Measuring subepidermal moisture to detect early pressure ulcer development: a systematic review

Objective: The aim was to assess evidence related to the measuring of subepidermal moisture (SEM) to detect early, nonvisible development of pressure ulcers (PUs).
Method: Using systematic review methodology, all quantitative animal and human research studies written in English were considered. In January 2021, PubMed, CINAHL, SCOPUS, Cochrane and EMBASE databases were searched. The primary outcome of interest was the validity of SEM measurement to detect early PU development. The secondary outcome was time to PU detection, sensitivity and specificity of SEM measurement, and the impact of SEM measurements on PU prevention. Data analysis was undertaken using RevMan and narrative synthesis.
Results: A total of 17 articles met the inclusion criteria. In all studies, a consistent abnormal deviation in SEM measurements corresponded with evidence of visual PU development. Time to PU development, explored in four studies, showed earlier detection of PU development using SEM measurement. RevMan analysis identified the mean difference in time to PU development (SEM measurement versus visual skin assessment, VSA) was 4.61 days (95% confidence interval: 3.94–5.28; p=0.0001) in favour of SEM measurements. The sensitivity of SEM measurements was reported in four studies, and scores varied from 48.3% to 100.0%. Specificity was also reported in four studies and scores ranged from 24.4% to 83.0%. The impact of the detection of abnormal SEM measurements on PU prevention was explored by one study. Results showed a 93% decrease in PU rates when staff acted on the results of the SEM readings.
Conclusion: The findings of this review identified that SEM measurement detects PU development earlier than VSA. Furthermore, when staff responded to abnormal SEM measurements, prevention strategies were enhanced, with a subsequent reduction in visible PU development. SEM measurement may therefore be a useful addition to PU prevention strategies.
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ischaemia • pressure ulcer • SEM • skin assessment • subepidermal moisture • visual skin assessment • ulcer • wound • wound care • wound dressing • wound healing

A pressure ulcer (PU) is a localised injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear.[1] External pressure and shear forces result in internal tissue deformations, resulting in two major damage mechanisms that are involved in the development of PUs.[2] Tissue ischaemia, with or without reperfusion injury, and cellular deformation caused by mechanical loading are the most commonly accepted aetiological factors in the development of PUs.[3–5] Lymphatic dysfunction caused by compression or ischaemia is also likely to contribute to PU development.[6]

In the early stages of PU development, inflammation triggered by tissue injury results in increased blood flow to the injured area, causing fluid accumulation below the epidermis.[7] This accumulation of fluid below the epidermis is known as subepidermal moisture (SEM).[7] Increased vascular permeability allows fluid to enter the extravascular space which leads to a build-up of oedema, which is not visible to the naked eye in the initial stages.[8] A change in SEM due to localised oedema or accumulation of interstitial fluid is a biomarker of a developing PU.[9] PU development is usually determined through visual skin assessment (VSA).[10] However, VSA relies on evidence of changes on the skin surface and does not consider what is happening beneath it.[11] This is problematic given that, when the damage becomes visually apparent, it is already too late to prevent the PU, as often the damage has emerged from the deeper layers

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outwards towards the skin surface.[12] SEM is therefore a biomarker that can potentially allow for the detection of PUs before visual damage occurs.[7] There has been a systematic review published previously exploring the use of SEM measurement.[12] The review incorporated four published studies, whereas there are over 17 articles currently published on SEM measurement. We therefore set out to review the updated evidence.

Methods

Research question

What is the ability of SEM measurement to detect early, nonvisible PU development?

Aim

The aim was to assess the use of SEM to detect early, nonvisible PU development.

Study design

A systematic review was undertaken following PRISMA guidance.[13] The primary outcome was the validity of SEM measurement to detect early PU development.

Secondary outcomes were:

- Time to PU detection
- Sensitivity and specificity of SEM measurement
- Impact of SEM measurements on PU prevention.

Inclusion and exclusion criteria

The inclusion criteria were all quantitative original animal and human research studies written in English. Studies focused on the early detection of PUs were included. Studies conducted in a laboratory setting and studies not discussing early detection of PUs were excluded.

Electronic searches

We searched the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library) (latest issue)
- PubMed (1946 to January 2021)
- Ovid MEDLINE (in process and other non-indexed citations) (latest issue)
- Ovid EMBASE (1974 to January 2021)
- EBSCO CINAHL Plus (1937 to January 2021)
- Scopus.

Table 1. Excluded studies

Study	Rationale for exclusion
Moore et al.[7]	Non-eligible study design (literature review)
Oliveira et al.[12]	Non-eligible study design (systematic review)
Peko et al.[16]	Non-eligible study outcome. Study conducted in a laboratory setting
Peko and Gefen[17]	Non-eligible study outcome. Study conducted in a laboratory setting
Gefen and Ross[18]	Non-eligible study design (educational review article)
Gershon and Okonkwo[19]	Non-eligible study outcome (early detection of PU development not discussed)

The keywords used in the search included:

- Pressure ulcer
- Pressure sore
- Decubitus ulcer
- Pressure injury
- Subepidermal moisture
- Assessment tool
- Risk assessment
- Nursing assessment.

