Sub-epidermal moisture assessment as a prompt for clinical action in treatment of pressure ulcers in at-risk hospital patients

Objective: This study assesses anonymous patient-level data on the use of sub-epidermal moisture (SEM) assessment technology as a tool in the prevention of pressure ulceration in at-risk hospital patients.
Method: The relationship between technology-generated prompts for clinical action (patient turning, application of pressure redistributing equipment, heel protection or cream) and consequent clinical action was evaluated using data cross-tabulations (using data aggregated over multiple anatomical sites); in a multilevel model with patients clustered within wards, clustered in turn within hospitals, and controlling for additional patient- and institution-level factors; and using receiver operating characteristic (ROC) analyses of anatomy-specific data. The ability of the SEM assessment technology to detect deep and early-stage pressure ulcers/injuries on specific anatomical areas of a patient's body on admission, earlier than visual and tactile skin tissue assessments (STA), was assessed.
Results: A total of 15,574 patient assessments ('cases') were reported on 1995 patients. Most incidences of nurse action were in response to a prompt from SEM assessments (4944/5494; 90.0%). An SEM delta (Δ)≥0.6 resulted in nurse action in 4944/13,071 cases (37.8%). The multilevel model revealed strong evidence that SEM Δ prompts were significantly associated with nurse action ($p<0.001$; adjusted odds ratio: 1.99).
Conclusion: In this study, SEM assessment technology effectively prompted nurse action moreso than skin reddening diagnosed via trained clinician judgement and STAs. While baseline responses of nurses' actions remained low, with or without SEM Δ prompts, findings verified the 'clinical utility' of SEM assessment technology as an objective prompt for early clinical action over and above existing mechanisms.
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clinical judgement • pressure ulcer • prevention • receiver operating characteristic curves • SEM assessments • skin assessment • sub-epidermal moisture • ulcer • wound • wound care • wound healing

Pressure ulcers (PUs), also known as pressure injuries or bedsores, are a type of hard-to-heal wound associated with significantly adverse clinical and financial implications. They are defined as 'localised damage to the skin and/or underlying tissue, as a result of pressure or pressure in combination with shear'.[1] Their prevention is a prominent aspect of effective healthcare delivery to patients. Health delivery campaigns, designed to improve standards of care (SOC) for patients, evidences the importance of improving this aspect of care and are fundamental to optimising healthcare in the UK National Health Service (NHS), and other health and social care areas. The introduction of the 'Stop the Pressure' programme in 2016, and its core curriculum, was developed to guide wound care education for nurses,[2] and has put the prevention of PUs at the forefront of patient care. The programme was designed to raise awareness, educate staff and develop preventative strategies to reduce PU development, and provides a framework for educating and training clinicians in wound care. Despite the success of the initiative, PUs are still problematic to patient health, with an annual incidence rate of 0.9% in England alone,[3] corresponding to approximately 200,000 people in the UK developing a new PU in 2017–2018.[4] Furthermore, the daily costs for treating patients with a PU are conservatively estimated at £1.4 million,[4] with the majority of this expense stemming from the clinical nursing time involved in treating and caring for this patient group.[5]

PUs are generally preventable, and guidelines from the National Institute for Health and Care Excellence (NICE)[5] state the importance of a comprehensive visual risk assessment of the patient's skin, alongside utilisation of appropriate validated risk assessment scales to identify patients considered most vulnerable. A skin assessment should involve a systematic full body examination, specifically over bony prominences, checking for signs of existing tissue damage and changes in skin condition, such as skin integrity, moisture, rashes and redness.[6] Although this method of risk stratification and diagnosis can be effective for specialists in skin integrity and tissue viability, it can be problematic for more generalist staff, who may not feel

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competent in their decision-making or possess the required experience and knowledge to judge when a patient's skin is deteriorating. Moreover, tissue damage is only visible when significant underlying deterioration has already occurred. Many pre-registration nurses in the UK are known to have limited education and training around tissue viability, and therefore timely diagnosis via skin and tissue assessments and clinical judgement is extremely challenging.[7] This is reiterated by Ayello et al.,[8] who found that 70% of nurses described not receiving enough education about wound prevention and care. A diagnostic latency in employing appropriate preventive strategies severely compromises patients' skin integrity.

The NHS and NICE recognise the importance of education and training in undertaking a visual skin assessment and subsequently deciding on appropriate clinical interventions,[5] but nursing staff still describe not having the competence to confidently identify patients at risk of PUs.[9] This means that employing appropriate clinical action, such as patient turning, application of pressure redistributing equipment, heel protection or cream, for patients at risk of developing a PU, can be delayed or not be implemented at all.

