Keck Medical Center of USC

Eden Medical
INNOVATIONS FOR HEALTHCARE

DFCon Diabetic Foot Global Conference

Development of Next-Gen Smart Mat to Measure Oxygenation and Ulcer Risk

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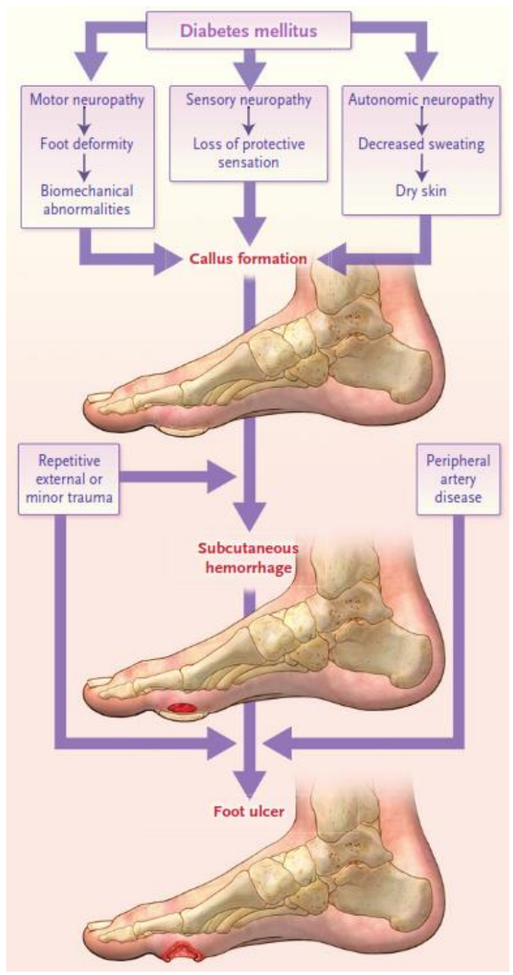
The Problem

