PRESSURE ULCER PREVENTION

The science of sub-epidermal moisture

Fundamental principles, clinical evidence & health economic outcomes

A global healthcare challenge

Pressure injuries (also known as pressure ulcers), are a major global healthcare problem occurring in both acute, long stay and community healthcare settings[1,2,3]. These injuries have a significant humanitarian and economic impact[4,5,6], but are largely considered to be a preventable[7] 'Never Event[8]'. For prevention to be successful, it is essential that patients at risk of a pressure injury are identified, and that appropriate interventions are initiated early. International expert guidelines for pressure injury prevention recommend patient assessment on admission, and daily thereafter[9].

Risk Assessment Tools (RATs) and a visual skin and tissue inspection by the clinician, to assess for early signs of skin damage, have been the standard of care for many years with over 200 risk assessment tools currently available to the clinicians. Despite this however, many of the RATs in clinical use, are subjective assessments[10], not anatomy-specific, subjective, and reported to have low predictive value[11]. Visual Skin and Tissue Assessments (STAs) also lack reliability and are based upon the subjective interpretation of the individual assessing the skin[12].

> "Visual skin inspection lacks reliability and is based upon subjective interpretation"[12]

One major deficiency with the current risk assessment processes is that they do not alert the clinician to the biological changes which occur beneath the skin surface. Tissue changes may occur beneath the observable skin level days before tissue breakdown and ulceration are visible at the surface[13]. These tissue changes that may lead to pressure injury development are caused by inflammation, triggered by prolonged pressure, shear

> "The leaked fluid accumulates as localised oedema also known as Sub-Epidermal Moisture (SEM)"[13]

forces, tissue deformation and ischaemia. The inflammation is stimulated over time, varying from minutes to hours and leads to a number of pathological changes. One early change is increased permeability of blood vessels which allows leakage of fluid from the vessels into the extracellular space. The leaked fluid accumulates as localised oedema also known as Sub-Epidermal Moisture (SEM)[13] and is therefore an early sign that tissue damage is happening which may lead to pressure injury development. This highlights the importance of early identification and the need for early intervention in pressure injury prevention.

An innovative and clinically proven technology – the Provizio® SEM Scanner, which provides an assessment of sub-epidermal moisture content, as an early indicator of pressure injury risk, is increasingly being adopted into clinical practice[14–16].

> "Reduction in pressure injury incidence of 90.5% in acute care"[17]

The Provizio SEM Scanner is a handheld, wireless, objective medical device that uses biocapacitance to identify increased risk of pressure injury to provide insight to the clinician that a patient without visible external signs of tissue damage is at risk of pressure injury development on the heel or sacrum. The Provizio SEM Scanner has been demonstrated as an effective tool supporting the prevention of pressure injury when used as an adjunct to standard of care with a weighted average reduction in pressure injury incidence of 90.5% in acute care facilities[17]. Economic modelling studies based on a conservative range of assumptions also suggest that the implementation of the SEM technology, as part of a prevention protocol are a dominant strategy compared to standard of care, since it lowers cost and increases QALYs (Quality Adjusted Life Years)[6].

The challenge of preventing pressure injuries

Prevention of pressure injuries is critically important in order to avoid the clinical, quality of life and economic challenges that they present. Assessment is based on clinical judgement and Risk Assessment Tools (RATs), examples of which include the Waterlow, Norton and Braden scales[19,20]. The assessments use semi-quantitative, judgement based observations to score the extent of risk factors, with the outcomes intended to influence how a patient is managed to prevent a presure injury. The use of RATs are supplemented by Skin and Tissue Assessments (STAs) – visible and palpation tests intended to identify a pressure injury. STAs appraise skin colour, blanchability, temperature, hardness and other palpable indicators of injury.

This current standard of care in risk assessment processes, is often complicated and dependent upon the subjective judgement of the clinician. RATs provide a universal whole body focus to pressure injury risk; such injuries however do not develop universally, but at specific anatomies such as the sacrum and heel. Pressure injury prevention programmes can be effective[21,22] but the predictive value of RATs may be low[23–30]. RATs can also be particularly challenging in patients with dark skin tones which can mask any visible changes[31]. Furthermore the outcomes from RATs may lead to pressure injury prevention strategies[32], but this is not always the case[33]. The results of RATs may even lead to unnecessary interventions in patients who are not at risk[33] and hence this may not reduce the incidence of pressure injury[26].

Prevention strategies may therefore be inappropriately or ineffectively used since such interventions may lag the time between when the damage actually begins and the time under the current standard of care at which it is detected and diagnosed. STAs for example may trigger the need for anatomy specific interventions, but this may only happen once the wound has become visible at the skin surface and at this point significant tissue damage may have already occurred.

> "When effective prevention is implemented it is highly likely to be cost saving"[34,35]

When effective prevention is implemented it is highly likely to be cost saving[34,35] compared with the cost for the treatment and management of a pressure injury. There is a clear need for an objective risk assessment method to help increase the likelihood of early identification of PI risk and early prevention strategies.

The effects of prolonged pressure on tissue

The principle causes of pressure injuries are pressure, friction, shear, moisture, and tissue deformation[36–38] (figure 1). Pressure injuries develop over time, they do not appear on the skin instantaneously[39] instead there is a sequential and gradual deterioration of cell structures which are subjected to bodyweight or external forces[40].

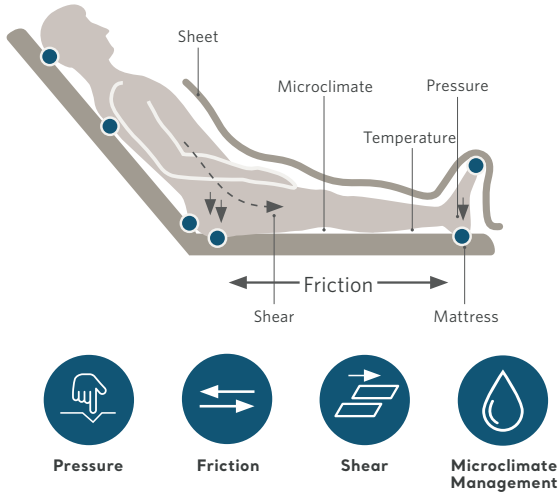


Figure 1: Pressure, shear, friction and microclimate

Pressure induced tissue damage occurs when too much pressure is applied to an area of the body for a prolonged period of time, resulting in small blood vessel collapse and ischaemia, or a restriction of blood supply and lymphatic flow to the tissues. Tissue damage is often more common over bony prominences, since the pressure may be 3–5 times greater than in tissues not affected by bony structures[41,42].

While pressure may be applied to the skin, the effects of pressure are frequently exacerbated by lateral shear forces[41,42]. Compression of tissue over bony prominences occurs concurrently with shear forces and are a key factor in pressure injury formation[43], leading directly to cell death. Skeletal muscle is the most sensitive to pressure[44] and prolonged pressure leads to deep pressure-induced tissue damage. The intensity and duration of pressure on deep tissues are key factors in tissue damage[45].

Tissue tolerance

The development of a pressure injury also depends on individual tissue tolerance; this is affected by many physical and environmental risk factors. The importance of other factors such as internal anatomy, excess heat and moisture on the skin will have an influence on the individual's susceptibility to pressure injury formation[9].

Evolving insights in pressure injury formation: The damage cascade & the inflammatory response

Important insights on how pressure injuries develop and progress in severity have been identified and published in recent scientific work[40]. This body of knowledge suggest three major contributors to cell damage and tissue necrosis namely: deformation, inflammation and ischaemia in the form of a damage cascade[46] (Figure 2).