Study selection

The article titles were assessed by two authors independently, and the abstracts (when available) were screened for their eligibility, according to the inclusion and exclusion criteria. The full-text versions of relevant studies were obtained, and the same two authors independently screened these against the inclusion criteria. Consensus between the two authors in relation to the studies and the data to be included was obtained through discussion when discrepancies were identified.

Data extraction

Data from the included articles were extracted and entered onto a predesigned table independently by the two authors using the following headings: study name; author; date of the study; setting; sample size; design; outcomes; and limitations.

Data analysis

First, the data were narratively summarised. Then, meta-analysis for the comparison of time to detection of a PU using SEM measurements versus VSA for three of the included studies was undertaken using RevMan (Cochrane Collaboration, UK).[14] Heterogeneity was investigated by calculating the I^2 statistic. Results of comparable trials were pooled using the fixed-effect model. Mean difference (MD) and 95% confidence intervals (CI) were calculated for the continuous outcome. This was followed by quality appraisal and a structured narrative synthesis of all the studies included, based on the outcome measures. All included studies were quality appraised using the Evidence-Based Librarianship (EBL) checklist.[15] This quality appraisal tool assesses the validity, applicability and appropriateness of a study, based on the four main steps of the research process:

- Population
- Data collection
- Study design
- Results.

According to this checklist, if the overall validity of the study (Yes/Total) is ≥75% or ((No+Unclear)/Total) is ≤25% then the study is valid.

Results

Overview of all studies

Fig 1 outlines the flow of articles through the review; six full-text articles were rejected (Table 1), and 17 articles were deemed to meet the inclusion criteria.

Study design

The studies were conducted between 2007[20] and 2020.[9,21–23] All employed an observational design (Table 2).

Study settings

The study settings included: nursing homes;[20,22,24,25,28,29,34] spinal cord injury centres;[26,27] a post-acute care centre;[30] a tertiary hospital;[31] medical/surgical wards;[32,35] a pain clinic;[21] and a paediatric orthopaedic setting.[23] In one study, this was carried out among patients in the Phase 1 clinical setting (medical/stroke) and a Phase 2 setting (admitted to any unit in the hospital from the emergency room).[33] Another study was carried out across six acute care and three post-acute care settings[9] (Table 2).

Study size

The mean sample size was 79±106.4 participants, ranging from 15 participants[30] to 417 participants.[28]

Quality appraisal of included studies

The EBL Appraisal checklist focuses on the four main domains of population, data collection, study designs and results.[15] The assessment of these domains is summarised in Table 3, where validity figures can be found as well as any not reported, or unclear issues identified in each domain.

The mean validity score for all studies was 73±15.8%. The minimum score was 36%,[35] while the highest overall validity was 95%.[22] Of the studies, 53% scored ≥75%, indicating that they were considered valid.[9,21–23,27,28,30,32,34]

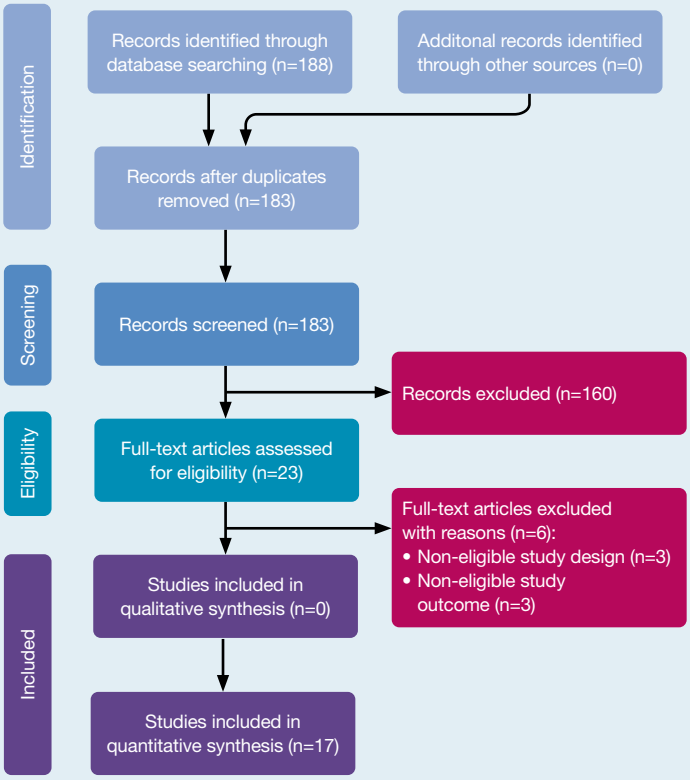
SEM measurement devices

NOVA Petite dermal phase meter: this dermal phase meter (NOVA Technology Corporation, US) was used in five of the included studies.[20,24,25,29,31] Readings are taken by placing the probe on the skin surface for five seconds, after which the impedance value of the skin is displayed in dermal phase units (DPUs). Readings range from 0–999, with higher readings indicating higher SEM.[20]