Common Pathway of Diabetic Foot Ulcer Occurrence and Recurrence

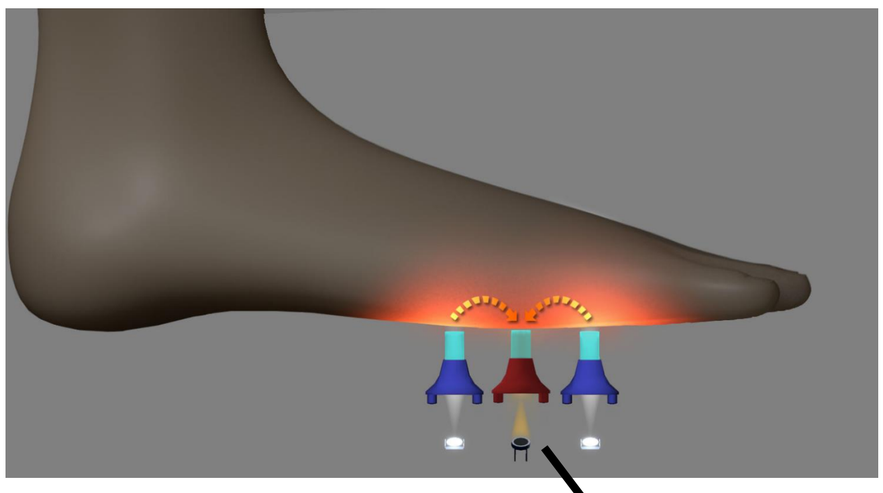


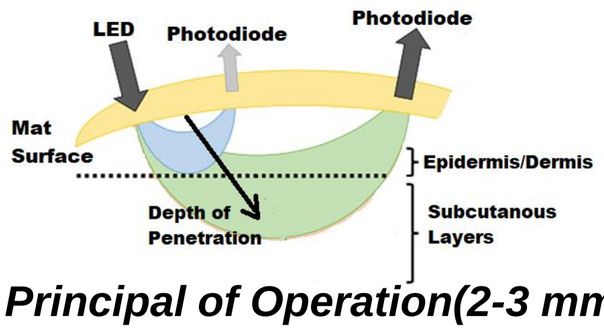
Key Facts-

- 9.1 to 26.1 million diabetic foot ulcers develop per year worldwide[1]
- 785 million outpatient visits(between 2007 and 2013) due to DFU and infection[2]
- $176 billion per year in US for diabetic direct costs[3]
- 40% DFU reoccurrence within 1 year(60% within 3 years[4]
- Strongest predictor of DFU is previous ulcer[5]
- Key Factors- early signs of skin damage(callus, blistering, or hemorrhage), repetitive shear stress, loss of sensation

- Early recognition is a key to preventive care- oxyhemoglobin (H_bO_2) and tissue oxygen saturation(S_t0_2) to characterize microcirculation dysfunction and oxygenation changes, the early biomarkers of ulcer formation.

Smart Mat Approach(730/850 nm)



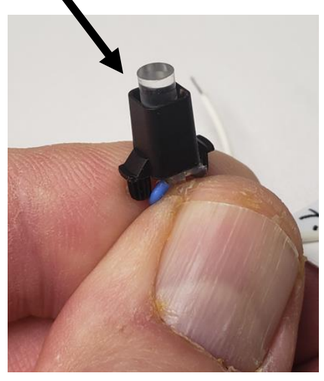


Principal of Operation(2-3 mm)

$$A = \varepsilon c l$$

A = absorbance (no units).
ε = Molar extintion coefficient (M^{-1} cm^{-1}).
c = Concentration (M).
l = pathlength (cm).

