Differentiating between Healthy Tissue and Early Stage Pressure Injuries: A Pilot Study of Effectiveness of the SEM Scanner

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Introduction
Pressure injuries (PI) are a significant burden on the healthcare system and on patients. Many different technologies have been investigated to detect and prevent PIs, however, a new handheld capacitance tool demonstrates merit in its ability to detect PIs. The purpose of these studies was to evaluate the SEM Scanner for accuracy and effectiveness in detecting the presence or absence of pressure injuries.

Study Overview

Objective:
- To compare SEM Scanner readings from the centers of confirmed stage I or II pressure ulcers or deep tissue injuries against SEM Scanner readings from the surrounding periwound areas
- To evaluate the reliability of the SEM Scanner readings at various anatomical sites in subjects without pressure ulcers and
- To collect informational SEM Scanner heel and sacral readings in subjects without heel or sacral pressure ulcers.

Methods:
This was a non-blinded case control study, looking at two cohorts of patients; those with and without pressure injuries. The subjects were initially assessed for skin damage using visual assessment then scanned at the same sites for the presence of tissue damage using the SEM scanner.

Results: SEM Scanner delta values below 0.6 indicated normal tissue
- Sensitivity and specificity exceed 80% for both sacrum and heels when a within subject change in SEM Scanner readings of ±0.5 is utilized. The SEM Scanner is a very effective device in the detection of Stage I Pressure Injuries (PIs) and Deep Tissue Pressure Injuries (DTPI).
- The SEM Scanner provides measurable data to the visual identification of the presence or non-presence of tissue injury. This easy to use hand-held device may revolutionize the pressure injury prevention and early detection, potentially, making it a ground-breaking device for aiding the current subjective, skill-based practice of pressure injury management.

Conclusions
Pending FDA decision, not for sale in the US

Patient Study Population

<table>
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<tr>
<th>Site Name</th>
<th>Site Number</th>
<th>Country</th>
<th>Consent N (%)</th>
<th>Assessed Completed N (%)</th>
<th>Screen Failure N (%)</th>
<th>Screen Not Completed N (%)</th>
<th>Consent not screened N (%)</th>
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<td>0 0</td>
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<tr>
<td>East Coast 2</td>
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<td>125 Subjects Enrolled</td>
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Disposition of Subjects