The literature reports sub-epidermal moisture (SEM) assessment technology as an adjunct to the current SOC in the detection of deep and early-stage PUs.[10–13] The technology assesses changes in tissue biocapacitance (evaluation of the electrical properties of the tissues located directly under the integrated sensor) to detect early tissue damage before it is visible on the patients' skin and alerts clinicians to patients who are at an increased risk of developing a PU.[11] Designed to be used as an adjunct to visual assessment and risk assessment scales, this technology prompts nursing action and the employment of early, anatomy-specific interventions, thus limiting the development of potential tissue damage. Providing an objective measure of the early signs of tissue damage means that the SEM assessment technology offers a mechanism to support objective clinical decision-making, empowering clinicians to make informed data-driven decisions about patients in daily practice.

Multiple studies demonstrate the benefits of using the SEM assessment technology in the prevention of PU incidence without a reliance on subjective clinical assessment. Ore et al.[14] found that staff who implemented SEM assessment technology on palliative care patients being cared for in the community reported that the SEM assessments had a positive impact on their clinical decision-making in 40% of the patients scanned and resulted in a 46.7% reduction in hospital-acquired PUs (HAPUs). Similarly, Okonkwo et al.[11] found that this technology identified early developing PUs in at-risk patients in a hospital setting when used by generalists on average five days earlier than specialists using visual skin assessment alone, exemplifying the ability of SEM assessment technology to empower clinicians who may feel less confident in their decision-making to take appropriate action. Raizman et al.[15] found a 93% reduction in HAPU incidence when SEM assessments were used in clinical decision-making to determine appropriate interventions, with staff reporting that using the SEM assessment technology increased their confidence in making such decisions. Other studies have also found that using this technology for PU prevention is associated with reduced incidence in a variety of clinical settings. Smith[16] found timely, anatomy-specific interventions on hospitalised patients considered at risk of skin damage, driven by SEM assessment data, resulted in no patients developing a PU during their stay, despite recording SEM readings that could be indicative of the early signs of pressure damage. Furthermore, Littlefield and Kellett[17] reported a 95% reduction in category 2–4 HAPUs in a sample of 234 patients when SEM assessment technology was incorporated into PU clinical pathways, suggesting that such readings prompted appropriate and early clinical interventions.

Aims

This study assesses the patient-level impact of SEM assessment technology when used as a diagnostic tool in the prevention of pressure ulceration in hospital patients.

Methods

Recent advances in SEM assessment technology have been used to reduce PU incidence alongside standard PU care pathways as an adjunct to the current SOC.[15] A global PU reduction programme (PURP) was implemented to evaluate the clinical impact of incorporating SEM assessment technology into everyday PU prevention care pathways. PURP is a potential tool to reduce incidence of PUs in hospital patients by enabling clinicians to collect data on the inclusion of SEM in clinical practice. PURP programmes are designed using a pragmatic framework to replicate routine clinical practice in daily PU care. The framework and implementation methodology aligns with NICE guidelines described in the Real World Evidence DSU Technical Support Document 17, 2016, and is compliant with the General Data Protection Regulation 2016/679.[18]

Clinicians were trained to perform SEM assessments on the sacrum and heel for at-risk patients. No changes were made to existing standard of PU care or PU protocols, except for the addition of SEM assessments in everyday PU prevention and care practice. Patient risk assessments were performed using risk assessment scales (Waterlow, Braden etc.) and visual assessments as per facility protocols; on admission, periodically as per SOC, and as required by clinician judgment.

Inclusion criteria were:

- A risk assessment score at or above medium risk and all high-risk patients (for example Waterlow >10)
- 18 years of age or older
- Able to provide verbal consent to scanning
- Unbroken skin on the heels and sacrum.

Patients who were unable to provide verbal consent,

and for whom the device was contraindicated, were excluded from the scanning. The PURP was designed as a quality improvement process using a pragmatic framework, to be used in everyday PU care practice with minimal modifications to existing care pathways. The device was used on-label and verbal consent was required before scanning patients. Due to the non-invasive and non-significant risk of use of the device, and a quality improvement-focused study design, these implementation studies were not subject to Institutional Review Board (IRB) oversight and ethics committee approvals.

Anonymised data were collected on assessments reported on patients from 25 facilities in the UK, Ireland, Belgium and Spain between June 2015 and February 2020. For each patient assessment, the following information was recorded: hospital; setting; ward; risk score scale used (if applicable); and risk score (if applicable). Setting type was dichotomised into two categories using the ward classification:

- Category A (including older patients/long-term care, orthopaedic/trauma, rehabilitation, stroke, neurology, medium-to-long-term stay medical and community settings)
- Category B (including general medical, intensive care unit (ICU), mixed surgical, renal, vascular, orthopaedic/short stay trauma, diabetes and palliative settings). Setting type was modelled as a binary indicator variable 'Setting'.