Beer-Lambert Law



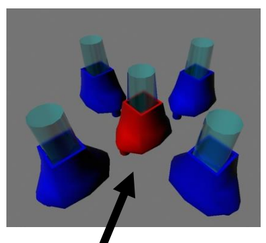
Light Pipe Pic

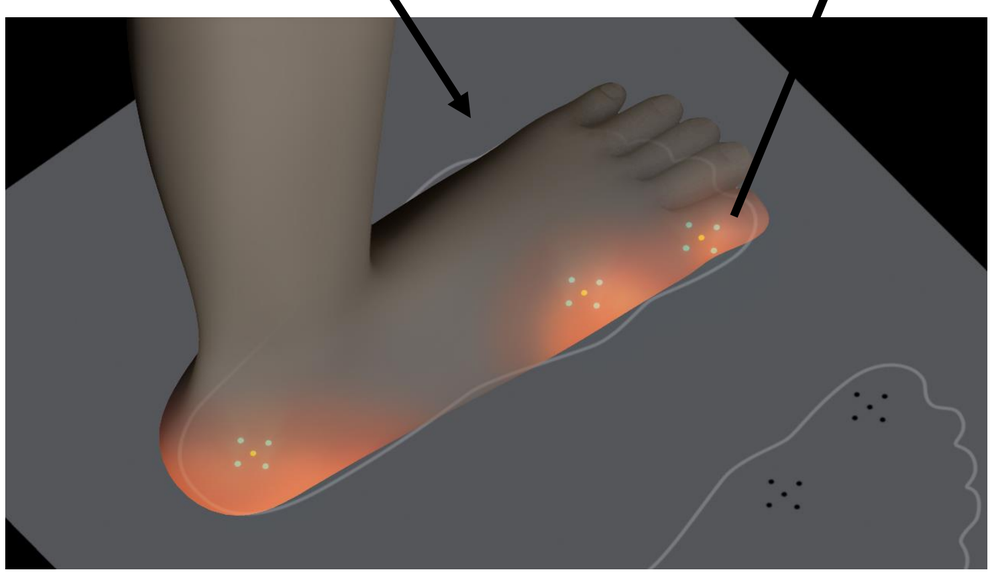
Smart Mat Storyboard

Smart Mat

Concept ID

Sensor Array

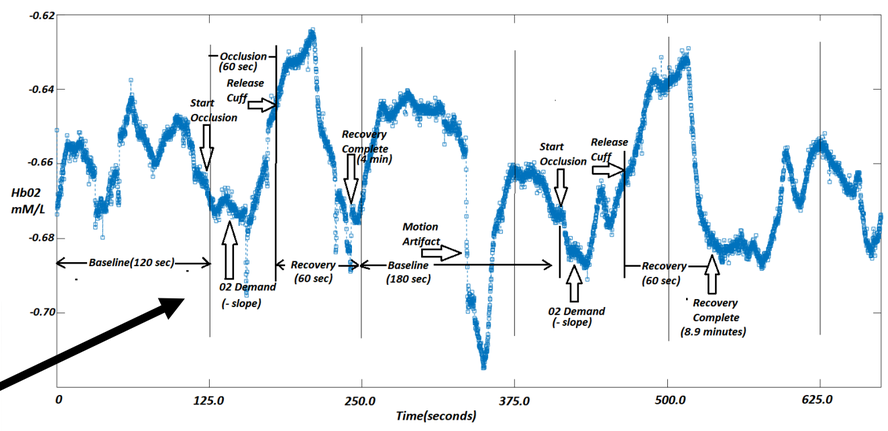




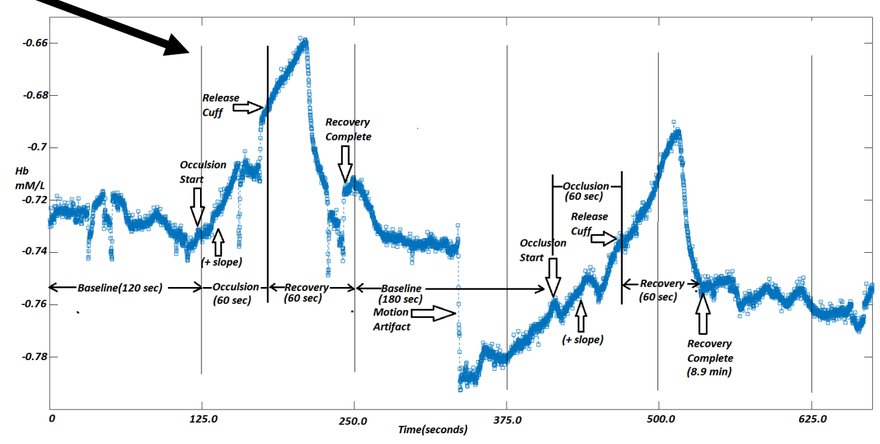
Smart Mat Design Layout

Bench Test Results

Occlusion Test (58 year old Type 2 diabetic)



Hb02 Plot



Hb Plot

Lessons Learned

- Dual Wavelength Near Infrared Method- Is sensitive enough to quantify and track the early biomarkers of ulcer formation(i.e. oxyhemoglobin, deoxyhemoglobin)
- Wide Dynamic Range- our dual wavelength NIRS technology has a dynamic range of 96 db (i.e. 16 bit resolution capability)
- System Responsivity- the input/output gain of the optical system is adequate to detect the hemoglobin markers for a diabetic subject

Conclusions

- Foot Ulcer Occurrence/Recurrence- is common and costly
- There is room for improvement in the effective management of diabetic foot ulcers, to reduce the risk of re-ulceration
- The Smart Mat is an innovative and new approach for reducing ulceration risk in the home setting to increase ulcer-free days

References

1. Diabetes atlas. 7th ed. Brussels: International Diabetes Federation, 2015, www.diabetesaltas.org)
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3. Ambulatory Care Diabetic Foot Cases in the U.S. Diabetes Care 2017 May 11
4. Armstrong DG, Boulton AJ, Bus SA, Diabetic Foot Ulcers and their Recurrence, N Engl J Med. 2017 Jun 15;376(24):2367-2375

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