**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 account for a total annual cost of $80 billion in direct cost and $460 billion in indirect cost. Despite the substantial morbidity due to diabetic neuropathy, ulcers are often not diagnosed and treated well after their formation. 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 blush. This color change can be monitored in susceptible areas of the foot such as 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 nontinted glass scale model. The nontinted 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 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 38.3% 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.

**Novelty**

- **Early Detection** – Based on using non-invasive information 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 ‘5-Skin-Color-Compartment’ colorimeter work of Sanaa Gepard and Todd Prystowsky
- **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/cost value** – 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 the 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**

**Product Description**

- **SmartSole:** Foot Ulcer Detection
  - **Advisor:** Dr. James Antaki
  - **Description of Design**
  - **Physical Component**
    - Retinted glass bathroom scale
    - Camera phone holder
    - LED lights
    - Data analysis program
  - **Analysis Component**
    - Converts to IR image and uses threshold values to obtain intensity and converts back to RGB
    - Searches RGB image for pixels that distinguish threshold range for distinct areas and turns them black
    - Image converted to binary image
    - Finds boundaries of all regions
    - Labels blanched regions and potential inflammation
    - If the potential wound > critical wound size and is within the bounds of the blanched areas then the display reads “Foot is Inflamed. Contact your primary care physician.” If it does not, it displays good to go!
  - **Final Design**
    - **Key Features**
      - Foot outlined for easy placement
      - Wide angle lens for viewing entire foot
      - One sheet is folded 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 prototypes
  - **Proposed Product**
    - ** Immediate Analysis of the Foot with patient version of program along with in-depth analysis by sending picture to the clinician with highlighted regions of interest**
    - **Potentially combine with LED photodiode circuit for improved real-time data analysis**

**Estimation of Product costs**

- **Materials**
  - **Base**
    - $10.00
  - **Lithium**
    - $0.00
  - **LED’s**
    - $0.67
  - **Alloys**
    - $0.66
  - **Data Analysis**
    - $5.00
  - **Total**
    - $26.67
  - **Percent Savings**
    - 3.8%

**Acknowledgements**

We would like to thank our advisor Dr. James Antaki and Dr. Conrad Zapanta for their help and support with this project

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