At Home Diabetic Plantar Ulcer Detection Device

Mritika Bhaumik, Matt Biegler, Mark Loh, Robert Mohard, Allison Tran and Alex Yoshikawa
Advised by Professor Antaki, Professor Zapanta, and Dr. Steed

Executive Summary

The objective of the project was to develop an at home diabetic plantar ulcer detection device. Currently patients must have frequent doctor visits in order to detect the formation of ulcers. Our device would reduce the number of required doctor visits as well as help catch ulcers earlier which would decrease the morbidity and complications The device is relatively cheap to produce and has the potential to report a wealth of information to the patient's primary physician besides the formation of an ulcer. In all, the device solves an unmet need, would result in massive savings, and has the ability to prevent ulcers in diabetic patients.

Clinical Need

- The formation of plantar ulcers in diabetic patients is the leading cause of amputations in the united states [1]
- Due to neuropathy, diabetics often cannot feel pain in regions where ulcers are forming which can result in infections, amputations, and death
- Regular visits are expensive and patients are usually not examined frequently enough to catch the early formation of the ulcers
- Therefore an ulcer detection device that could be used at home would dramatically reduce the costs and morbidity associated with diabetic plantar ulcers

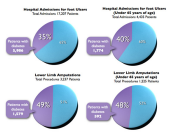

Figure 2: Hospital admissions and amputations due to foot ulcers [2]

Description of Market

- Due to the fact that there is a high prevalence of diabetic patients, with over 18 million people diagnosed, the market size for an at home diabetic prevention unit is substantial.
- Current products include custom orthotics and infrared technology that cannot record the development of ulcer formations.
- The alarming inability patients may note the development of an ulcer due to neuropathy created a large opportunity for detection products for patient use and patient-physician communication.
- An in-home foot ulcer diagnostic device does not fall under the current Medicare reimbursement codes .
- We propose that a new code will be made for in-home foot ulcer diagnostic devices that are dependent upon the diagnosis of diabetes with neurological manifestations .

Overview of Device

Description of Design

The housing of the device is made from medium density fiberboard (MDF) and is slanted to allow users to sit and prevents users from exerting high forces on the scanner. The user places his or her foot on device and presses a button which initiates the AutoIt script on the tablet. The thermochromic material that the foot rests on changes color based on temperature and the scanner automatically takes an image. The script then calls a MATLAB executable which analyzes the image and classifies it as either ulcerous or non-ulcerous. A log file of the diagnosis is generated and the tablet displays the result of the test to the user before returning to the initial instructions screen.

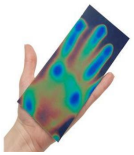

Figure 3: Thermochromatic material[3]

Experimental Validation

- Nickels and quarters were heated and placed under the foot to simulate ulcer
- Thermocouples were used to ensure that the coins were about 4 fahrenheit hotter than the rest of the foot
- These images were compared to control images and used to develop the algorithm

Part	Source	Estimated Bulk Price
Scanner	Wholesale Supplier	~$40.00
Thermochromic Paint	Edmund Scientifics	~$8.00
Arduino Board	SparkFun	$47.16 (for 100+)
Electrical Wire	Outsourced	~$0.50
LCD Screen	Prime Electronic Components	$8.99
Housing	Manufactured	$2
Glass	Outsourced	$1
	Total Materials Cost:	~$113.00

Figure 4: Final product bill of materials

Figure 5: Current prototype

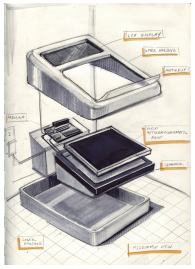

Figure 6: Final prototype design

Image Processing

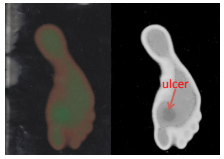

Figure 7: Image before and after filtering

First the image is run through several filters in MATLAB in order to eliminate noise. The red pixels are then selected fro the image. Depending on the histogram of red pixel values the algorithm classifies the image as either ulcerous or non-ulcerous

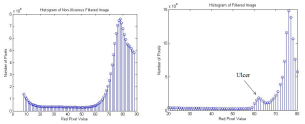

Figure 8: Histograms of normal foot (left) and simulated foot image with ulcer (right)

Novelty of Concept

- Only at-home ulcer diagnostic device
- Thermochromatic material to detect temperature differences due to ulcer formation
- Novel algorithm that can detect ulcers from image
- Device can potentially diagnose a host of other problems associated with diabetes such as the formation of charcot foot

Anticipated Regulatory Pathway

- Exempt form Premarket Approval via 510(k)
  - -substantially equivalent to existing devices
- Safe and Effective
  - -"Probable benefits outweigh any probably risks"
- Class I Device
  - -Not intended to support or sustain life
  - -Not intended to prefvent impairment (only a screening tool)
  - -Low risk and potential for harm

Future Work

- Tablet should be replaced by a microprocessor with an L.E.D. screen
- Scale should be made to withstand additional weight
- Actual tests with real diabetic patients must be performed
- Implement additional diagnostics (e.g. for charcot foot)
- Mail out pictures and log files to database

Acknowledgements

We would like to thank Dr. Antaki and Dr. Zapanta for acting as our faculty advisors. We would like to thank our TA, Greg Johnson, for all the help he has given us. Finally, we would like to thank Dr. Steed who acted as our clinical contact and gave us useful experience drawn from his experiences as a surgeon.

References

[1] Green, M. F., & Aliabadi, Z., PhD. (2002). Diabetic Foot: Evaluation and Management. *Southern Medical Journal*, section 1. Retrieved from <http://www.medscape.com/viewarticle/426997>.
[2] Sorensen, L., T. Wu, M. Constantino, and D. K. Yue. "Foot Examination." *The University of Sydney*. Diabetic Foot Disease. Web. 13 Dec. 2011. <http://sydney.edu.au/medicine/diabetes/foot/Fexam1.html>.
[3]"Liquid Crystals ." . LCR Hallcrest, n.d. Web. 5 Dec 2011. <http://www.colorchange.com/liquidcrystals>.
[4] http://www.diabetes.org/diabetes-basics/diabetes-statistics/