SEM scanner: eight studies measured SEM using the Sub-Epidermal Moisture Scanner (Bruin Biometrics (BBI), LLC, US).[9,21–23,30,32,33,35] The SEM scanner, a low-frequency, handheld bioimpedance device, uses measures of biocapacitance to assess changes in the tissue of patients with and without PUs. The SEM scanner displays the SEM delta value (Δ), the difference between the highest and lowest readings. In three studies, an SEM delta value of >0.5 was suggestive of the presence of early pressure damage.[22,32,35] Meanwhile, in four studies, an SEM delta value of >0.6 was the cut-off.[9,21,30,33] The SEM cut-off value was not reported in one study.[23]

Dermal Phase Meter: four studies measured SEM using a Dermal Phase Meter (DPM) (MoistureMeter D, Delfin).[26–28,34] The DPM works by measuring the dielectric constant in relation to stratum corneum thickness. Values range from 1–80 dielectric constant (vacuum/air=1; pure water=78.5; normal skin approximately=40), with higher DPM readings indicating higher levels of oedema/inflammation.

Fig 1. PRISMA flow diagram for study selection



Primary outcome

Validity of SEM as a measure of early PU development: O'Brien et al.[32] reported that 40% of patients (19/47) developed a total of 21 Stage 1 PUs, all of which had sustained elevated SEM levels before visual signs of damage became evident. The authors suggested that this indicated 100% sensitivity of SEM readings in predicting PUs.

Okonkwo et al.[9] reported a VSA-PU incidence of 26% (n=48), whereas an SEM-PU incidence of 23% (n=42) was identified. The authors determined that all SEM-positive values preceded or coincided with PU diagnosis by VSA. However, in 12% (n=6) of the cases of a VSA-PU, the SEM measurement was not identified as being abnormal prior to VSA-PU development.

Moda Vitoriano Budri et al.[22] reported a VSA-PU incidence of 12.7% (n=19) and an SEM-PU incidence of 78.7% (n=118). The authors reported that PU detection was 25 times greater using SEM compared with VSA.

Gefen and Gershon[30] determined the VSA-PU rate as 6.7% (n=1). The authors indicated that all participants

Table 2. Study characteristics

Study	Setting and sample	Country	Study design	SEM device
Okonkwo et al.[9]	Inpatient facilities (six acute care and three post-acute care settings (189 participants)	US	Blinded, longitudinal, prospective clinical study	Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC)
Bates-Jensen et al.[20]	Nursing home residents (35 participants)	US	Descriptive cohort study	NOVA Petite dermal phase meter (NOVA Technology Corp, US)
Gershon[21]	Pain clinic (50 participants)	US	Observational study	Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC)
Moda Vitoriano Budri et al.[22]	Nursing home residents (150 participants)	Ireland	Observational, quantitative, prospective study design.	Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC)
Bates-Jensen et al.[23]	Paediatric orthopaedic (24 participants)	Ireland	Prospective descriptive study	Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC)
Bates-Jensen et al.[24]	Nursing home residents (31 participants)	US	Descriptive cohort study	NOVA Petite dermal phase meter (NOVA Technology Corp, US)
Bates-Jensen et al.[25]	Incorporates participants from prior studies (Bates-Jensen et al. 2007,[20] Bates-Jensen et al. 2008[24])	US	Descriptive cohort study	NOVA Petite dermal phase meter (NOVA Technology Corp, US)
Guihan et al.[26]	Spinal cord injury (32 participants)	US	Prospective, single-arm post-test observational design	DPM (MoistureMeter D, Delfin Technologies, Ltd, Finland)
Harrow and Mayrovitz[27]	Spinal cord injury centre (16 participants)	US	Prospective, single-visit, single-rater, observational study	DPM (MoistureMeter-D Delfin Technologies Ltd, Finland)
Bates-Jensen et al.[28]	Nursing home residents (417 participants)	US	Observational	Delfin MoistureMeter D (Delfin Technologies, Ltd, US) dermal phase meter
Kim et al.[29]	Nursing home residents (29 participants)	Korea	Longitudinal observational study	NOVA Petite dermal phase meter (NOVA Technology Corp, US)
Gefen and Gershon[30]	Post acute care centre (15 participants)	US	Observational, prospective cohort pilot study	Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC, US)
Park et al.[31]	Tertiary hospital (22 participants)	Korea	Longitudinal observational study	NOVA Petite dermal phase meter
O'Brien et al.[32]	Medical and a surgical unit (47 participants)	Ireland	Descriptive prospective observational study	SEM Scanner (Bruin Biometrics Europe, Ltd, UK)
Raizman et al.[33]	Phase 1: medical/stroke Phase 2: acute care unit, any unit in the hospital from the emergency room (89 participants)	Canada	Evaluation study	Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC, US))
Bates-Jensen et al.[34]	Incorporates participants from a previously conducted study (Bates-Jensen et al. 2017[28])	US	Observational	Delfin MoistureMeter D (Delfin Technologies, LTD, Greenwich, Connecticut) dermal phase meter
Smith[35]	Medical-surgical ward (35 participants)	UK	Practice evaluation	Sub-Epidermal Moisture (SEM) Scanner (Bruin Biometrics (BBI), LLC)

in the at-risk group exhibited elevated (Δ≥0.6) SEM readings in at least one anatomical location for two or more consecutive days. For one patient (6.7%) who developed a suspected deep tissue injury (sDTI) of the heel during the study, SEM measurements were abnormal two days before VSA.