Direct deformation

Prolonged tissue deformations lead to cell death at a microscopic level beneath the surface of the skin, which subsequently triggers an inflammatory response within the tissues[46]. Inflammation is the body's first response to tissue damage and a mechanism to combat injury[40]. Tissue and cell stresses trigger cellular pathways that initiate inflammation.

A key factor in pressure injury development is the prolonged nature of these stresses which trigger chronic inflammation and over expressed, uncontrolled pathology, including destructive proteinases and an oxidative environment[47–49]. This lack of control allows inflammation to progress unabated to become harmful rather than helpful to tissue repair.

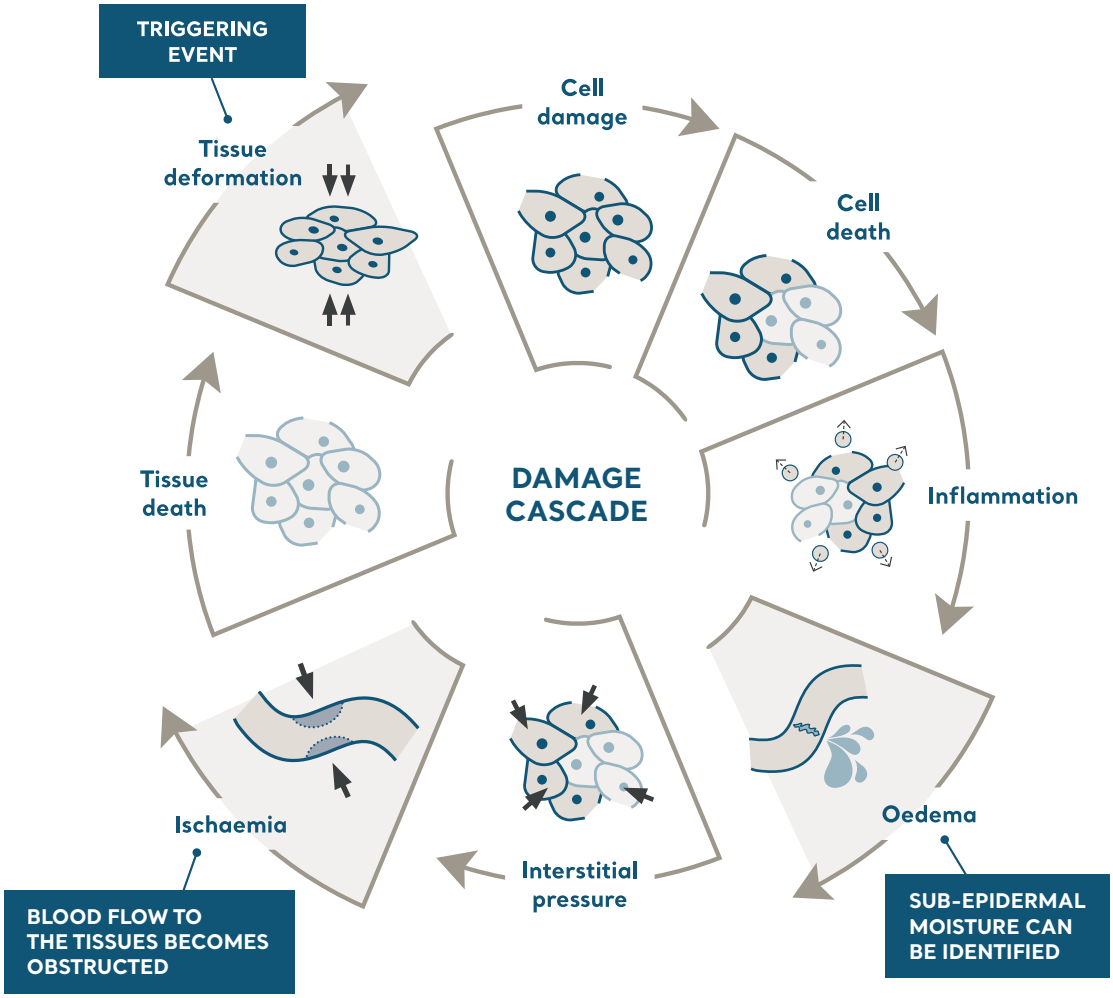


Figure 2: Cycle of Pressure Injury: adapted from Gefen A, 2020[39]. The SEM Scanner for Early Pressure Ulcer Detection: A 360-degree Review of the Technology. Wounds International. Vol 11, Issue 3: p22-30

The damage cascade in pressure injury formation

3 major contributors to cell damage: Deformation, Inflammation & Ischaemia[40]

Key points

- **Deformation:** prolonged tissue deformations lead to cell death at a microscopic level beneath the skin surface, which subsequently triggers an inflammatory response[40].
- **Inflammatory response:** cell death triggers inflammatory oedema in the tissues, increasing the mechanical load on the cells and tissues and increasing interstitial pressure[40].
- **Ischaemic damage:** Localised oedema gradually increases the interstitial pressure within the tissues which then begin to obstruct blood vessels[40].

Inflammatory response

A key feature which appears early in the inflammatory response is increased vascular permeability at the injured site. This is to assist healing and to allow leukocytes that control wound healing and protect against infection to leave the blood vessels to gain access to the site of injury.

Tissue timeline of the inflammatory response to pressure related damage

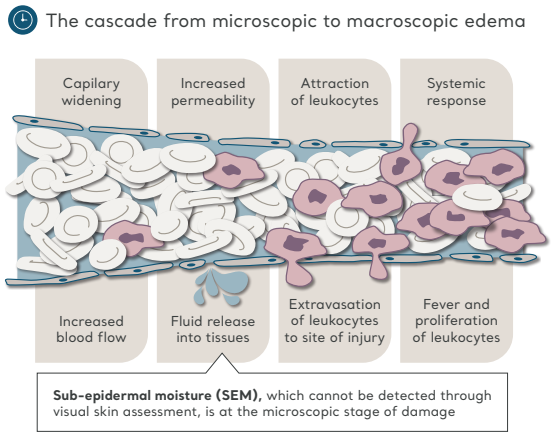


Figure 3: The inflammatory response to pressure-related damage
Source Reference: Amit Gefen, PhD, Professor in Biomedical Engineering, Tel Aviv University

Tissue hydration is maintained in balance by osmotic pressure, pressure in the vasculature and drainage via the lymphatic system. In patients subjected to pressure, friction and shear tissue deformation disrupts the intracellular cytoskeleton leading to cell damage. Inflammatory and immune cells which are required for normal tissue repair and removal of debris[50] migrate out of the blood vessels into the tissues in a process known as extravasation. This is normal in inflammation and causes the oedema visible around an acute skin injury. Intravascular plasma leaks into the tissue leading initially to oedema[51] also known as **Sub-Epidermal Moisture (SEM)**. This process is exacerbated by repeated tissue deformation which intensifies the inflammatory response by the release of further chemokines (signalling proteins secreted by the cells) leading to overexpression of inflammation which tips over into tissue damage instead of repair. Microscopic SEM is invisible by the eye[52]. By the time skin damage is visible to the eye, significant deep tissue injury and pressure injury formation are likely to have occurred[51].