Up to three anatomical locations: the sacrum, left heel and right heel, were considered per patient assessment, with all three locations being measured in the majority of cases. Any skin reddening at each location was recorded as confirmed by trained clinicians (recorded using the binary variable 'Reddening'). The trained clinician made the distinction between blanchable and non-blanchable erythema during their assessment. The SEM delta (Δ) readings of any scan taken at each location were also recorded. Delta readings were coded as high (≥0.6) or low (<0.6); with high delta readings indicating a high risk for developing PUs and a need for subsequent nurse action. A composite measure was derived such that the recording of one or more high delta readings on the SEM assessment technology was considered to act as a prompt for nurse action. This dichotomised variable was modelled using the binary indicator variable 'Prompt'.

Nurse action following the SEM delta reading was also reported. Action could comprise one or more of the following: patient repositioning; transfer of patient to a pressure-redistributing mattress; use of heel boots or heel elevation; use of barrier creams or dressing. A composite measure was derived such that the recording of one or more unambiguous instances of nurse action was considered to represent nurse action. This dichotomous variable corresponding to nurse action was modelled using the binary indicator variable 'Action' and was treated as the primary outcome measure in the analyses.

Table 1. Descriptive summary of sample

Variable	Frequency (valid %)
Hospital (n=15,574)	
Site 1	576 (3.7%)
Site 2	617 (4.0%
Site 3	132 (0.8%)
Site 4	550 (3.5%)
Site 5	67 (0.4%)
Site 6	98 (0.6%)
Site 7	98 (0.6%)
Site 8	91 (0.6%)
Site 9	658 (4.2%)
Site 10	3270 (21.0%)
Site 11	439 (2.8%)
Site 12	385 (2.5%)
Site 13	552 (3.5%)
Site 14	61 (0.4%)
Site 15	187 (1.2%)
Site 16	557 (3.6%)
Site 17	729 (4.7%)
Site 18	508 (3.3%)
Site 19	307 (2.0%)
Site 20	289 (1.9%)
Site 21	330 (2.1%)
Site 22	381 (2.4%)
Site 23	2549 (16.4%)
Site 24	161 (1.0%)
Site 25	1982 (12.7%)
Ward setting (n=15,574)	
Category A	9665 (62.1%)
Category B	5909 (37.9%)
Risk tool used (n=12,618)	
Norton	2097 (16.6%)
Purpose T	552 (4.4%)
Waterlow	7987 (63.3%)
Yes/No	1982 (15.7%)
Risk score recorded where used (n=12,618)	
Score recorded	6444 (51.1%)
No score recorded	6174 (48.9%)
Valid scanner delta reading obtained (n=15,574)	
At sacrum	13,341 (85.7%)
At right heel	14,480 (93.0%)
At left heel	14,208 (91.2%)
Definitive observation of skin reddening at one or more locations (n=15,375)	
Reddening observed	5172 (33.6%)
No reddening observed	10,203 (66.4%)
Consequence of scanner readings at all locations (n=15,574)	
Prompt for nurse action given	13,071 (83.9%)
No prompt for nurse action given	2503 (16.1%)
Consequence of prompt (n=15,574)	
Action taken by nursing staff	5494 (35.3%)
No action taken by nursing staff	10,080 (64.7%)
Variable	**Mean±standard deviation (range)**
Scanner delta reading	
At sacrum (n=13,341)	0.773±1.30 (0–25)
At right heel (n=14,480)	0.836±1.14 (0–22)
At left heel (n=14,208)	0.838±1.18 (0–22)

Table 2. Outcome by prompt status (all cases)

Outcome	Nurse action	No nurse action	Total
Prompt for action (SEM Δ≥0.6)	4944 (90.0%, 37.8%)	8127 (80.6%, 62.2%)	13,071 (83.9%, 100.0%)
No prompt given (SEM Δ<0.6)	550 (10.0%, 22.0%)	1953 (19.4%, 78.0%)	2503 (16.1%, 100.0%))
Total	5494 (100.0% , 35.3%)	10,080 (100.0%, 64.7%)	15,574 (100.0%, 100.0%)

SEM—sub-epidermal moisture; row and column percentages, respectively, are given in brackets after frequency values

Table 3. Outcome by prompt status (cases with no reddening)

Outcome	Nurse action	No nurse action	Total
Prompt for action (SEM Δ≥0.6)	2829 (86.6%, 34.8%)	5312 (76.6%, 65.2%)	8141 (79.8%, 100.0%)
No prompt given (SEM Δ<0.6)	436 (13.4%, 21.1%)	1626 (23.4%, 78.9%)	2062 (20.2%, 100.0%)
Total	3265 (100.0%, 32.0%)	6938 (100.0%, 68.0%)	10,203 (100.0%, 100.0%)