Bates-Jensen et al.[20] indicated that SEM was responsive to changes in VSA, and a higher SEM predicted a greater likelihood of erythema/Stage 1 PU (odds ratio (OR)=1.26 for every 100 dermal phase units (DPU) increase in SEM, p=0.04). The OR of 1.26 indicated that SEM predicted 26% of the erythema/Stage 1 PUs that developed and were visible on the skin.

Bates-Jensen et al.[24] found that SEM values predicted 32% of the erythema and/or Stage 1 PUs that developed and were visible at the sacrum. The authors reported

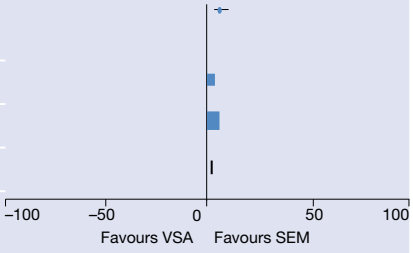
Table 3. Evidence-based librarianship (EBL) quality appraisal checklist domains

Study	Population of study domain	Data collection domain	Study design domain	Results domain	Overall validity
Bates-Jensen et al.[20]	40% inclusion/exclusion criteria, sample size, selection bias	66.6% outcome measure time	60% outcome measure report, research methodology	66.6% external validity, confounding variables	59%
Bates-Jensen et al.[24]	40% inclusion/exclusion criteria, sample size, selection bias	66.6% outcome measure time	60% outcome measure report, research methodology	66.6% external validity, confounding variables	59%
Bates-Jensen et al.[25]	40% inclusion/exclusion criteria, sample size, selection bias	66.6% outcome measure time	60% outcome measure report, research methodology	66.6% external validity, confounding variables	59%
Guihan et al.[26]	40% Inclusion/exclusion criteria, sample size, selection bias	66.6% outcome measure time	80% outcome measure report	66.6% external validity, confounding variables	64%
Harrow and Mayrovitz[27]	80% sample size	43% data collection instrument, outcome measure time, statistics free from subjectivity, service delivery	100%	100%	77%
Bates-Jensen et al.[28]	80% inclusion/exclusion criteria	83.3% data collection instrument	100%	50% recommendations for future research, confounding variables, subset analysis	77%
Kim et al.[29]	40% inclusion/exclusion criteria, sample size, informed consent	43% data collection instrument, outcome measure time, statistics free from subjectivity, service delivery	80% research methodology	66.6% recommendations for future research, confounding variables	56%
Gefen and Gershon[30]	80% sample size	83.3% data collection instrument	100%	83.3% recommendations for future research	86%
Park et al.[31]	60% inclusion/exclusion criteria, sample size	50% data collection instrument, statistics free from subjectivity	80% research methodology	83.3% external validity	68%
O'Brien et al.[32]	80% sample size	83.3% data collection instrument	100%	100%	90%
Raizman et al.[33]	60% inclusion/exclusion criteria, informed consent	50% data collection instrument, statistics free from subjectivity	100%	83.3% external validity	73%
Bates-Jensen et al.[34]	80% inclusion/exclusion criteria	83.3% data collection instrument	100%	50% recommendations for future research, confounding variables, subset analysis	77%
Smith[35]	60% inclusion/exclusion criteria, sample size	16.6% data collection instrument, data collection methods, statistics free from subjectivity, outcome measure time	40% research methodology, ethical approval, outcome measure report	33.3% external validity, subset analysis, confounding variables	36%
Okonkwo et al.[9]	100%	66.6% data collection instrument	80% research methodology	100%	82%
Gershon[21]	80% sample size	83.3% service delivery	100%	100%	90%
Moda Vitoriano Budri et al.[22]	100%	83.3% data collection instrument	100%	100%	95%
Bates-Jensen et al.[23]	80% sample size	83.3% data collection instrument	100%	100%	90%

Fig 2. Forest plot: mean difference in time to pressure ulcer development using SEM versus VSA measurements

Study or subgroup	SEM Mean	SEM SD	SEM Total	VSA Mean	VSA SD	VSA Total	Weight	Mean difference IV, Fixed, 95% CI
Moda Vitoriano Budri et al.[22]	14.4	5.8	118	8.2	6.3	19	4.9%	6.20 (3.18,9.22)
O'Brien et al.[32]	5.5	2.5	31	1.5	1.4	21	39.4%	4.00 (2.94, 5.06)
Okonkwo et al.[9]	7.14	2.17	42	2.24	2.15	48	55.7%	4.90 (4.01, 5.79)
Total (95% CI)			**191**			**88**	**100.0%**	**4.61 (3.94, 5.28)**

Heterogeneity: Chi²=2.73; df=2 (p=0.26); I²=27%
Test for overall effect: Z=13.52 (p<0.00001)



VSA—visual skin assessment; SEM—subepidermal moisture; CI—confidence interval; IV—inverse variance (RevMan)

that a higher SEM predicted a greater likelihood of erythema/Stage 1 PU at the sacrum (OR=1.32 for every 100 DPU increase, p=0.03).

