Treating Raised SEM Deltas (∆) Achieves Repeatable and Sustainable Prevention Of Avoidable Pressure Injuries/Ulcers (PI/Us) in All Care Setting

December 13th, 2023
Bruin Biometrics, LLC issues an update on the progression of the clinical and health economic data resulting in major milestones in 2023.

The Status Quo

- The outdated standard of care fails to detect damage accurately and early enough and fails to direct treatment to the anatomy requiring it.
- The outdated standard of care fails to prevent broken PI/Us adequately despite heroic efforts by the multi-disciplinary team.
- The current standard of care fails patients' and residents with dark skin tone as skin redness is challenging to diagnose in this cohort.
- SEM assessment technology addresses all of these needs with utility far exceeding the outmoded standards of care. Using the device puts an end to overtreatment based solely on risk scales with visual and tactile skin inspection, which inadequately identifies damage in a timely or accurate way.

A Timely Update Is Required:

- Bruin Biometrics have now completed an extensive program of clinical and health economic research.
- Evidence base is now robust in depth and breadth with a strong mix of journals and authors, countries.
- Mode of action and impact on outcomes in a variety of care settings and cost efficiencies are proven.
- Leading clinicians around the world especially in Europe and North America accept the concept.
- US FDA have accepted new data on the mode of action and approved a revised device description.
- UK DHSC Drug Tariff announcement that provided payment for Scanner sensors at the point of care for all of the UKs at home patients.
- US CMS approved an application for an ICD-10 PCS procedure code related to the SEM scanning procedure (XX2KXP9) which will become effective on April 1, 2024, and will play a significant role in promoting standardization of the procedure.
- Increasing number of national and expert bodies PI/U prevention care guidelines are including the use of SEM assessment.

What Does This Mean In Clinical Practice?

Concept of SEM is now proven in the published literature

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SEM = Localized Edema and Persistent Focal Edema

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Fluctuations in SEM levels can be accurately measured via Provizio® SEM Scanner

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Detects skin changes which precede and predict later stage tissue death, an initially microscopic condition, later a macroscopic condition

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Enabling increasing adoption of the technology globally, supporting PI/U incidence rate reductions in all care settings

The evidence base now describes three distinct effects of SEM assessment technology:

Detection effect: early detection of raised SEM deltas (Δ), regardless of skin tone.

Treatment effect: anatomy specific treatment of localized edema.

Prevention effect: reduction in PI/U incidence in all population types.

Detection Effect
A patient or residents' skin and tissue can deteriorate during a regular episode of care, such that safe patient discharges are a challenge for the health care system and the incidence of PI/Us can exceed 28% in critical care.[ii]

The device is detecting "skin changes which precede and predict later stage tissue death" (Figure 1, left side), an initially microscopic condition, later a macroscopic condition. This poses the question…what clinical utility, is provided by the Scanner compared to the outdated standard of care that fails patients daily?

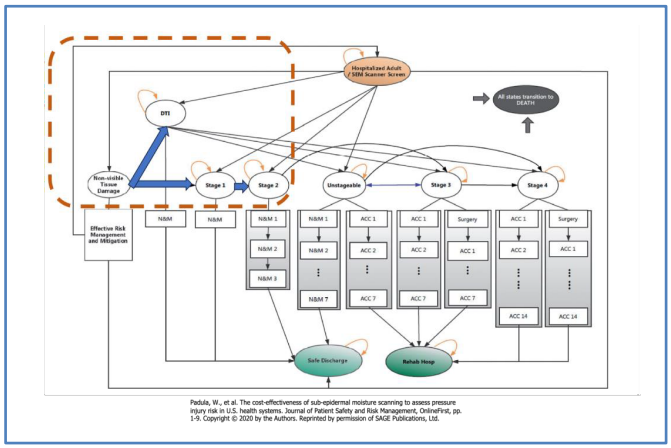

Figure 1

Clinical judgment alone is incapable of detecting invisible tissue damage. Its sensitivity and specificity, which may approximate a normal distribution in light skin tone patients is random akin to a coin toss.

By contrast, the device presents 87.5% sensitivity and 32.9% specificity for patients deteriorating from no damage on admission to a staged PI/U (the blue arrows inside the orange box, Figure 1), even with full whole-body interventions, 28% of patients developed a later-stage injury under the current standard of care.[iv]

Answering the question on device sensitivity and specificity:

- Okonkwo *et al.* (2020) [iv] noted in their blinded study that patients continued to receive preventive interventions during routine care. Interventions work well enough to confound the deterioration from healthy to damaged tissue in a clinical study setting where withholding interventions was prohibited by Independent Review Boards as unethical. The days of conducting pure studies where the patient suffers "in the name of good science" to produce perfect test environments are thankfully consigned to history.
- Moore *et al.* (2022)[v], in their systematic review of SEM Scanner evidence, noted that both sensitivity and specificity are influenced by preventive measures – *"a true positive true-positive occurs when there is an elevated SEM measurement combined with a visible PU, meanwhile, a false-positive is said to occur when there is an elevated SEM measurement without visible PU development. A key question arising from this review is whether an elevated SEM in isolation, without the presence of a visual PU, is in fact a false-positive."*
- Following up on the question of whether what was seen as a false positive was, in fact, such, Brunetti *et al.* (2023) [v] noted that the ability of the Scanner to measure and quantify localized edema explains the 'presumed false-positive' conundrum put forth in previous clinical studies, *"In prior in-human studies, SEM positive measures which did not concurrently, or prior to study conclusion result in a PU confirmed by clinical judgment were necessarily classed as false positives. These ex vivo data suggest that the device could have detected limited localized oedema which either deteriorated to an observed ulcer (leading to a true positive), stayed the same, or resolved during the studies, leading to presumed false positives.".*

