.68

Description of Design

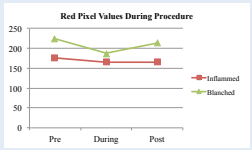
Physical Component

Retrofitted glass bathroom scale



Camera phone holder

Light Source

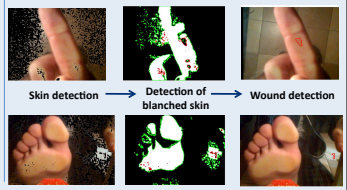


- Patient inserts phone on platform, steps on scale one foot at a time
- Pictures taken as pressure applied and foot blanches
- Inflamed area remains red
- Pictures sent to analysis program in MATLAB

Analysis Component

- Converts to HSV image and uses threshold values of hue and saturation to detect skin, converted back to RGB
- Searches RGB image for pixels between threshold range for inflamed areas and turns them black
- Image converted to binary image
- Find boundaries of all regions
- Labels blanched regions and potential inflamed area
- If the potential wound > critical wound size and within the bounds of the blanched areas then the display reads "Foot is inflamed. Contact you primary care physician." If it does not, it displays good to go."

The program also outputs the original image, and a binary image with the blanched areas circled in green and the potential wound areas in red for 3rd party confirmation

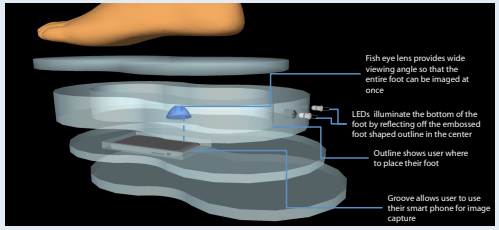


Final Design

Insert Phone in Video Mode → Patient Steps on Device One Foot At-A-Time → Remove Phone & Send Video to Analysis Program → Patient Gets Instant Preliminary Status → Data Sent to 3rd Party Analysis

Key Features:

- Foot outlined for easy placement
- Wide angle lens for viewing entire foot
- One sheet is frosted and LEDs are placed along the sides, allowing for edge lighting under the foot for the camera exposure
- Program reads in video , removes noise of loading/ unloading, and breaks down color analysis frame by frame surrounding blanching as in prototype
- Immediate Analysis of the Foot with patient version of program along with in-depth analysis by sending pictures to the clinician with highlighted regions of areas of interest
- Potential to combine with LED/photodiode circuit for improved real-time data analysis



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Novelty

- **Early Detection –** Based on using non-blanchable inflammation as indicator of preliminary ulcer formation. Current treatments focus on post-ulcer care
- **Detecting Color Change –** Incorporates capillary refill into device that can monitor changes over time. Inspired by the h Skin-Color-Compensated Colorimeter work of Sanna Gaspard and Todd Przybycien
- **Use at home** - Will allow patients to be remotely monitored without having to come into the doctor's office to get a checkup. It will also encourage frequent, self-monitoring
- **Low cost device –** This product uses existing products thus cutting down on the production cost.
- **Relatively quick approval time –** We estimate that the approval time will be relatively short, as it is very similar to products that we currently have, such as a bathroom scale and pulse oximeters

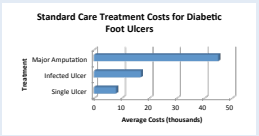
Market Description

Potential Market:

- Prevalence of diabetes mellitus is increasing worldwide; by the year 2025, an estimated 300 million people will have diabetes
- In U.S. alone, up to 5 million foot ulcers in any given year and diabetic foot ulcer market is estimated to be approximately a $2 billion of the estimated $10 billion global advanced wound care market
- Our predominant potential customer and end-user market, which includes those individuals with diabetes and clinicians who purchase either the analysis software or the combined product, is therefore continually growing

Competition:

- Since no other current product is specifically targeted for early-detection of foot ulcers, competition to the proposed product current post-ulceration treatments including debridement, infection control, offloading, and specialized dressings, and amputation.
- The high cost of current standard treatment is linked to the high rate of healthcare utilization among patients with diabetic foot ulcerations (29.4% of U.S. population)
- In a strict economic comparison to the worst-case scenario of amputation , our preventative monitoring device would lead to significant reductions in the incidence of foot ulcerations and lower-extremity amputations as well as a the costs savings is estimated to be nearly $90,000



Clinical Indication	Number of Patients in US (in millions)	Available Patient Market (in millions)
Diabetic Foot Ulcers	1.7	0.73
Venous Stasis Ulcers	1.2	0.56
Pressure Ulcers	2.5	0.8
Total	5.4 million	2.09 million

Figure 2. Graph showing the average cost for ulcer treatment and potential available market

Reimbursement:

- Reimbursement is on a case-by-case basis, though historically, Medicare does not reimburse for preventative devices or services
- However, we would argue for reimbursement on the basis that currently 23.1% of people on Medicare have diabetes and are at risk for ulceration and that given the high cost of post-ulceration treatment and increasing incidence, a low-cost preventative measure would ultimately save healthcare providers' money.

Anticipated Regulatory Pathway

- Class I device because it : is not purported to support or sustain human life, it does not present a potential unreasonable risk of injury, and it does not have substantial importance in preventing impairment of human health

- Anticipated regulatory pathway: 510 (k) regulatory approval process since mechanical component is substantially equivalent to another device which is legally marketed and class I device, a glass bathroom scale

- In addition, its operational analytic principles are similar to pulse oximeters and CADe devices, both class II devices.

This less stringent approval process would both reduce the cost and speed up time to market of our device, thereby increasing its overall value.