SEM—sub-epidermal moisture; row and column percentages, respectively, are given in brackets after frequency values

Table 4. Parameters from multilevel multiple logistic regression model

Variable	p-value	Odds ratio	95% CI for OR
Prompt (SEM Δ≥0.6 (reference: no prompt given: SEM Δ<0.6)	<0.001	1.99	(1.79, 2.23)
Reddening (reference: no skin reddening observed)	<0.001	1.99	(1.34, 1.57)
Setting (reference: Type 1)	0.801	1.16	(0.38, 3.54)
Risk tool (reference: no tool used)	0.004	6.00	(1.80, 20.0)

CI—confidence interval; OR—odds ratio; SEM—sub-epidermal moisture

Table 5. Parameters from multilevel multiple logistic regression model (skin reddening deleted)

Variable	p-value	Odds ratio	95% CI for OR
Prompt (SEM Δ≥0.6 (reference: no prompt given: SEM Δ<0.6)	<0.001	2.10	(1.89, 2.34)
Setting (reference: Type 1)	0.860	1.11	(0.36, 3.43)
Risk tool (reference: no tool used)	0.005	5.76	(1.71, 19.5)

CI—confidence interval; OR—odds ratio; SEM—sub-epidermal moisture

Statistical methods

An independent retrospective analysis of the dataset was performed in Stata Version 14 I/C (Stata Corp., US) and SPSS (Version 26.0) (IBM Corp., US). The dataset was analysed and summarised descriptively. Nurse action or absence of action in response to the presence or absence of an SEM assessment technology-derived prompt was cross-tabulated for all cases.

The data formed a three-level hierarchy, with patient assessments at the lowest level of the hierarchy (Level 1), clustered within wards at the second level of the hierarchy (Level 2) and hospitals at the upper level (Level 3). To assess the significance of the SEM technology prompt on the probability of nurse action, a multilevel random intercepts multiple logistic regression model was constructed, regressing the binary outcome of nurse action ('Action') on the key variable 'Prompt' acting on Level 1; and controlling for observation of skin reddening ('Reddening') also acting at Level 1, type of ward ('Setting') acting at Level 2, and whether or not a risk-scoring tool was used ('Risk Tool') acting at Level 3. The large proportion of missing risk score data precluded the use of this variable in a multilevel model. However, the presence or absence of a risk tool was available for inclusion in the model.

The variance partition coefficient (VPC) derived in the main model was calculated to assess the relative contributions to residual variance accounted for by variation between patients within wards and hospitals, and by variation between hospitals and between wards within hospitals. However, for binary response models, there is no single VPC measure, since the Level 1 variance is a function of the mean, which depends on the values of the explanatory variables in the model. Hence, a simulation method was used to estimate Level 1 variance for a null model.

The possibility of skin reddening being a contributory cause of nurse action was assessed in sensitivity studies. A cross-tabulation analysis was derived for all cases where skin reddening had not been observed; and a corresponding multilevel analysis excluding the 'Reddening' variable was also conducted.

The discriminatory ability of the SEM assessment technology at each anatomical location was determined by classification tables of SEM Δ≥0.6 and SEM Δ<0.6. Receiver-operating characteristic (ROC) analysis

Table 6. Scanner indications by skin reddening (frequency)

Anatomical location	Prompt status	Reddening	No reddening	Total
Sacrum	Prompt given (SEM Δ≥0.6)	1990	4698	6688
	No prompt given (SEM Δ<0.6)	1204	7567	8771
	Total	3194	12,265	15,459
Right heel	Prompt given SEM Δ≥0.6)	2468	6656	9124
	No prompt given (SEM Δ<0.6)	838	5483	6321
	Total	3306	12,139	15,445
Left heel	Prompt given (SEM Δ≥0.6)	2431	6511	8942
	No prompt given (SEM Δ<0.6)	811	5616	6427
	Total	3242	12,127	15369

SEM—sub-epidermal moisture

Table 7: Sensitivity and specificity for reddening: scanner reading ≥0.6

Anatomical location	Sensitivity	Specificity
Sacrum	62.3%	61.7%
Right heel	74.6%	45.2%
Left heel	75.0%	46.3%

Table 8. Outcome by skin reddening (cases with no SEM delta prompt)

	Nurse action	No nurse action	Total
Reddening observed	114 (20.7%, 29.7%)	270 (14.2%, 70.3%)	384 (15.7%, 100.0%)
No reddening observed	436 (79.3%, 21.1%)	1626 (85.8%, 78.9%)	2062 (84.3%, 100.0%)
Total	550 (100.0%, 22.5%)	1896 (100.0%, 77.5%)	2446 (100.0%, 100.0%)