2023 Milestones

Milestone 1: The USA Food and Drug Administration acknowledge the mode of action by accepting an expanded labelling K231830 September 2023.[1]

Where the technology detected raised SEM Deltas (Δ) (positive SEM result), interventions provided to patients treated the localized edema detected by the Scanner and prevented visible signs that would have been identified by skin tissue assessments. Therefore, localized edema detected by the Scanner, which was subsequently treated by interventions, resulted in negative (no PI/U) skin and tissue assessments via visual and tactile methods, classifying these test results in Okonkwo 2020 necessarily at the time as "false positives". Later published evidence by Brunetti *et al* (2023) proved what was stated by Okonkwo at the time: they were not in fact "False positives".

Non-visible damage is entirely missed by the current standard of care, and anatomy-specific interventions occur only after visible signs manifest. The diagnostic accuracy of the Scanner for these earliest stages of damage with an area under the curve of 67.13%, means that more of the patients' anatomies are detected more accurately and days earlier than under the current standard of care.[iv]

In skin laboratory tests the sensitivity of the Scanner for localized edema was **100%** and specificity was **97.5%.**[vi] In other words, the Scanner detects accumulations of fluid locally with almost perfect reliability. FDA acknowledged these data for expanded labeling (K231830, September 2023)[1].

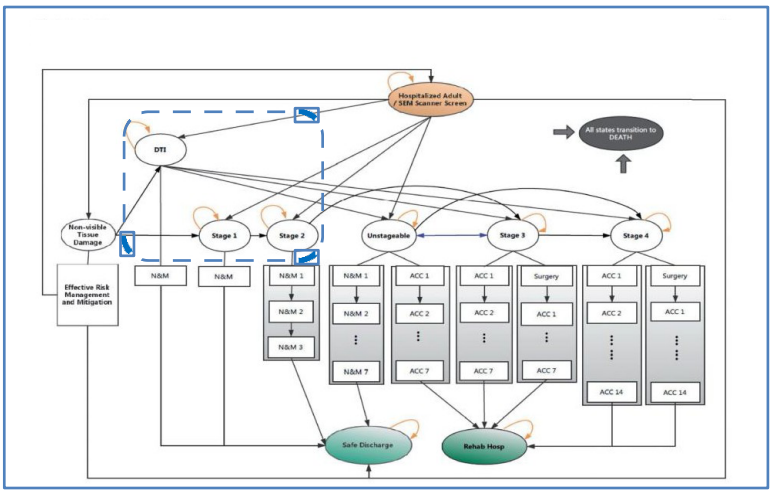

Figure 2

The outdated standards of care also approach randomness in their accuracy for detecting macroscopic tissue damage (inside the blue dotted line, Figure 2) and that the Scanner provides significantly increased certainty where randomness existed previously.[vii]

- The sensitivity and specificity of clinical judgment is 50.6% sensitivity and 60.1%[viii] specificity for these ulcers inside the blue dotted line (DTI, Stage 1, blood blisters for Stage 2). Dark-skin tone patients are failed entirely.
- Scanner offers **82.2%** sensitivity, **51% specificity**, with an area under the curve of **78.09%** provides clinicians with the best detection method available, far exceeding clinical judgment alone.[ix]

The Scanner is the only device that gives practitioners the ability to:

a. Detect skin changes which precede and predict later stage tissue death more accurately than any other method; and,
b. Detect skin changes which precede and predict later stage tissue death earlier than any other method.

This is the etiological and pathophysiological paradigm shift at the heart of the clinical utility picture of the Scanner.

Treatment Effect

The device targets specific anatomies, not the whole patient. Scanning the most common PI/U locations of the sacrum and heel.

When prompted by Scanner readings, nurses were two times more likely to act *but* did so on 1/3 of anatomies[x], and when they did so, they reduced the incidence of broken skin pressure ulcers by 62%.[xi] Ensuring objective, intelligent, targeted, early treatment of skin and tissue in trouble. Interventions at this stage of damage are as per treatment of a stage 1 PI/U such as a.) offloading specific anatomies, b.) changing surfaces, c.) dressing, d.) creams: the most basic of interventions.

These treatments largely work for the early-stage tissue damage (Figure 3). The data show that nurses know how to direct care with the data presented.[x] This treatment paradigm shift is at the heart of the clinical utility picture of the Scanner.

