Abstract

With diabetes rates on the rise in the United States, diabetic foot ulcers have become increasingly prevalent, resulting in nearly 75,000 annual cases at a cost of $5 billion. A key component to this cost is due to expensive wound therapies which can exceed $3,200 per week. Wound size reduction method is unreliable with a positive predictive value of less than 60%. Diffuse Near-Infrared Spectroscopy (DNIRS) uses 70-MHz modulated light in the diagnostic window (650-900nm) non-invasively to discriminate between oxygenated and deoxygenated hemoglobin levels. A preliminary study demonstrated a positive predictive value of 90% and specificity of 80% (p=0.002) in predicting healing. These data indicate that it could be possible to objectively predict healing in 4 weeks using DNIRS and make decisions to cease or continue expensive treatments based on physiological conditions and health of the wound. Discontinuing ineffective treatments after 4 weeks could have potentially saved over $12,600 per patient, based on the treatment regimen of patients in this study.

Objective

The goal is to give clinicians a means to:

• Assess the efficacy of treatment modalities used in chronic and diabetic wounds in patients.
• Reduce the time and improve accuracy in predicting healing to allow faster changes in treatment regimen if necessary.

Hypothesized wound healing model

Oxyhemoglobin concentration ([HbO2]) and deoxyhemoglobin concentration ([Hb]) are calculated from measured values of µa by minimizing the difference between the left and right sides of the following equation:

\[ \frac{\mu_a}{\mu_{aO2}} + \frac{\mu_a}{\mu_{aHb}} + \frac{\mu_a}{\mu_{aHbO2} + \mu_{aHb}} \frac{1}{H_H} = \mu_{a,\text{measured}} \]

where:
- \( \mu_a \) and \( \mu_{aO2} \) are the molar extinction coefficients of oxy- and deoxyhemoglobin,
- \( \mu_{aHb} \) and \( \mu_{aHbO2} \) are the molar extinction coefficients of deoxy- and oxyhemoglobin,
- \( \mu_{a,\text{measured}} \) is the absorption coefficient of pure water at each wavelength (\( \lambda \)),
- \( H_H \) is held constant at 70%.

Research Hypothesis

It is hypothesized that decreases in oxygenated and total hemoglobin concentrations over time will be predictive of healing in diabetic foot ulcers.

Frequency-Domain Near Infrared Spectroscopy

Diffuse near infrared (NIR) spectroscopy provides quantitative information about tissue beneath the wound surface. Optical Absorption Coefficient (µa) at NIR wavelengths is determined mainly by deoxygenated and oxygenated hemoglobin. Optical Reduced Scattering Coefficient (µs') gives information about tissue structure (organization, composition).

Summary of human study

- 30 patients with diabetes mellitus
- Wounds <1 cm2
- Ankle-Brachial Index > 0.75
- Acute osteomyelitic bone prior to enrollment
- Moist wound healing protocols
- Offloading when appropriate
- Debridement and hygiene

Results of Human Study

The rate of change in hemoglobin concentration over time was quantified by fitting a linear trend line to the plots of [Total Hb], [Oxy Hb], and [Deoxy Hb] vs. time.

<table>
<thead>
<tr>
<th>Healing Status</th>
<th>Healing Non-Healing</th>
<th>Healing</th>
<th>Non-Healing</th>
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</thead>
<tbody>
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<tr>
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</table>

Average Potential Savings

$12,600 / patient

Average Potential Savings

$370,000+

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