SEM—sub-epidermal moisture; row and column percentages, respectively, are given in brackets after frequency values

Table 9. Receiver operating characteristics (ROC) parameters

Anatomical location	AUROC	95% CI for AUROC	p-value*
Sacrum	66.0%	(64.9%, 67.1%)	<0.001
Right heel	62.5%	(61.5%, 63.6%)	<0.001
Left heel	62.5%	(61.5%, 63.6%)	<0.001

AUROC—area under the ROC; CI—confidence interval; *assessing the hypothesis that AUROC=0.5

compared the diagnostic utility of SEM assessment technology against skin reddening, as diagnosed by trained clinicians as a confirmatory test, using 'Skin reddening' as the test variable. For each location, an ROC curve was derived, and overall performance was assessed using the area under the ROC curve (AUROC). Sensitivity and specificity were calculated for the set threshold.

Results

Descriptive summary of data

A total of 15,574 patient assessments ('cases') were reported on 1995 patients. Individual patients were assessed on between one and 56 occasions. The median number of assessments per patient was 13 (interquartile range: 7–25 assessments). Multiple assessments conducted on the same patient were assumed to be equivalent to one assessment conducted on the same total number of different patients.

Risk tools were applied in 12,618 (81.0%) of cases. Valid scans were obtained from the sacrum in 13,341 cases (85.7%); from the right heel in 14,480 cases (93.0%); and from the left heel in 14,208 cases (91.2%).

The sample is summarised descriptively in Table 1.

Cross-tabulations of nurse action by prompt and skin reddening

Table 2 shows the numbers of cases of nurse action. Absence of action in response to the presence or absence of an SEM assessment technology-derived prompt was cross-tabulated for all cases, irrespective of skin reddening. The threshold SEM assessment technology delta value for a prompt for action (SEM Δ ≥0.6) was reached in 13,071 out of 15,574 (83.9%) patient assessments.

Nurse action was reported in 35.3% of cases (5494/15,574). In 90.0% of these cases, incidences of nurse action were in response to a prompt from the SEM

Fig 1. Receiver operating characteristic curve for scan readings at the sacrum

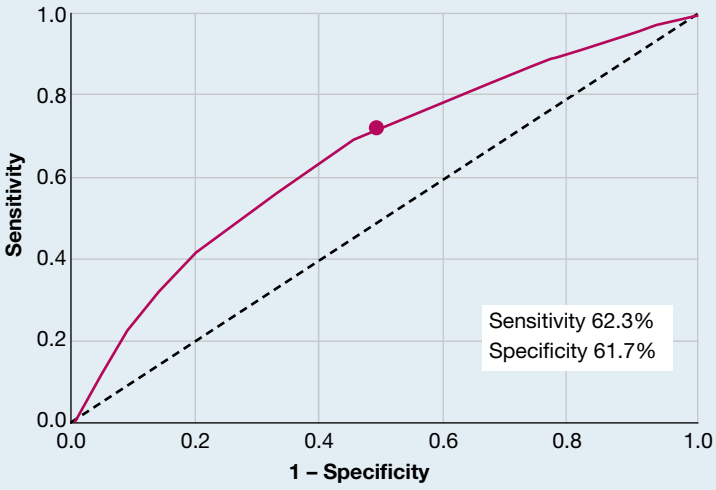
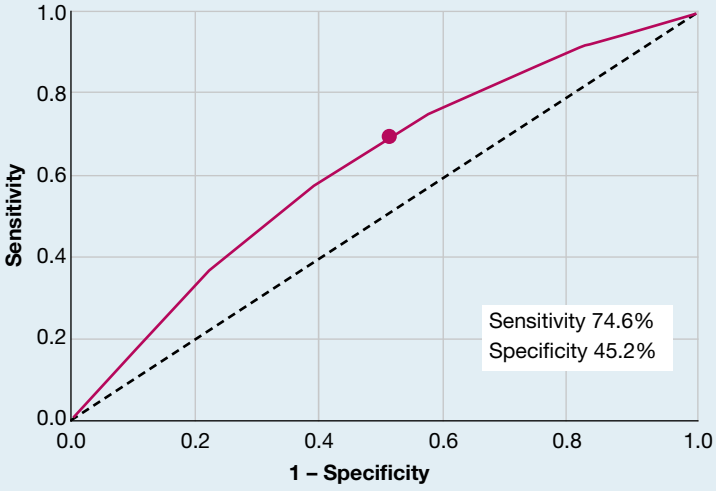


Fig 2. Receiver operating characteristic curve for scan readings at the right heel



assessment technology (4944/5494). In the aggregate, an SEM Δ≥0.6 resulted in a nurse action of any kind in 37.8% of cases (4944/13,071). The majority of cases in which no prompt was given resulted in no nurse action (1953/2503; 78.0%). A positive predictive value (PPV) was defined as an SEM Δ≥0.6 (prompt given) corresponding to a clinical nurse action, whereas a negative predictive value (NPV) was defined as an SEM Δ<0.6 (no prompt given) and no nurse action. Hence on this sample, the PPV of SEM assessment technology was low (37.8%), while the NPV was high (78.0%); based on a prevalence for nurse action of 35.3%. Both PPV and NPV would be expected to be affected by changes in the prevalence statistic.