The inflammatory response to pressure related damage

Key Points:

- Mechanical loading and tissue compression from external forces deform the skin
- The effects on the skin is multifaceted; through a number of different pathways the damage triggers inflammation, hypoxia and cell death
- Ischaemia reduces the supply of nutrients to the tissue allowing toxic metabolites to accumulate
- Ischaemia may also be followed by reperfusion which itself triggers inflammation
- Lymphatic dysfunction may also be related to the severity of pressure injury allowing the accumulation of fluid and metabolic waste products because extravascular fluid drainage is reduced
- Tissue deformation an internal shear stress cause cell death

Ischaemic damage

Localised oedema gradually increases the interstitial pressure within the tissues which then begin to obstruct blood vessels[40]. The interrupted supply of oxygen, micronutrients, combined with the failure to remove toxic metabolites may lead to tissue ischaemia and irreversible tissue damage. It is acknowledged that early cellular damage can occur within minutes which can lead to tissue ischaemia several hours later[40].

The role of sub-epidermal moisture

International pressure injury clinical practice guideline recommendations – skin & tissue assessment[9]:

Recommendation 2.6: 'Consider using a sub-epidermal moisture/oedema measurement device as an adjunct to routine clinical skin assessment. (B2, strength of recommendation↔).'[53]

Recommendation 2.7: 'When assessing darkly pigmented skin, consider assessment of skin temperature and sub-epidermal moisture as important adjunct strategies. (B2, strength of recommendation↑).'[54]

Inflammatory changes in the skin and underlying tissues may precede skin surface changes by 3 to 10 days[51]. Identifying increasing or fluctuations in SEM early is therefore critical to effective pressure injury prevention[51]. SEM is a biophysical marker for possible pressure injury formation in at risk patients[52]. The presence of SEM above a defined threshold allows prevention strategies to be implemented even before visible damage, increasing the likelihood of success in preventing pressure injuries as recognised and referenced in the updated International Clinical Practice Guidelines for Pressure Injury Prevention and Treatment[9].

The biocapacitance of tissues

SEM can be identified by assessing the biocapacitance of tissue. Biocapacitance is the capacity for a biological system to store an electric charge. The magnitude of biocapacitance is proportional to the amount of sub-epidermal moisture in the tissue. Biocapacitance is identified using a sensor with two insulated non-invasive electrodes placed onto the skin (Figure 4). Detecting biocapacitance does not require radiofrequency emissions or any current to be passed into the tissue.

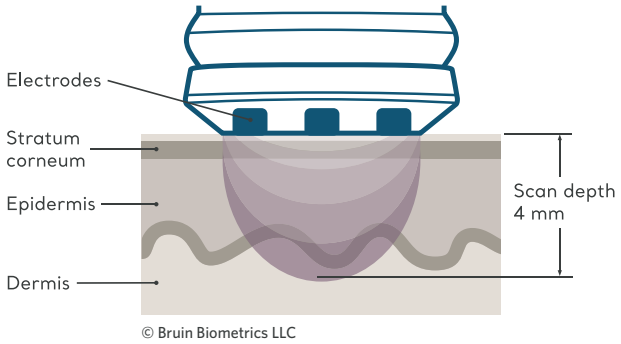


Figure 4: Measurement of tissue biocapacitance

Assessments are based on passive electrical properties of the tissue being assessed[55]. Changes in biocapacitance related to changing levels of SEM in the tissue can be detected in this way. The reading of SEM values exploits differences between the dielectric constants of materials that make up tissue. Dry tissue has a low dielectric constant whilst water has a dielectric constant that is 20 x higher. A SEM sensor pressed against an area on the skin measures the electrical capacitance of the sensor[40] which is affected by the moisture within the underlying skin tissue to a depth of approximately 4 mm. The extensive physical science that underpins the mode of action of the SEM assessment technology is well established and has been described in detail[56].

SEM as an indicator of early tissue damage: Foundational research

A series of comprehensive laboratory and international clinical studies, have demonstrated the sensitivity and precision of the SEM assessment technology and its superiority over other non-invasive tissue assessment methods. Specifically:

- SEM has been shown to differentiate between erythema and category/stage 1 pressure injuries in nursing home residents[57].
- Higher SEM scores are associated with early pressure injury damage in nursing home residents with dark skin tones[58], a particularly challenging group of patients to assess using standard risk assessment processes.
- SEM scoring has been shown to be effective for the early detection of pressure injury related damage in patients with spinal cord injury[59] and importantly was able to differentiate pressure injury associated damage from intact skin[60].

The original concept of the SEM assessment technology was conceived by Barbara Bates-Jensen a global leader in wound care, and developed in conjunction with UCLA's Schools of Nursing, Engineering and the Wireless Health Institute. Bates-Jensen conducted extensive, independent, formal clinical trials on SEM and its relationship to pressure injury pathogenesis. These studies identified the foundational science and fundamental principles that establish the relationship between SEM and pressure injury damage[57–63] and set the scene for the development of a commercial SEM Scanner and the further expansion of the evidence base to demonstrate its effectiveness.

Anatomical models –'Phantoms' representing the posterior heel in which pressure injury form by sustained bodyweight forces and tissue deformations, and the left cheek and chin representing sites in which medical device-related pressure injury caused by continuous positive airway pressure (CPAP) masks frequently form, have been conducted[56]. Phantoms were created using a 3d-printed heel skeleton laid over with soft tissue substitute material cut to size as a soft tissue analogue. The cheek and chin phantoms were plastic skulls overlaid with the diaper soft tissue analogue. Water was injected in 1 ml increments and SEM Scanner readings were taken. The Provizio SEM Scanner and its predecessor model – the SEM 200 discriminated incremental increases in fluid volume of 1 ml with a statistical significance of $p<0.00001$.[13]

In clinical practice the assessment technology identifies increased risk of pressure injuries 5* days earlier, before visual skin assessment does[64] and enables tissue damage to be detected in dark-toned skin[58] which presents challenges in STA. The SEM assessment technology was evaluated in 15 patients in a post-acute care facility using VSA, ultrasound (U/S) and SEM scanning. In patients with existing suspected deep tissue injury, U/S and SEM showed consistent agreement in assessment outcomes in this study[65].

International foundational clinical studies have formally evaluated the sensitivity and specificity of the SEM assessment technology and the clinical utility of the device. The findings from these studies demonstrate how biocapacitance, the basis for the operation of the SEM assessment technology, can complement visual skin and tissue assessments, facilitate earlier identification of the risk of specific anatomies developing pressure injuries and help inform earlier anatomy specific intervention decisions than visual skin and tissue assessments alone. More detailed information and an overview of the key results from these foundational research studies is provided in the clinical evidence section of this brochure.

> "these studies demonstrate how biocapacitance, the basis for the operation of the SEM assessment technology, (...) facilitates earlier identification of the risk of pressure injuries."

Provizio® SEM Scanner

The Provizio SEM Scanner is a hand-held wireless, non-invasive device, used adjunctively with standard of care (figure 5). The device objectively alerts clinicians to specific anatomical areas of a patient's body at risk of pressure injury before visible damage manifests at the skin surface. The Provizio SEM Scanner reports biocapacitance of the tissue of a specific anatomy as a non-dimensional unitless SEM value. The device compares sequential SEM measurements across a specific anatomy and reports the maximum difference between SEM values at the inflamed tissue site with those from adjacent, healthy tissue sites called a SEM Δ.

When a patient

- has a Δ <0.6 at an anatomical site they may have tissue at lower risk of pressure injury development
- has a Δ of ≥ 0.6 at an anatomical site they may have tissue at increased risk of pressure injury development

Figure 5: The Provizio SEM Scanner

Key insights

- The data facilitates earlier and anatomically specific interventions designed to reverse the damaging effects of pressure and prevent pressure injuries from breaking through the skin[66]
- In comparison to Skin and Tissue Assessment (STA), the Provizio SEM Scanner supports clinicians to identify specific anatomical areas – the heels and sacrum at increased risk of pressure injury development on admission 5 days* earlier[66] regardless of skin tone[58]

The Provizio SEM Scanner is intended to be used by healthcare professionals as an adjunct to the standard of care when assessing the heels and sacrum of patients who are at increased risk for pressure injury. It is easy to use with integrated features that take a reading only when the contact between the device and the patient's skin is optimal.