Bates-Jensen et al.[25] reported that SEM identified 88% of the erythema/Stage I PUs. The authors determined that a higher SEM predicted a greater likelihood of erythema/Stage I PU and Stage II PU in people with dark skin tones one week later (OR=1.88 for every 100 DPU increase in SEM; p=0.004).

Guihan et al.[26] found a VSA-PU rate of 69% (n=22). The authors determined that SEM was lowest for healthy skin (39.3±12.6 DPU) and higher for skin where erythema/Stage 1 PU was present (40.8±10.4 DPU).

The study by Harrow and Mayrovitz[27] included 16 participants with spinal cord injury with Stage III or IV PUs. All included participants had an existing PU in this study. A control site of healthy skin was also assessed in each of the study participants. The authors reported that SEM at PU sites was greater by 9.0% than control sites (p<0.05). SEM was higher at sacral locations than ischial at control sites by 20% (p<0.005).

Bates-Jensen et al.[28] examined the relationship between SEM measurements and VSA concurrently, over a 16 week period, over the sacrum and ischium. The authors determined that the incidence of PU was 46% (n=191) in this study. The authors concluded that an SEM value of 39 tissue dielectric constant units predicted 41% of future skin damage while visual ratings predicted 27%, meaning that SEM assessment holds promise as an objective measure of early PU development compared with VSA.

Kim et al.[29] found that SEM values of Stage 1 PU were higher than those of non-PU skin and blanching erythema (p<0.05). The OR of blanching erythema to normal skin was 1.003 (p=0.047) based on SEM readings one week prior, and that of the concurrent SEM value was 1.004 (p=0.011). The OR of Stage 1 PU to normal skin/blanching erythema was 1.003 (p=0.005) based on SEM values one week prior, and OR for concurrent SEM value was 1.007 (p=0.030). SEM measurements were associated with concurrent and future (one week later) skin damage at both trochanters.

Park et al.[31] reported the number of patients with blanching erythema was 45.5% (n=10), those with blanching erythema and category I PU was 22.7% (n=5); and those with blanching erythema and Category II PU was 13.6% (n=3). SEM measurements in Category I PU were higher than those in patients who had no PU or blanching erythema.

Raizman et al.[33] conducted a two-phase study. In Phase 1, patients were given a standard of care (SoC) risk assessment and interventions, and were scanned with an SEM scanner; however, resulting SEM scores were not used to determine interventions. Phase 2 was the same as Phase 1, except the resulting SEM scores were used in conjunction with risk assessment scores to determine appropriate interventions and care planning. In Phase 1, 13.5% (n=12) of patients developed a visible PU. In Phase 2, 1.0% (n=2) of patients developed a visible PU. The authors determined that the use of the SEM measurement resulted in a 93% decrease in PUs. Furthermore, while the breakdown of PU risk assessment score was not given in this paper, the authors have stated that, as a group, the patients in Phase 2 were at higher risk for PU development than those in the Phase 1 group; however, fewer patients in Phase 2 developed a PU compared with patients in Phase 1.

Bates-Jensen et al.[34] reported the incidence of heel erythema and all PU stages as 76% (n=318), PU (all stages, no erythema) was 30% (n=126), incidence of Stage 2 or greater PU was 5% (n=21), and the incidence of Stage 1 PUs was 25% (n=105). The relationship between SEM measurements and future damage was modelled using SEM measurements one week prior to visualised skin damage. Higher SEM was related to future Stage 1 PU and DTI development.

In Bates-Jensen et al.,[23] SEM and VSA-PU were measured in children. The incidence of VSA-PU was 54% (n=13). The authors reported that SEM for blanchable erythema and Stage 1 PU was higher (range: 3.2–3.7 pF), and significant at trochanters and heels (left trochanter: p=0.003; right trochanter: p=0.02; right and left heels: p=0.000). A summary of findings from each study can be found in Table 4 and the percentages of

