Evaluation of a novel device using capacitance of the detection of early pressure ulcers (PU), a multi-site longitudinal study

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Clinical Trial Design: How to determine validity in the absence of an objective gold standard

Determining the validity of a test in wound care is potentially confounded by three challenges:

• Challenge 1- All of the current Gold Standard tests are subjective.

• Challenge 2- Intervention complexities: It is difficult to create a control study because practitioners have to intervene when PUs are deemed to have occurred or when patients are at risk. Interventions are facility specific and not completely standardized.

• Challenge 3- Clinical study design options are limited. A true randomized controlled trial, for example, is unfeasible.

Study Overview

Objective: To evaluate the clinical utility of the SEM Scanner as an adjunct to clinical judgment for the early detection of pressure ulcers in patients compared to clinical judgment using Visual Skin Assessment (VSA).

Methods:
• A multi-site, prospective longitudinal study
• N = 189 subjects recruited from 12 sites across the US and UK. Care settings include acute care hospitals and nursing home / elder home facilities
• Record SEM values and nurses’ VSA concurrently for medium to very high risk patients daily for up to 20 days of observation
• SEM Scanning conducted by “generalists” (dedicated users)
• VSA conducted by Skin / Wound care Specialists
• Participants were blinded to each others’ assessments
• Detection Definition
  • SEM+ Detection = SEM ∆ ≥ 0.6 (2 of 3 consecutive days)
  • VSA+ Detection = 1 day positive

Endpoint / Goal: Time to Detection

Results: SEM Scanner Detects PUs 5 days, on average, before Nurse VSA+

• Time to Detection (Days Earlier than VSA+)

Conclusions

• The study shows and as shown by other studies that SEM is a good biophysical indicator of developing pressure injuries before visible signs of damage appear at the surface
• Results show that tissue damage, by measuring SEM, was detectable days earlier before nurse visual assessment
• SEM Scanner is now being adopted into clinical practice across the UK and Canada. Hospitals using the SEM Scanner have seen dramatic reductions in HAPU incidence and related costs, and are able to better monitor the effectiveness of interventions, or adjust accordingly.