Table 3 shows the corresponding cross-tabulation for the sensitivity study conducted on all cases where skin reddening had not been observed. Percentages indicate the cases in each cell as a proportion of: (i) total numbers of prompts for action given or not given (i.e., column totals); (ii) total numbers of either nurse action or no nurse action (i.e., row totals). The threshold SEM Δ value for a prompt for action (≥0.6) was reached in 79.8% of patient assessments (8141/10,203).

In this subgroup of cases, 86.6% of incidences of nurse action were in response to an SEM Δ prompt (2829/3265). The PPV was 34.8% (2829/8141) while the NPV was 78.9% (1626/2062), based on a prevalence for nurse action of 32.0%. The similarity to the proportions obtained in the corresponding analysis conducted on all cases revealed no evidence that reddening substantively affected the outcome of SEM Δ prompts.

Multilevel modelling

The multilevel model results demonstrated a significantly strong association of SEM assessment prompts with nurse action ($p<0.001$; adjusted odds ratio (OR): 1.99), indicating that the odds of nurse action when an SEM Δ≥0.6 prompt was given were approximately double the odds of action when a prompt was not given.

The model also revealed strong evidence that, independently, skin reddening and use of a risk tool were both significantly associated with nurse action ($p<0.001$ for skin reddening, adjusted odds ratio: 1.45; $p<0.004$ for use of a risk tool, adjusted odds ratio: 6.00). Setting type was not significantly or substantively associated with nurse action. All model parameter values are summarised in Table 4.

The VPC was evaluated at 24.8%; i.e., 24.8% of residual variance was accounted for by variation between wards within hospitals and between hospitals, leaving 75.2% accounted for by variation between patients within wards and hospitals.

A sensitivity analysis excluding the 'Reddening' variable revealed that the substantive effect of reddening on the scanner prompt was low; suggesting minimal confounding of the effects of a scanner prompt by skin reddening. Model parameters from the sensitivity analysis are summarised in Table 5.

Diagnostic properties

Table 6 summarises the performance of the SEM assessment technology as a prompt for action at each of the measured anatomical sites, by cross-tabulating against skin reddening.

Considering skin reddening to be the 'gold standard' predictor, the sensitivities at each anatomical location associated with the given threshold of SEM Δ>0.6 were calculated and are summarised in Table 7. It is recognised there is currently no validated 'gold standard' predictor for deeper layers; however, a range of campaigns, including the 'React to Red' national UK campaign, identified this as one of the warning signs for potential

skin damage.[19] The SEM assessment allows for an extra measure to be considered during the assessment period. A true positive (TP) was defined as an SEM Δ prompt of ≥0.6 and subsequent skin reddening as diagnosed by trained clinicians via STAs. A true negative (TN) was defined as an SEM Δ<0.6 and no skin reddening. Sensitivity and specificity results were calculated using standard methods as defined by the US Food and Drug Administration.[20]

Sensitivity was higher at the right and left heels than at the sacrum; and specificity was higher at the sacrum than at the right and left heels.

The numbers of cases of nurse action and absence of action in response to the presence or an absence of skin reddening for all cases where an SEM Δ prompt was not given was also cross-tabulated (Table 8).

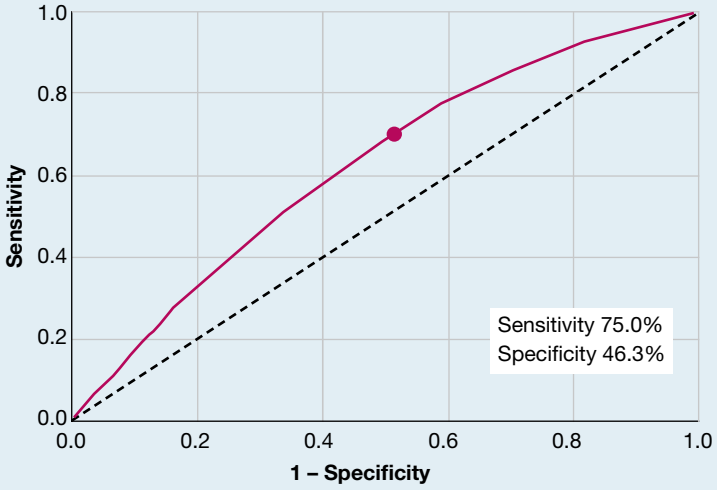
Skin reddening was noted in 15.7% of cases (384/2446) when no SEM Δ prompt was received. In this subgroup of cases, the PPV of skin reddening was 29.7% (114/384). Both values are quite similar to the corresponding values obtained from the entire data set.