Table 4. Summary of findings

Study	Anatomical sites assessed	Main findings
Okonkwo et al.[9]	Sacrum Heels	• Early detection of PU by device measurements was analysed using the true positive subset of PU results (i.e., PU diagnosed by SEM delta value ≥0.6 and skin and tissue assessment) • For 42 true positive PUs in the intent-to-treat population, SEM delta value of ≥0.6 occurred 4.7±2.4 days earlier than diagnosis by skin and tissue assessments. • For the sacrum, left heel and right heel, detection by the device preceded diagnosis by skin and tissue assessment by 4.7±2.6, 5.1±2.3, and 4.3±2.4 days, respectively
Bates-Jensen et al.[20]	Right/left trochanter Right/left ischium Right/left buttock Sacrum	• 28 grade 2+ pressure ulcers (PUs) developed in 16 subjects • High subepidermal moisture (SEM)=greater skin damage • SEM measurements were lowest at normal skin: 96.7±122.3; higher for erythema/Grade 1 PU=191.5±187.6; and highest for Grade 2 PU=568.9±319.5 • SEM predicted the development of erythema/Grade 1 PU one week later, OR=1.26 per 100 DPU; OR for predicting PU deteriorating to Grade 2+ was not statistically significant (p≤0.05)
Gershon[21]	Sacrum Heels	• Among the participants, repeated localised measurements did not differ significantly at or around a single anatomic site • The heel had a slightly higher variation than the sacrum, although the variance was <0.6 SEM units, indicating that there is likely no inflammation at these sites in patients who are not at risk for PUs and who show no visual signs of localised tissue inflammation
Moda Vitoriano Budri et al.[22]	Sacrum Heels Anterior part of the head of the humerus (control site)	• The incidence of SEM-PU was 78.7% (n=118) • A total of 43.3% (n=65) of participants were affected in one anatomical site, and 56.7% (n=85) of the participants had an SEM-PU in ≥2 anatomical sites (multisite SEM-PU) • The sacrum was the most frequent anatomical site affected with 58.7% of SEM-PU occurring in this area. No SEM-PUs occurred in the control site • SEM assessment detected PUs on average 8.2 days before they appeared visually on the skin's surface • PU detection was 25 times greater using SEM measurements compared with visual skin assessment
Bates-Jensen et al.[23]	Sacrum Heels Left/right buttock Left/right ischium Left/right trochanter	• Blanchable erythema incidence was 21% (n=5) • Stage 1 PU incidence was 42% (n=10) • DTI incidence was 4% (one sacral DTI) • Stage 2 or greater PU incidence was 4% (one heel stage 2 PU) • For skin that was assessed as normal in this population, SEM for trunk was 2.65–2.76 pF and for heels 2.37–2.41 pF • SEM for blanchable erythema and stage 1 PU was higher (range: 3.2–3.7 pF) and significant at trochanters and heels (left trochanter: p=0.003; right trochanter: p=0.02; right and left heels: p=0.000) • SEM was higher with pain (significant at sacrum and heels)
Bates-Jensen et al.[24]	Right/left trochanter Right/left ischium Right/left buttock Sacrum	• 15 Grade 2+ PUs developed in eight participants • High SEM=greater skin damage • SEM measurements were lowest at normal skin: 104±114; higher for erythema: 185 DPU±138; higher for Grade 1 PU=264±208; and highest for Grade 2 PU=727±287 • SEM was associated with concurrent skin damage and future (one week later) development of erythema/Grade 1 sacral PU
Bates-Jensen et al.[25]	Right/left trochanter Right/left ischium Right/left buttock Sacrum	• 13 participants with light skin tones developed 21 Grade 2+ PUs over 20 weeks; three participants with dark skin tones developed nine Grade 2+ PUs over 20 weeks • 16 PUs developed over sacrum • High SEM=greater skin damage • Normal skin=83.45±100.62; erythema/Grade 1 PU=150.42±128.21; Stage 2+ PU=564.42±368.53 • SEM predicted erythema/Grade 1 PU one week later [95% CI]: light skin tones–OR=1.14 per 100 DPU; dark skin tones–OR=188 per 100 DPU • SEM values predictive of Grade 2+ PUs one week later (95% CI): light skin tones–OR=1.01 [1.001–1.01] per DPU; dark skin tones–OR=1.02 [1.007–1.024] per DPU • SEM threshold values (50 DPU, 150 DPU and 300 DPU) used to detect skin damage [95% CI]: 50 DPU—detected erythema/Grade 1 in dark skin tones [OR=5.3]; 50 and 150 DPU— detected Grade 2+ PUs one week later in dark skin tones [OR=8.5]; 300 DPU–detected Grade 2+ PUs in light skin tones [OR=4.3]
Guihan et al.[26]	Sacrum Buttocks Ischium Trochanter Heels	• 11 participants developed 14 PUs: Stage I (n=7); Stage II (n=3); Stage III (n=2); Stage IV (n=2) • 22 participants developed 66 cases of erythema/Stage I PUs: sacrum (n=7); buttocks (n=17); ischium (n=15); trochanter (n=6); heels (n=21) • SEM values were lowest for normal skin=39.3±12.6 DPU; erythema/Stage I=40.8±10.4 DPU • Sacrum and heels had higher erythema/Stage I PUs occurrence; increased skin damage=increased SEM values
Harrow et al.[27]	Sacrum Ischium	• 16 subjects with spinal cord injury with Grade III or IV PUs at the sacrum or ischium were included • SEM values at the PU site was higher than at the control site by 9.0% ((51.1–46.9)/46.9) (p=0.02) • SEM differed between PU and uninvolved skin at the ischia but not the sacrum (53.0 versus 41.1) (p<0.0005) • SEM was greater for the sacral site than the ischial site (51.4 versus 41.1) (p=0.02)