The advantages of identifying sub-epidermal moisture include

- Objective, anatomically specific assessment
- Intelligent technology supporting targeted incidence reduction
- Earlier awareness of increased risk of pressure injury enabling earlier action
- Non-invasive, non-significant risk and rapid results
- Applicability across all skin colours
- Digitally enhanced for easy adoption into existing work flows and care pathways with built in data transfer
- Easy and intuitive to operate: a high proportion of nurses who tested the SEM assessment technology were able to accurately use the device with only 10 minutes of training

Clinical evidence

The Provizio SEM Scanner is supported by an extensive body of clinical evidence relating to device functionality, clinical utility and standard of care (Figure 6).

This section will review some of the key foundational studies which demonstrates how the Provizio SEM Scanner differentiates between healthy and damaged tissue earlier than visual skin assessment.

It will present practical and pragmatic real world data to support the clinical utility of the device as an adjunct to current standard of care in risk assessment processes.

Finally two economic modelling studies suggest that the implementation of the SEM assessment technology, as an adjunct to standard of care is highly likely to lead to significant financial benefits and cost savings[6,18].

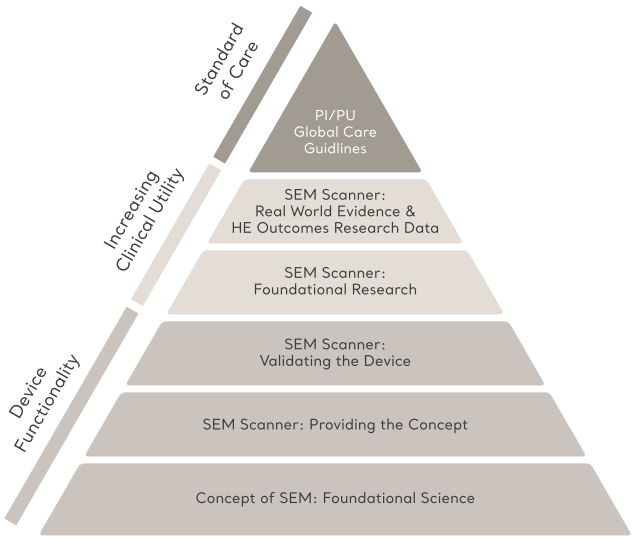


Figure 6: Provizio SEM Scanner Evidence Hierarchy: device functionality, clinical utility & standard of care

Foundational clinical studies

A blinded clinical study using a sub-epidermal moisture biocapacitance measurement device for early detection of pressure injuries[66]

Journal: Wound Repair and Reg 2020; 1-11. https://doi.org/10.1111/wrr.12790

Authors: Okonkwo H, Bryant R, Milne J Molyneaux D, Sanders J, Cunnigham G, Brangman S, Eardley W, Chan G.J, Mayer B, Waldo M, Ju B.

Study objectives

- To evaluate the sensitivity and specificity of the SEM assessment technology in detecting early pressure injury compared to clinical judgement.
- To characterise the timing of SEM changes compared to the diagnosis of pressure injury by skin assessment.

Methods

- Multicentre longitudinal international study conducted in 9 specialist centres in the USA and 3 in the UK.
- 189 patients enrolled (46.7% males/53.3% females); 182 included as intention to treat (ITT).
- **Inclusion Criteria:** ≥ 55 year of age; could be followed for at least 6 consecutive days; reduced mobility; determined to be at risk of developing a pressure injury (Braden scale ,15; Waterlow scale > 10).
- **Exclusion Criteria:** existing pressure injuries; broken skin at either the sacrum or heels, which would compromise bioelectrical impedance measurements; moisture lesions or incontinence associated dermatitis; biomechanical or other limitations preventing protocol-driven assessments.
- **Assessment:** Participants were assessed daily for risk of pressure injury by wound care specialists using either the Braden scale or Waterlow score.
- Participants skin tone was categorised with the Fitzpatrick Skin Classification Scale to permit between group comparisons.
- **SEM Scanner Assessment:** After skin assessment, SEM Scanner measurements were obtained from the sacrum (6 readings) and heels (≥ 3) by clinical staff blinded to the SEM results.
- PI prevention measures used during patient care were documented – repositioning, turning, use of special beds, dressings or topical treatments.

Key results

- Compared with standard risk assessment, the SEM assessment technology had > 80% sensitivity and between 30% and 40% specificity.
- The SEM assessment technology detected damage to the sacrum, left and right heel 4.7 ± 2.6, 5.1 ±2.3 and 4.3 ± 2.4 days respectively sooner than skin assessment did (Figure 7).

Study interpretation

Prevention of pressure injury remains a major challenge in all healthcare settings. Prophylactic measures currently rely on clinical assessments of skin temperature, rigidity and visible characteristics which are often plagued by poor inter-rater reliability. By objectively measuring subdermal changes that precede palpable or visible indicators of pressure injury, SEM assessment technology may prove useful in pressure injury prevention initiatives as a method for the early detection of soft tissue damage.

This study demonstrates how biocapacitance, the basis for the operation of the SEM assessment technology, **provides high sensitivity in detecting increased risk of pressure injury 5 days (median) before visual assessment does.** The specificity results of this study were confounded through the unusually high level of interventions (even though study staff were blinded to the SEM Scanner results), such as more frequent turning, that likely reversed tissue damage before physical manifestation with visible signs of damage that would be detected by STA. Acknowledging specificity limitations the data from this study suggest that SEM can complement visual STA and facilitate the identification of the risk of specific anatomies developing pressure injuries.

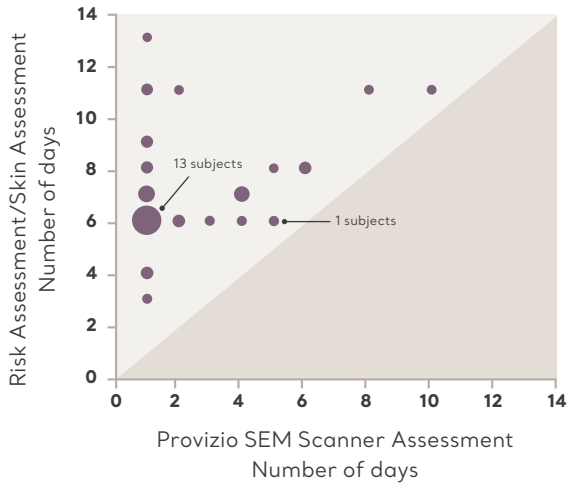


Figure 7: SEM assessment technology alerts to increased risk of pressure injury earlier than clinician

Evaluating the sensitivity, specificity, and clinical utility of algorithms of spatial variation in Sub-Epidermal Moisture (SEM) for the diagnosis of deep and early stage pressure induced tissue damage[67]

Journal: Journal of Wound Care
2021; Vol 30 (1): 41-53
Authors: Gershon S, Okonkwo H

Primary objectives

To evaluate the ability of an objective test, the SEM, to discriminate between subjects with confirmed PI with intact skin versus those with no pressure damage. Sensitivity and specificity tables and Receiving Operator Characteristics (ROC) curves were analyzed to compare the diagnostic accuracies of gold standard Skin Tissue Assessments with the SEM test.

Secondary objectives

To gather data about characteristics of damaged versus healthy tissue and develop, post-hoc, a clinically useful algorithm with robust sensitivities and specificities that can be further evaluated longitudinally and deployed in clinical practice.

