

Smartphone-based tissue oxygenation imaging device to monitor diabetic foot ulcers as a low-cost remote patient monitoring tool

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Introduction

>37M people with diabetes in USA
<https://www.cdc.gov/diabetes/data/statistics-report/index.html>

1 in 3 develop Diabetic Foot Ulcers (DFUs)
Armstrong, D. G., Boulton, A., & Bus, S. A. (2017). Diabetic Foot Ulcers and Their Recurrence. The New England Journal of medicine, 376(24), 2367–2375.

Gold-standard assessment - Visual inspection of size, smell, color

Remote patient monitoring is vital post pandemic

GAP: No mobile tool to monitor physiological information, except digital wound size.



SmartPhone Oxygenation Tool (SPOT)

SPOT validated against a commercial device

KENT (Commercial Device) VS SPOT

- 14 DFU cases
- Tissue oxygenation (oxygen saturation) distributions are similar across the two devices

Oxygen saturation maps correlated 57-90% across 14 cases, with a 75% median correlation

	WL Image	KENT	SPOT
Subject 1			
Subject 3			
Subject 5			

Study @ Univ of Miami Wound Care Center, Miami, FL (Dr. Kirsner)
Kaile, PhD Dissertation 2023

Objective

Smartphone-based optical device for remote patient monitoring of tissue oxygenation in DFUs - because oxygen is vital for wound healing



SPOT differentiates high-risk from low-risk DFUs

Using HbT-based contrast, differentiated high-risk from low-risk DFUs with 100% sensitivity & 80% specificity

• 19 DFU cases
• Images corrected for melanin
• Tissue oxygenation distributions differed in low-risk & high-risk cases.

ROC Analysis

Subject 1: Day 1 (Post-Amputee)			
Subject 2: Day 1 (Pre-Surgery)			
Subject 2: Day 2 (Post-Surgery)			

Low-risk (stable) DFU vs High-risk (complicated) DFU vs Low-risk (stable) DFU

Study @ Madras Diabetes Research Foundation & Dr. Mohan's Diabetes Specialties Center, Chennai, India (Dr. Mohan)

Kaile, PhD Dissertation 2023

Ongoing Efforts

Skin color classification using AI towards melanin corrections

AI Dermatochroma Analytica (AIDA) uses k-means unsupervised model
Hamrani et al., Comp Methods & Programs in Biomedicine (submitted) 2024

Tissue curvature correction models

Convex geometry needs Height & Angle correction
Concave geometry needs only Height correction

Roy et al., Optica Biophotonics Congress 2024

Smartphone-based Optical Device + App

- * Non-contact
- * Non-invasive
- * Low-cost
- * Smartphone-app for automated data acquisition & analysis

* Diffuse reflectance signals from SPOT have >94% correlation to light propagation model (Monte-Carlo)

Conclusions

SPOT device can potentially triage DFU patients who require immediate clinical intervention across subjects of any skin color (or racial/ethnic groups). On a long-term, SPOT can serve as a remote patient monitoring tool for DFU assessment.

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