Table 4. Summary of findings (continued)

Study	Anatomical sites assessed	Main findings
Bates-Jensen et al.[28]	Sacral Ischial tuberosities	• During the study period, 41% of participants (n=173) had no skin damage at any trunk site. Only one DTI was identified on the sacrum or other trunk areas among the 417 participants over the 16 weeks • SEM was lowest for normal skin (37.1 TDC), and significantly higher for erythema (38.4 TDC), stage 1 PUs (39.3 TDC), and stage 2+ PUs (40.1 TDC) at the sacrum (F (3199)=17.22, p<=0.0001) • Mean SEM for participants with normal sacral skin on all observations was similar across Munsell skin tone groups: and 37 TDC (SD 7.7) for those with light skin tones, 38 TDC (SD 7.4) for those with medium skin tones, and 37 TDC (SD 7.3) for those with dark skin tones • The incidence of erythema and all PU stages over the 16 weeks was 52%
Kim et al.[29]	Sacrum Coccyx Both buttocks Both ischia Both trochanters	• SEM values for grade I PU was higher than that of no injury or blanchable erythema • After adjustment with covariates, odds ratios of blanching erythema to normal skin and stage 1 pressure injury (PU) to blanching erythema/normal skin were statistically significant (p<0.05). • OR of blanching erythema to normal skin was 1.003 (p=0.047) by one week prior SEM value, and that of concurrent SEM value was 1.004 (p=0.011) • OR of stage 1 PU to normal skin/blanching erythema was 1.003 (p=0.005) by one week prior SEM value, and that for concurrent subepidermal moisture value was 1.007 (p=0.030) • SEM was associated with concurrent and future (one week later) skin damage at both trochanters
Gefen et al.[30]	Sacrum Heels	• Among the 15 participants (10 women, mean age: 74±10.9 years), there was a consistent agreement between SEM and US when sDTIs existed • For one patient who developed a heel sDTI during the study, SEM readings were abnormal two days before VSA indicated tissue damage and three days before the appearance of a hypoechoic lesion in the US
Park et al.[31]	Buttocks Both ischial tuberosities Both trochanters Sacral Coccyx	• SEM measurements in category I were higher than those in patients who had no PU or blanching erythema • The values were 208.7±76.5 units for Category I PU, 164.8±107.5 units for blanching erythema, and 115.9±32.6 units for normal skin (p<0.001)
O'Brien et al.[32]	Sacrum Heels	• This study set out to explore the relationship between nurses assessment of early PU damage and SEM measurements • 40% (n=19) of the population were classified as having abnormal skin. Among these 19 participants, a total of 21 PUs were identified • All were classified as Stage I (nonblanchable erythema) as per EPUAP grading classification • The most common anatomical location for this pressure damage was the sacrum (81%, n=17), followed by left heel (14%, n=3) and right heel (5%, n=1). In 66% (n=31) of participants the SEM delta readings were abnormal. Of these, 41 had elevated SEM readings, 22 patients had elevated SEM deltas for one anatomical site only, eight had elevation on two sites and one patient had elevated SEM all three sites • Elevated SEM reading at the sacrum was most common (59%) followed by the left heel (29%) and right heel (12%). Correlations were identified as being strong for the sacrum (r=0.65), medium for the right heel (r=0.43) and low for the left heel (r=0.23). On further analysis, the overall correlation for nurses' visual assessment and SEM readings for patients who developed subsequent Stage 1 PUs was conducted, whereby r=0.47 (p=0.001), demonstrating a medium correlation between nurses' visual skin assessment and SEM findings
Raizman et al.[33]	Sacrum Heels	• This study was conducted over two phases • Phase 1: patients were provided standard-of-care risk assessment and interventions and were scanned with the SEM scanner, but the resulting SEM scores were not used to determine interventions. This gave a baseline PU incidence rate • Phase 2: this phase is the same as Phase 1 except the resulting SEM scores were used in conjunction with risk assessment scores to determine appropriate interventions and care planning • In Phase 1, 12 of the 89 subjects or 13.5% developed visible PUs: Stage I (n=4); Stage II (n=6); Stage III (n=1), and deep tissue injury (n=1). In Phase 2, two of the 195 subjects or 1.0% developed visible PUs: Stage I (n=1) and 1 Stage II (n=1) • Patients in Phase 2 were more incontinent, less mobile, and had longer lengths of stay than those in Phase 1. The use of the scanner resulted in a 93% decrease in PU development
Bates-Jensen et al.[34]	Heels	• SEM was similar for right and left heels for those participants with no heel damage over the entire 16 weeks of the study (mean: 29.2 TDC, SD: 5.9 and mean: 29.0 TDC, SD: 5.8, right and left heel, respectively). • SEM at the heels was significantly lower when DTI was observed, compared with those with no damage observed (p=0.007). Compared with DTI, SEM was significantly higher for erythema (both p=0.005)
Smith[35]	Sacrum Heels	• On admission, 91% (n=32) of patients had SEM delta values >0.5 indicating inflammatory changes that without clinical intervention could develop into PUs. However, none of the 35 patients developed a new PU during their inpatient stay