ROC analyses conducted to assess the capability of SEM assessment technology readings to discriminate between cases of skin reddening and no skin reddening are illustrated in Figs 1–3.

Parameters from the ROC analyses and AUROC for each anatomical location are summarised in Table 9.

The AUROC statistics demonstrate a slightly higher diagnostic utility of SEM assessment at the sacrum when compared to both heels. As anticipated, the ROC curve and the corresponding AUROC statistic are almost identical in the left heel and right heel (Figs 2 and 3).

Fig 3. Receiver operating characteristic curve for scan readings at the left heel



Discussion

Results from this analysis show that in patients at risk for developing PUs, an SEM assessment prompt (SEM Δ≥0.6) was reached in 83.9% of all reported cases (13,071/15,574). Notably, an SEM Δ prompt was reported in 79.8% (8141/10,203) of all cases where no skin reddening was recorded.

The above finding should be placed in the context of the current standard of PU prevention care pathways, by consideration of what might be expected to occur if the SEM assessment technology were not in place. Risk assessment scales are whole body assessments and do not provide anatomy-specific risk data. Clinical judgement via STAs is subjective and a confirmatory diagnosis of a stage 1 PU is provided only after it visibly manifests on the skin surface.[21] The result is an outdated care pathway that neither enables clinicians to detect early-stage PUs, nor provides anatomy-specific interventions. In other words, the current standard of PU prevention care is not significantly effective in preventing PUs.

In everyday practice, when SEM assessment technology is implemented within existing PU prevention pathways, an SEM Δ prompt (Δ≥0.6) as well as a subsequent clinical diagnosis of skin reddening may be considered as a prompt for nurse action or enhanced interventions. In cases where both skin reddening and an SEM Δ prompt are recorded, either or both prompts may be the cause of any subsequent action, i.e., interventions. Results from this analysis demonstrated that an SEM Δ prompt was a more decisive call for action than skin reddening: in cases where a high SEM Δ reading (i.e., ≥0.6) but no skin reddening was recorded, 34.8% (2829/8141) of cases resulted in nurse action, compared with 29.7% of cases (114/384) in which skin reddening was observed but no SEM Δ prompt was reported. The probability of nurse action was highest (44.2%) in cases where both skin reddening and SEM Δ prompts were recorded; and lowest (21.1%) when neither skin reddening nor SEM Δ prompts were recorded. Specifically, in cases where skin reddening was not observed, the SEM assessment technology prompt raised the probability of nurse action by 64.9%: increasing from 21.1% to 34.8%. In cases where skin reddening was observed, the SEM Δ prompt raised the probability of nurse action by 48.8%: increasing from 29.7% to 44.2%.

The time to an SEM Δ prompt versus confirmatory diagnosis of skin reddening via STAs and clinical judgement was not collected as part of this analysis. Clinical studies in the literature suggest that an SEM Δ prompt (Δ≥0.6) indicates a high risk for developing PUs at a specific anatomy, representing the diagnostic utility of SEM assessment technology in the early detection of developing PUs, even before visible signs manifest on the skin surface.[9,11]

However, this analysis demonstrated that despite an SEM Δ prompt, subsequent clinical interventions (nurse action) did not always follow. A high proportion of patient assessments triggered an SEM Δ prompt, and only about one-third of these prompt instances (34.8%) actually resulted in nurse action. It appears that there is

a gap in understanding the clinical significance of SEM as an early biomarker in detecting early subclinical changes within a specific anatomy before they are visibly diagnosed.

The multilevel model also confirmed the relative importance of the SEM assessment technology compared to skin reddening as a predictor of nurse action, with the odds of action about double (OR: 1.99) in cases where the SEM assessment technology gave an SEM Δ prompt. The AUROC statistics, ranging from 62.5% to 66.0% (95% confidence interval (CI): 61.5–67.1%, p<0.001) exceeded the diagnostic accuracy of nurse practitioner clinical judgement alone.[22] These results align with Okonkwo et al.[23] who reported an AUC of 67.1% (95% CI: 60.0–74.6%, p<0.001) in a blinded study which enrolled 182 intention-to-treat at-risk patients, and reported sensitivities of 82–87% and specificities of 51–88%, with AUCs ranging from 78.0–91.8% (95% CIs: 72.2–88.1%, 84.0–95.4%, p<0.001), exceeding clinical judgement in a second observational study which enrolled 125 subjects with diagnosed PUs and 50 healthy subjects.[11] It is noteworthy that, despite the clinical rigour that is typically seen in formal clinical studies, results from implementing SEM assessment technology in everyday PU prevention practice demonstrate a diagnostic utility that far exceeds standard clinical judgement in detecting anatomically specific early stage PUs.