Methods

- Setting: 2 cohorts were included:
  - Cohort 1: with PIs (n=125 nursing homes or assisted living facilities).
  - Cohort 2: healthy subjects without PI (n=50 physicians office)
- The cohort without PIs was selected to match the inclusion and exclusion criteria for the cohort with a PI
- **Inclusion Criteria:** >18 years of age, willing and able to consent to the study; agreed to have skin assessments and SEM Scanner readings; stage 1 or 2 PI, if the injury was an unbroken blister
- **Exclusion Criteria:** broken skin at the assessment site; any factors that prevented a reading being made at an anatomic site; legal representatives who did not understand the aims of the study, conditions that seriously compromised the patient's ability to complete the study
- **Assessment:** Intact skin PI were identified with an area of non-blanchable redness (stage 1) and those having a visible DTPI. The Braden RAT was used for PI risk assessment

SEM Scanner readings: Conducted in a spatial pattern around the PI at seven points around the bony prominence of the heel and sacrum. Where a PI pre-existed SEM readings were taken at up to 16 points around the PI in addition to the centre of the wound (Figure 8)

Key results

- Mean spatial SEM measures within healthy tissue subjects and within damaged tissue subjects were statistically similar.
- Mean spatial SEM measures within anatomies of damaged tissue subjects were significantly different ($p<0.05$).
- There was no significant difference between spatial readings in healthy subjects.
- Algorithms computed a range of SEM delta thresholds to evaluate the sensitivity and specificity of the scanner.
- SEM algorithms using spatial SEM data significantly exceeded diagnostic accuracy of current clinical judgement alone.
- Receiving Operator Curves computed areas-under-the-curve indicated that the diagnostic accuracy of the SEM Scanner exceeded clinical judgment

Study interpretation

Repeated measures of SEM over healthy tissue are broadly spatially consistent indicating that healthy tissue is not abnormally locally inflamed. SEM measures between subjects with confirmed healthy tissue versus subjects with confirmed pressure damaged tissue are significantly different. SEM Scanner readings are unlikely to be adversely affected by patient specific factors, such as comorbidities or skin tone. The SEM assessment technology was found to be very effective. It brings objective information that would be helpful as an adjunct to clinical judgement and the current standard of care. Early detection of PI is key to prevention of injury progression and in the development of effective prevention and treatment plans

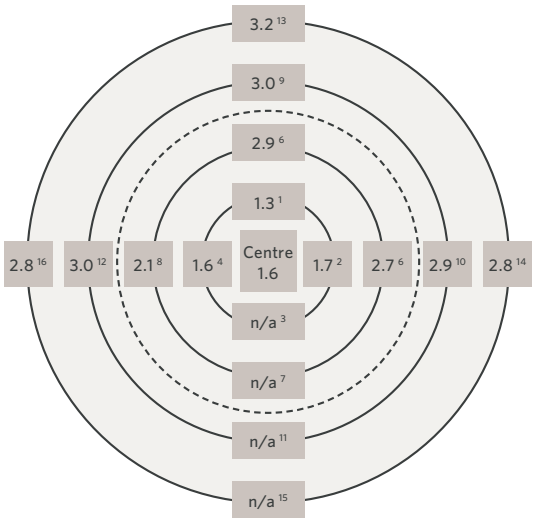


Figure 8: Spatial distribution of SEM at and around a PI

The relationship between nurse's assessment of early pressure ulcer damage and sub-epidermal moisture measurement: A prospective explorative study[68]

Journal: Journal of Tissue Viability 2018;27(4):232-237.

Authors: O'Brien G, Moore Z, Patton D, O'Connor T.

Study objectives

- To establish the relationship between visual skin assessment and SEM measurements.
- To establish whether measurement of SEM was more accurate and timely in detecting skin changes when compared to visual skin assessment alone

Methods

- A descriptive prospective observational study in 2 wards within a 62 bed general hospital in Ireland
- **Participants:** 47 consenting patients (18 male, 29 female) at high risk of pressure injury (Norton score) without existing pressure injury
- **Exclusion criteria:** Patients with existing pressure injury, non-consenting; not at risk (Norton score), active and mobile
- **Follow up:** 4 weeks or until discharge or transfer
- **Assessment:** Daily scans with the SEM assessment technology on the sacrum and both heels. A delta reading of >0.5 (≥0.6) indicated a high risk of pressure injury
- **Care Plan & Outcomes:** Preventative interventions were implemented according to local practice, but care plans were not altered based on the SEM results. Nurses also conducted VSA. VSA and SEM measurements were correlated and these correlations were categorised as low, medium or strong

Key results

- 40% (n=19) had abnormal skin according to VSA
- 21 Stage 1 pressure injuries developed on the sacrum (n=17;81%) and heels (left n=3;14%, Right n=1;5%) **all had elevated SEM deltas before visual signs of damage (100% sensitivity)**
- Specificity was 83%; false positives had insufficient follow up time
- Medium correlation (r=.47) between VSA and SEM outcomes for patients who developed a stage 1 pressure injury was recorded
- VSA and SEM Scanner correlations were strong for the sacrum (r=.65); medium for the right heel (r=.43); low for the left heel (r=.23)
- SEM Scanner detected damage on day 1.5 ± 1.4;VSA detected pressure injury on day 5.5 ±2.5; days earlier than VSA (Figure 9)

Study interpretation

This study confirms the feasibility of SEM measurements as an adjunct to assessing for early pressure injuries, it supports the findings from the Okonkwo et al study[65] enabling improved methods of risk assessment to quantify patient risk for pressure injuries. SEM measurements identified damage, on average 4 days sooner than stage 1 pressure injuries were visually detected, **The SEM assessment technology had high sensitivity and specificity scores for stage 1 pressure injuries**.

SEM assessment technology detects damage earlier than skin assessment (days)

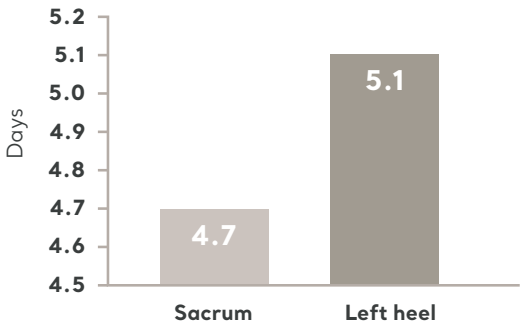


Figure 9: SEM Detection of damage

Real World Evidence

Utility of a sensor-based technology to assist in the prevention of pressure ulcers: A clinical comparison[15]

Journal: International Wound Journal. 2018;15(6):1033-1044

Authors: Raizman R, MacNeil M, Rappl L.

Study objectives

To evaluate the clinical utility of incorporating the SEM assessment technology into clinical workflow and of associating interventions informed by the SEM assessment technology with decreases in pressure injury incidence.

Methods

This study was conducted in 2 phases:

Phase 1 – Conducted from April 4 to May 4, 2016
Patients were provided with a standard of care risk assessment and interventions and scanning by SEM Scanner but the resulting SEM scores were not used to determine interventions.

Phase 2 – Conducted from May 4 to September 30, 2016
Identical to phase 1 except that the resulting SEM scores were used in conjunction with risk assessment to determine appropriate interventions and care planning.

Key results

- A total of 284 patients were evaluated in the 2 phases on 3 wards over a 7 month period

Phase 1 results

- 12/89 patients developed pressure injuries (4 category 1, 6 Category 2, 1 Category 3 and 1 Deep Tissue Injury (DTI).