Prevention Effect

PI/Us kill tens of thousands and injure millions of patients per year, and the problem is getting worse, notably in the USA, except in facilities using the Scanner in a modernized care pathway.[ixxi,vii,iv] Real World Data were published in a "meta-analysis", one of the highest forms of clinical evidence.[xx,xi]

Prevention is achieved through the detection of the earliest signs of skin changes which precede and predict later stage tissue death and the application of targeted, timely interventions before skin and tissue damage has progressed too far.[xiv]

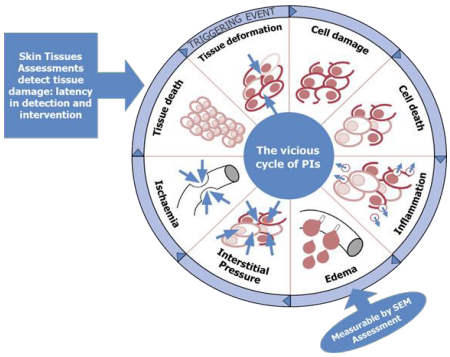

Figure 3

Cycle of Pressure Ulcers: Adapted from Gefen, A., et al. (2020).
Update to device-related pressure ulcers: SECURE prevention. COVID-19, face masks and skin damage.
(Journal of Wound Care Vol 29, NO 5, May 2020. Figure reprinted by permission of MA Healthcare Ltd.)

Milestone 2: UK Reimbursement for Community Care Use

The UK Drug Tariff announced that it would provide payment for Scanner single-use sensors at the point of care for all of the UKs at home patients. It did so after review of the contemporary evidence for and against the Scanner and approved sensor payment coverage for approximately 9 million patients in the UK across all four nations.

Milestone 3: US CMS ICD 10 PCS Procedure Code

US CMS have approved an application for an ICD-10 PCS procedure code related to the SEM scanning procedure (XX2KXP9) which will become effective on April 1, 2024, and will play a significant role in promoting standardization of the procedure.

Milestone 4: Expert Groups from an increasing list of countries and specialties including the use of SEM assessment in their guidelines

Examples include:

- 2023 Guidelines for Prevention of Perioperative Pressure Injury by the Association of perioperative Registered Nurses (AORN) recognize the need technology-based examinations of skin and tissue status. Recommendation 7.2.1 states the following: "Technology-based skin assessments that focus on the biophysical changes (i.e., biocapacitance……. may be used");[xxi]
- Spinal cord injury consensus statement in New Zealand recommends "use a sub-epidermal moisture (SEM) Scanner" as part of comprehensive skin and tissue assessments for managing PIs for those with spinal cord injuries. This statement (September 2021) is part of the Accident Compensation Corporation's (ACC's) work in collaboration with the Ministry of Health and Health Quality & Safety Commission New Zealand to prevent pressure injuries in people at highest risk.[xx]

- SEM assessment is included in standard pressure injury prevention protocols as part of the official Polish Wound Management Guidelines.[xxiii]
- NPIAP, USA include the use of SEM assessment in the Skin/Tissue Assessment section of version 2.0 of the Standardized Pressure Injury Prevention Protocol Checklist. "Consider enhanced skin assessment methods ….. SEM, …." [xxiv]

Milestone 5: Health economic modelling presents a cost-effective outcome but importantly an outcome that frees up Nursing time.

Health economics studies most recently published show clinical and economic utility "*the incremental cost of SEM assessment as an adjunct to VSA [Visual Skin Assessments] is £8.99 per admission, and SEM assessment is expected to reduce the incidence of hospital-acquired pressure ulcers by 21.1%, reduce NHS costs and lead to a gain of 3.634 QALYs.*"[xxv]

Adding on the prevention effect of earlier interventions makes the economic case overwhelmingly compelling. A recent project in Glasgow, UK, cited a saving of 7.15 hours of nursing time per day per ward from the "unexpected benefits" of the use of the Scanner: "*A time and motion study identified that it took one nurse 6mins 30 seconds to reposition a patient this equates to a minimum saving of 7.15hrs daily*." Incidence reduced from 5.77/1000 to 0.00/1000.[xxvi]

In a world in which nursing time and resource is at a premium and overtreatment is occurring under the old standard of care not using the Scanner (4 eyes, Q4 assessments of at-risk patients, over repositioning, overuse of dressings prophylactically), the use of the Scanner saves one whole nurse FTE per ward per day from needlessly repositioning patients or residents.

SEM assessment technology measures localized edema, also reported in the literature as SEM or PFO, which when treated, the incidence of broken skin PI/U reduces significantly. Doing so saves nurse time, beds days, materials use and other avoidable expenditure.

For further information contact: Kate Hancock, EVP External Communications: khancock@bruinbiometrics,

[1] K231830, September 2023: "The Provizio SEM Scanner S measures the electrical capacitance of tissue ("Biocapacitance"), below the electrode when placed on the patient's skin. Biocapacitance is a biophysical measure of changes in sub-epidermal moisture ("SEM") a physiological process associated with pressure-induced tissue damage, The Provizio SEM Scanner S is designed to measure changes in SEM which is equally known in literature as persistent focal edema, or localized edema."

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