Data from daily bedside use of SEM assessment technology reported PU incidence reductions ranging from 26.7% to 90.5% in a variety of care settings.[10,16,24–26] These incidence reduction rates may stem from: first, the 'diagnostic effect' of SEM assessments technology detecting more of the right at-risk patients, at a specific anatomy; and, second, the 'intervention effect', namely, early, anatomy-specific interventions being provided at a time when they are more effective in reversing pressure-induced damage. Moreover, these results were achieved with care practitioners choosing to implement additional interventions in one-third of at-risk patients—the diagnostic effect—where SEM values were elevated at specific anatomies. Collectively, these data suggest the need for a serious translational science discussion of an updated care pathway, where SEM assessments, adjunctive to risk assessment scales and clinical judgement, enable care practitioners to act on objective data, on the right patients, on at-risk anatomies. The value-based quality outcome of such a care pathway is a substantial, at scale and sustainable reduction in broken skin PU incidence rates. These results are exciting, particularly in light of the fact that real-world care practitioners achieved these results using existing, readily available interventions and without needing any new staff.

Limitations

Missing data in routine clinical practice, for a variety of reasons, is an intrinsic limitation to collecting real-world evidence. Where site administrators were not able to retrospectively gather data and/or a definitive action was not recorded, these data were conservatively classified as 'no action', including:

- Those indicating that the need for action was assessed but action could not actually be taken, such as 'patient refused' etc.
- Those indicating that although direct patient intervention was not currently possible, intention for action was recorded, such as '[equipment] on order
- Those indicating that equipment was already in situ
- Those indicating absence of equipment noted.

These cases were not removed from the analysis. However, had they been removed, the predictive capability of the SEM assessment technology may have improved slightly. The effect would be expected to be marginal, as the majority of cases could be unambiguously classified as 'action taken' or 'no action taken'.

The odds of an action in response to a risk assessment scale used were about three times higher (OR: 6.0) than in response to an SEM assessment prompt (OR: 1.99). However, data provided for this analysis captured nurse actions in response to using a risk assessment scale alone and not in response to the risk scores. This effect of using risk assessment scales must be considered in light of the fact that:

- All patients included in this analysis were already at risk of developing PUs
- Risk assessment scales are whole body assessments (not anatomy specific)
- Nurse action in response to a high risk assessment score was defined as the standard of PU prevention and care.

In contrast, SEM assessments are anatomy-specific and provide objective SEM Δ prompts for the left heel, right heel and the sacrum. Moreover, a PURP was implemented in all facilities with the primary objective of reducing PU incidence rates using SEM assessment technology as an adjunct, where previous standard care pathways and prevention protocols were not significantly effective. Implementing SEM assessments was the only singular change to the existing SoC protocols.

The multilevel model does not account for the 'clustering' within patients; with multiple assessments being conducted on the same patients. While this is not expected to have any substantive effect on the analytical results, the repeated assessments of the same patients by clinical staff may be suggested as a possible reason for the generally low levels of response to either the SEM assessment technology prompt or skin reddening observation: staff may perceive that after initial action has been taken following the first instance of a prompt on a particular patient, multiple actions conducted on the same patient are not necessary within a certain timeframe, regardless of subsequent prompt instances.

Conclusion

Results from this study align with those in existing literature in advancing the understanding of the clinical

utility of SEM assessments in PU prevention. When implemented daily, at the bedside, as an adjunct, SEM assessments enable objective and improved nurse practitioner clinical judgement with timely, targeted interventions. Health professionals should now consider a translational approach, with a focus on clinical decision-making science, to implementing this technology into everyday PU care pathways. **JWC**

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Reflective questions

- How critical to PU prevention is early anatomy-specific detection of pressure ulcers (PUs) via objective sub-epidermal moisture (SEM) assessments?
- How can SEM delta (Δ) prompts be used as effective prompts for nurse action in the prevention of broken skin PUs?
- When an objective SEM Δ prompt is received, what is the likelihood of action?
- In everyday practice, are SEM assessments more effective in a call for targeted interventions than visual observation (reddening) of the skin? Why?
- How well does SEM assessment technology discriminate between cases of patient skin reddening and non-skin reddening, in deep and early pressure-induced damage?
- How could implementing SEM assessments into everyday care practice enable healthcare practitioners to rethink and update existing PU prevention pathways?