Phase 2 results

- 2/195 patients developed pressure injuries (1 Category 1 and 1 Category 2)
- This illustrated a 93% reduction in Hospital Acquired Pressure Injury compared to phase 1.

Study interpretation

Pressure injury rates dropped significantly between Phase 1 and Phase 2 when the SEM assessment technology was incorporated into initial and ongoing assessments. In Phase 1 nurses did not change their practice in prevention strategies and nosocomial rates did not decrease. The addition of the SEM assessment technology did not significantly impact assessment time, and interventions followed standard protocols from risk assessment and visual assessment. **The 93% decrease in pressure injury incidence was attributed to the use of the SEM assessment technology to guide interventions.**

Is it time to re-evaluate the inevitability of ulcers at the end of life?[69]

Journal: International Journal of Palliative Nursing, 2021 Nov 2; 27(9):440-448. doi: 10.12968/ijpn.2021.27.9.440. PMID: 34846932

Author: Raine G

Study objectives

A pragmatic study was conducted to assess the feasibility of preventing SCALE (Skin Changes at Life's End) pressure injuries/ulcers (PIs) using SEM technology as an adjunct to routine care in a 22-bed inpatient hospice.

Methodology

All patients were scanned on admission, subsequent patient scanning was carried out thereafter in line with the facilities algorithm. Daily SEM scanning was introduced to the prevailing standard of care to support device-trained practitioners' clinical judgment in detecting developing, non-visible PIs. Preventive interventions were initiated by clinical judgment informed by Waterlow scores, visible, tactile skin-tissue assessments, and SEM scanner readings.

> "All nurses (100%) reported that an SEM delta (Δ) ≥0.6 alerted them to take additional actions on patient care."

Results

- Prior study PI incidence of the sacrum and heel areas was 9%.
- The 6-month study period reported a 4.8% PI incidence, 7/146 consenting patients developing a PI, resulting in a 47% reduction in incidence rates (95% CI:1.09, 8.47).
- All nurses (100%) reported that an SEM delta (Δ) ≥0.6 alerted them to take additional actions on patient care.

Post study conclusion, SEM devices were deployed for a full-scale implementation into routine clinical practice.

Data from patient safety incident reports indicated a consistently decreasing PI incidence rate after fully implementing the device into routine clinical practice.

Facility nurses reported a 69% PI incidence reduction in year one of implementing SEM assessments in routine clinical care- 15 months post-study completion.

Post-hoc estimation of the difference in proportions between the prior study data and post-study data resulted in a statistically significant absolute PI reduction of 6.26% at the 95% confidence interval (95% CI: 3.18, 9.81, $p<0.001$) with SEM assessments as the only addition to routine clinical practice.

During a period of 6 months in 2020 (year two), a 100% PI incidence reduction was demonstrated for several months.

Implementing a new approach to pressure ulcer prevention[16]

Journal: Journal of Community Nursing; 34 (4)

Authors: Ore N, Carver T

Study objectives

This pilot study aimed to evaluate implementation of the SEM assessment technology as an adjunct to standard of care in pressure ulcer prevention in 2 community nursing bases in the UK.

Methods

- Two district nursing bases enrolled 17 palliative care patients who received standard of care and preventive interventions.
- **Inclusion Criteria:** Patients with Waterlow score 10–19 who were able to be scanned for 3 consecutive days.
- **Exclusion Criteria:** Broken skin was not scanned and visual skin checks were documented after SEM scans.
- **Scanner Readings:** Patients with SEM delta ≥ 0.6 were considered at high risk and preventative interventions were escalated using a clinical decision matrix aligning with standard of care.

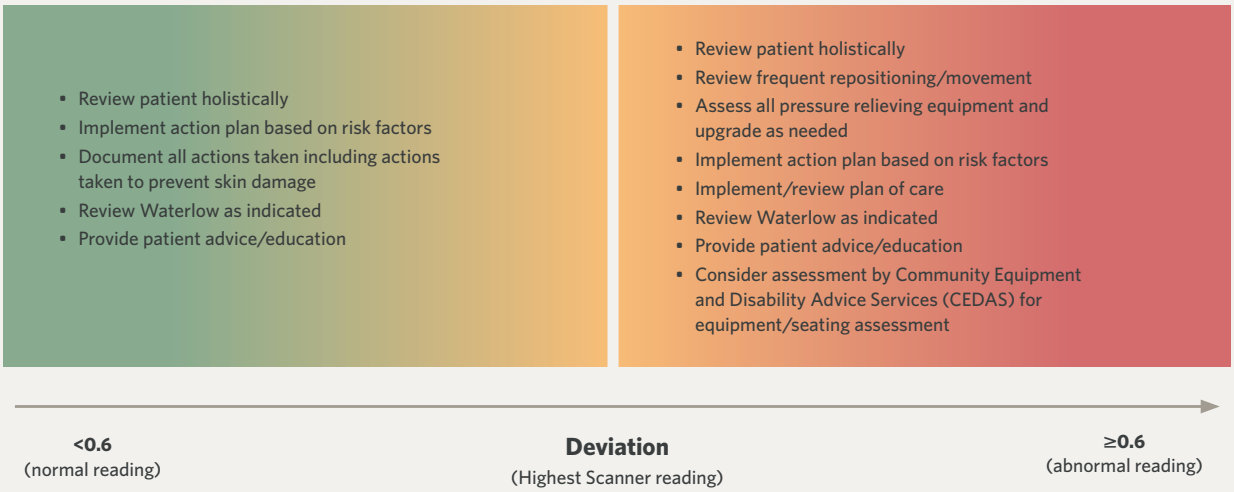
Key results

- Implementation of the SEM assessment technology into existing PI prevention pathway resulted in a reduction in community acquired pressure injury (CAPI) incidence by 26.7% from 16.1% to 11.8%; 88%(n=15) of patients remained PI free.
- Clinical judgement informed by SEM deltas resulted in 82% (n=14/17) of nurses reporting that SEM delta had changed their clinical decision making.

Study interpretation

Results from this pilot study highlight the clinical significance of objective data from the SEM Scanner supporting clinical judgement in CAPI prevention. Data from the SEM Scanner, coupled with clinical skill and knowledge, supports decision making, care planning and resource allocation.

SEM Scanner Matrix



Clinical judgement should always be utilised. Review scanning frequency if clinical concerns/deterioration of condition.

Adapted from: Ore N, Carver T (2020) Implementing a new approach to pressure ulcer prevention. Journal of Community Nursing 34[4].

Figure 11: SEM Scanner Decision Matrix utilized by Ore N, Carver T (2020)

Sub-epidermal moisture assessment as an adjunct to visual assessment in the reduction of pressure ulcer incidence[70]

Journal: Journal of Wound Care, 31(3), 208-216. https://doi.org/10.12968/jowc.2022.31.3.208

Authors: Ousey K, Stephenson J, Blackburn J

Study Objectives

The main aim of this study was to statistically analyse real-world Pressure Ulcer Reduction Program (PURP) data to assess the effectiveness of sub-epidermal moisture (SEM) assessment technology as an adjunct to visual assessment, to reduce pressure injury (PI) incidence alongside standard PI care pathways.

Methods

- SEM scanning technology via a real-world pressure ulcer reduction program (PURP) was implemented in 28 global facilities in 12 different care settings.
- 28 institutions were included in 5 countries; UK, Canada, Belgium, Spain and Ireland.
- All patients were at risk of developing a PI.
- PI data was collected pre and post PURP implementation.
- Data was analysed by an independent group of Biostatisticians at the University of Huddersfield, United Kingdom.
- A meta-analysis was conducted at the ward/site level to estimate the effect of PURP implementation and its impact on PI incidence reduction pre and post PURP implementation.
- A sensitivity analysis was conducted to assess the effect of individual wards/sites on the overall results.

Key Results

- PI incidence reductions were achieved in all 28 facilities with no new interventions and no new staff.
- Six (6) sites achieved statistically significant reductions in PI incidence post PURP implementation ($p<0.05$).
- 100% PI incidence reduction was achieved in 19 facilities.
- The **meta-analysis** revealed:
- A statistically significant **3 fold decrease in PI incidence** post-implementation of SEM assessment technology:
  - An overall relative risk (RR) = 0.38 (95% CI 0.26 to 0.56, $p<0.01$), **meaning that the risk of PI incidence post PURP implementation is reduced to one-third of the risk pre-PURP**.
  - A sensitivity analysis of the data revealed no evidence that any individual setting exerted excessive influence on the results – Universal PI incidence reductions independent of the care setting.

"Incorporating such an approach for the strategic management of PI has the potential to enable clinicians to identify developing tissue damage before it is visible on the patient's skin and employ appropriate early interventions to limit the devastating effects that PI can cause to patients in their care."[69]

Study Interpretation

This paper describes the important real-world utility of the SEM assessment technology in daily PI care. This paper in combination with other data published[15,68] establishes the technology as a critical tool for:

- Achieving consistent PI incidence reduction, with very minimal changes to existing facility protocols.
- No new interventions were required and no additional nursing time.
- The study is applicable to all care settings.

Sub-epidermal moisture assessment as a prompt for clinical action in treatment of Pressure ulcers in at-risk hospital patients[71]

Journal: Journal of Wound Care, 31(4), 294-303. https://doi.org/10.12968/jowc.2022.31.4.294

Authors: Ousey K, Stephenson J, Blackburn J

Study Objectives

The aim of this study was to analyse patient-level impact from the real world Pressure Ulcer Reduction Program (PURP) sites to assess the impact of SEM assessment technology when used as a diagnostic tool in the prevention of PI in at risk patients. The data analyses the relationship between SEM delta prompts and nurse practitioner clinical action in terms of patient-level impact including SEM Δ indications at specific anatomies, skin reddening, and interventions provided.

This paper represents a second publication from the University of Huddersfield by Professor Karen Ousey.

Methods

- SEM scanning via a real world PURP program was implemented in 28 global facilities in 12 different care settings.
- Valid data for patient level analysis was obtained from 25 global facilities in 4 countries; UK, Belgium, Spain and Ireland.
- All patients were at risk of developing a PI.
- Data was analysed by an independent group of Biostatisticians at the University of Huddersfield in the UK.
- SEM delta was grouped into 'reddening' via visual skin assessment (VSA) and 'non-reddening' cohorts.
- A SEM delta ≥ 0.6 was considered as a 'prompt' for clinical action or nurse action.
- Diagnostic accuracy of the technology (Sensitivity and specificity curves) was calculated using 'skin reddening' as the gold standard reference test.

Results

- A total of 15,574 patient assessments ('cases') were reported on 1995 patients.
- A SEM Δ ≥0.6, i.e., a prompt for action, was reported in 83.9% (13,071/15,574) patients.

Clinical Action/Nurse Action results

- Nurse action was reported in 35.3% of cases (5494/15,574).
- Where a nurse action was reported, 90% (4944/5494) of the actions were in response to a SEM delta prompt (≥0.6).
- In cases where no prompts were given, no nurse action was reported in 78% cases (1953/2503)

Analysis results for cases without skin reddening (10,203 cases):

- An SEM delta ≥0.6 was reached in 79.8% of cases (8141/10,203).
- Of the 3265 cases where a nurse action was recorded, 86.6% were due to a SEM delta prompt.

Multi-level Modelling Analysis

- The odds of a nurse action when a SEM delta prompt (≥0.6) was given was double the odds of an action when a prompt was not given (odds ratio, OR = 1.99).
- Nurses are twice as likely to act or intervene on a patient with a SEM delta prompt. This was a statistically significant result ($p<0.001$).

Sensitivity and Specificity analysis

- Skin reddening was considered as the reference gold standard for the purpose of this analysis.
- The diagnostic accuracy of SEM assessments (AUC curve) ranged from 62.5% to 66.0% and was statistically significant ($p<0.001$). This exceeds the diagnostic accuracy of clinical judgement.
- These results align with Okonkwo et al. who reported an AUC of 67.1% (95% CI: 60.0–74.6%, $p<0.001$).

Probability analysis

- In cases where skin reddening is not observed, SEM prompts raise the probability of nurse action by 64.9%.
- In cases where skin reddening is observed, SEM prompts raise the probability of nurse action by 48.8%.

Study Interpretation

This study demonstrates that SEM prompts (≥0.6) enable nurses to objectively act on at-risk anatomies. The analysis of the results for cases without skin reddening shows the utility of the device in action. These are cases whereby the current Standard of Care (SOC) and risk assessment tools (RAT's) would have missed and highly likely resulted in PI development. The device identified these patients at high risk of developing and enabled nurses to act on the at-risk anatomies – a direct response to SEM prompts.

The diagnostic accuracy of SEM technology is very robust in real-world conditions and is close to the results reported in formal, controlled clinical studies. This demonstrates the robustness of the technology and its clinical utility in PI care pathways. The SEM assessment technology indicates risk earlier than skin reddening, or diagnosis via VSA as seen in the cases where no skin reddening was observed (64.9% probability). These results demonstrate the need for an objective tool that aids nurses in providing timely interventions. Even when skin redness is observed, nurses tend to act on SEM prompts. Therefore, SEM assessments are more objective and more reliable for early interventions.

Evaluating the Impact on Hospital Acquired Pressure Injury/Ulcer Incidence in a United Kingdom NHS Acute Trust from Use of Sub-Epidermal Scanning Technology[72]

Journal: Journal of Clinical Nursing; 2021; 30.17-18: 2708-17

Authors: Nightingale P, Musa L

Study Objectives

To measure the impact of adding scanning technology to the prevailing standard of care pathway on the incidence of category 2–4 hospital-acquired pressure injury (PI).

Method

A formal, repeatable, pragmatic framework (a study framework designed to mimic routine clinical care and practices in the real-world care settings) was followed to evaluate:

1. The impact on reportable PI incidence
2. The HCP experience-changes in decision making and the interventions prompted by SEM results
3. Health Economic impact

Clinical areas chosen (low mobility and patient population at risk of PI) included:

- Two (2) trauma orthopaedic wards (Ward A and D)
- One (1) medical ward (Ward B)
- 697 patients were enrolled during a 6 month period (February to September 2019)
- A health care assistant (non-qualified support staff) acted as the site monitor
- Patients were scanned daily for a minimum of 3 days
- The study adopted a 3 phase approach: preparation, 6 month PURP period and post-PURP
- No other changes were made to the standard of care (SOC) PI prevention pathway other than the addition of the SEM assessment technology

Inclusion Criteria

- Patients with a Waterlow >10
- Unbroken skin on the heels/sacrum
- Able to be scanned for at least 3 consecutive days
- 18 years or over
- Able to provide verbal consent

Exclusion Criteria

- All patients with a Waterlow <10
- Patients for whom the device was contraindicated

Interventions were implemented in accordance with clinical judgement, Waterlow scores, visual skin assessment (VSA) results, and SEM scanner readings. If no damage was visible, but the SEM deltas indicated damage, interventions were applied.

Results

Across all 4 wards Pre PURP incidence 1.48% – post PURP incidence 0.29%, an overall reduction of 81% (p=0.011 at 95% confidence interval CI: 0.38–1.77).

- 16151 readings.
- >0.6 recorded in 58% (n=9356) – of these 74% (n=6966) reported no visual skin discolouration.
- 42% readings <0.6 only 6% (n=909) noted visual discolouration.
- 100% of all staff said that SEM Scanner was easy to use.
- 83% patients – clinical decision making was impacted by scanner readings.
- Scanning was quick and easy (<5min).

Hawthorne effect: Study design and the hospital's previous focus on PI prevention including the fact that the staff were already trained and focused on PI prevention for more than 1 year suggests the confounding effects of Hawthorne to this study are minimal.

Clinical profile of the SEM Scanner – Modernizing pressure injury care pathways using Sub-Epidermal Moisture (SEM) scanning[16]

Journal: Expert Review of Medical Devices (2021), 18, 833-847.

Authors: Bryant RA, Moore ZE, Iyer V

Study objectives

Primary: A comprehensive review of SEM technology from a device, safety and efficacy perspective.

Secondary: To share the results of the introduction of SEM assessment technology into routine clinical practice.

Methods

- 34 facilities – 31 acute care (AC), 1 hospice care (HC), and 2 community care setting (CC) in 4 countries.
- Cohort of 2,439 patients.
- Scans of heels and sacrum conducted in addition to local prevention protocols of at-risk patients.

Results

- Intervention data collected for 1830 patients across 27 AC sites.
- 90.5% (weighted) Hospital Acquired Pressure Injury (HAPI) reduction.
- 74% reported 0% HAPI/U during the PURP.
- 72% patients received additional interventions as a result of the objective data delivered by the device.
- Clinical decision making was impacted in 69% of cases.
- The HC cohort revealed a 47% reduction in PI incidence rates.
- 27% HAPI reduction was recorded in a CC setting.
- The second community care setting reported a 100% reduction in CAPI – these data were presented separately at EWMA 2020."

Study interpretation

Use of the SEM assessment technology in 31 acute care settings led to a weighted average reduction in HAPI incidence of 90.5% through clinically effective management of at risk patients. Clinicians implemented SEM assessment technology into local pressure injury prevention pathways, the only change being the addition of the SEM assessment technology.

From a real world data perspective, **the SEM assessment technology used in this multicentre evaluation increases reliability and objectivity in an otherwise complex but essential skin and risk assessment platform.** It is a tool that can be deployed at the point of admission for an accurate determination of the risk of HAPI; essential for root cause analysis and for tracking the value of quality initiatives.

Most importantly, with a modest investment in training, SEM analysis can be integrated into existing care pathways rapidly and easily, and utilised by bedside caregivers to provide real time information about tissue integrity.

Health economic studies

The following 2 health economics and outcomes research (HEOR) suggest that SEM assessment technology "when implemented into clinical practice is highly likely to lead to significant financial benefits and cost savings.[18]"

Modelling the cost-benefits arising from technology aided early detection of pressure ulcers[18]

Journal: Wounds International; 2020; 11(1); 12-17.

Authors: Gefen A., Kolsi J., King T., Grainger S., Burns M.

Study objectives

To test the probabilistic and cost-benefit of the SEM assessment technology as an adjunct to standard of practice of visual skin assessments in pressure injury prevention.

A probabilistic model is a graphical map and mathematical representation of all the possible outcomes of a series of related choices in a process e.g. a care pathway. The map weighs possible actions against one another, at junctures of decisions based on the probabilities that these actions will be taken in real-world conditions. Each juncture branches to further possibilities of outcomes and more branches and nodes – this is called a decision tree.

Methods

- The decision trees were used to model the financial benefit of utilising the SEM assessment technology in a pressure injury prevention strategy through an increase in the probability of early detection of a HAPI thus allowing earlier targeted assumptions.
- 2 different decision trees were required for the probabilities of detection and treatment of pressure injuries:
  - For the current standard of care.
  - For the SEM assessment technology as an adjunct to the standard of care.
- The decision tree was the same in both analyses with only the detection probabilities and costs differing at the relevant nodes.
- Two alternate acute hospital scenarios were modelled of lower (1.6%) and higher (6.3%) HAPI incidence rates, under a conservative range of assumptions and input parameters found in the literature.

Key results

- Implementation of the SEM assessment technology as an adjunct to the current care practice of VSAs is highly likely to lead to significant financial benefits and cost savings. For an average NHS Trust with around 41 thousand admissions per annum the estimated total savings for implementing the scanner would be in the range of £0.6 – £3.3 million per annum. These costs reflect:

1. Detection and treatment of non-visible tissue damage (a pre-category 1 injury which is not possible without the SEM.
2. A higher rate of detection of category 1 HAPIs than is possible without the SEM Scanner and, therefore, prevention of potential category 2–4 HAPIs.
3. Avoidance of some unnecessary interventions for patients without HAPIs, due to higher confidence by clinicians to rule out HAPIs with the SEM Scanner readings.

Study interpretation

Using probabilistic modelling, the SEM assessment technology used as an adjunct to the standard of care is likely to lead to significant financial benefits and cost savings. The estimated cost savings could range from £0.3M to £3.3M per annum.

The cost effectiveness of sub-epidermal moisture scanning to assess pressure injury risk in U.S. health systems[6]

Journal: Journal of Patient Safety and Risk management (2020) 0 (0):1-9

Authors: Padula W, Malaviya S., Hu E, Creehan S, Delmore B Tierce J.C.

Study objectives

To evaluate the cost-effectiveness of SEM assessment technology adoption in comparison to existing hospital acquired pressure injury (HAPI) guidelines structured around risk assessments.

Methods

- A Markov cohort model was developed to analyse the cost-effectiveness of SEM Scanners in comparison to existing prevention guidelines, based on current clinical trial data from the U.S. healthcare sector perspective in the acute, acute rehabilitation and skilled nursing facility settings.

Key results

- Integration of SEM Scanners yielded cost savings of $4,054 US Dollars and a 0.35 quality adjusted life years (QALYs) gained per acute admission.
- For every 1000 admissions in high-risk acute care, sub-epidermal moisture scanners could avert around seven hospital-acquired pressure injury-related deaths and decrease hospital-acquired pressure injury-related re-hospitalization by approximately 206 bed-days.

Study interpretation

SEM Scanners are cost effective as a value added component of a pressure injury prevention protocol. Technologies such as the SEM Scanner give providers objective measures of risk.

- "SEM Scanners are a cost-effective means of documenting pressure injury risk."[6]
- "This technology circumvents the high cost of most pressure injuries in facilities and may achieve Return On Investment (ROI) in less than one year."[6]

"SEM Scanners are a dominant strategy compared to standard of care as it lowers costs and increases QALYs"[6]

"This technology circumvents the high cost of most pressure injuries in facilities and may achieve Return On Investment (ROI) in less than one year."[6]

Summary

The SEM assessment technology has been demonstrated as an effective tool supporting the prevention of pressure injury when used as an adjunct to standard of care. The scientific principles, safety, efficacy and clinical utility of the SEM scanner technology are now well established.

The SEM assessment technology provides the ability to act early with clinical interventions to support pressure injury prevention.

Furthermore, its integration into standard care has been demonstrated in a large real world evidence programme in over 2400 patients (by November 2020) in whom Hospital Acquired Pressure Injuries/Ulcers (HAPI/Us) reduced by a weighted average of 90.5% in the acute setting.

Economic modelling using pressure injury reduction data as inputs and to inform assumptions suggest that when the SEM Scanner technology is integrated into standard of care in pressure injury prevention, it is a dominant intervention compared to standard of care and has the potential to deliver increased quality adjusted life years (QALYs).

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