DPU—dermal phase units; OR—odds ratio; CI—confidence interval; DTI—deep tissue injury; PU—pressure ulcer; US—ultrasound; sDTIs—suspected deep tissue injury; VSA—visual skin assessment; TDC—tissue dielectric constant; SD—standard deviation; EPUAP—European pressure Ulcer Advisory Panel

Table 5. Percentages of SEM-PU and VSA-PU

Study	SEM-PU	VSA-PU
Bates-Jensen et al.[20]	SEM predicted 26% of the erythema/Stage 1 PUs that developed and were visible on the skin	Not reported
Bates-Jensen et al.[24]	SEM predicted 26% of the erythema/Stage 1 PUs that developed and were visible on the skin	Not reported
Bates-Jensen et al[25]	SEM identified 88% of the erythema/Stage I PUs that were visible at the sacrum and buttocks	Not reported
Guihan et al.[26]	Not reported	69% (n=22)
Harrow and Mayrovitz[27]	Not reported	All patients had an existing visible PU
Bates-Jensen et al.[28]	Not reported	46% (n=191)
Kim et al.[29]	Not reported	Not reported
Gefen and Gershon[30]	Not reported	6.7% (n=1)
Park et al.[31]	Not reported	Blanching erythema= 45.5% (n=10) Blanching erythema and category I PU=22.7% (n=5) Blanching erythema and category II PU=13.6% (n=3)
O'Brien et al.[32]	66% (n=31)	45% (n=21)
Raizman et al.[33]	Not reported	Phase 1: 13.5% (n=12) Phase 2: 1% (n=2)
Bates-Jensen et al.[34]	Not reported	Heel erythema and all PU stages=76% (n=318) PU (all stages, no erythema)=30% (n=126) Stage 2 or greater PU=5% (n=21) Stage 1 PU=25% (n=105)
Smith[35]	91% (n=32)	0% (n=0)
Okonkwo et al.[9]	23% (n=42)	26% (n=48)
Gershon[21]	0% (n=0)	0% (n=0)
Moda Vitoriano Budri et al.[22]	78.7% (n=118)	12.7% (n=19)
Bates-Jensen et al.[23]	Not reported	54% (n=13)

SEM—subepidermal moisture; PU—pressure ulcer; VSA—visual skin assessment

SEM-PU and VSA-PU in each of the included studies can be found in Table 5.

In two studies, none of the patients developed a VSA-PU, meaning that comparative data could not be presented between SEM-PU and VSA-PU development.[21,35] Smith[35] included 35 patients in a single medical–surgical ward. On admission, 91% (n=32) of patients had delta values >0.5 indicating inflammatory changes that without clinical intervention could develop into PUs. However, none of the 35 patients developed a new PU during their stay. Gershon[21] determined whether levels of SEM from repeated measures at a localised area confirmed the absence of a PU in healthy participants. The authors reported that repeated measurements did not differ significantly at or around a single anatomical site. The heel had a slightly higher variation than the sacrum, although the variance was <0.6 SEM units, indicating that there was likely no inflammation at these sites in patients who were not at risk for PU.

Secondary outcomes:

Time to PU development: four studies reported on time to visual PU development versus SEM-PU development (Table 6).[9,22,30,32]

A meta-analysis included three studies;[9,22,32] one study was not considered appropriate for meta-analysis as only one patient developed a PU.[30] Fig 2 outlines the forest plot of the mean difference (MD) in time to PU development using VSA versus SEM measurements. As can be seen, the MD in time to PU development was 4.61 days (95% CI: 3.94–5.28; p=0.00001) in favour of SEM measurements.

Sensitivity and specificity of SEM measurement: four studies reported on the sensitivity of SEM measurements.[9,22,32,34]

In Bates-Jensen et al.[34] the sensitivity ranged from

Table 6. Time to pressure ulcer development (SEM versus VSA)

Study	Difference in time to PU development, days	Day of detection (VSA)	Day of detection (SEM)
Bates-Jensen et al.[20]	Not reported	Not reported	Not reported
Bates-Jensen et al.[24]	Not reported	Not reported	Not reported
Bates-Jensen et al.[25]	Not reported	Not reported	Not reported
Guihan et al.[26]	Not reported	Not reported	Not reported
Harrow and Mayrovitz[27]	Not reported	Not reported	Not reported
Bates-Jensen et al.[28]	Not reported	Not reported	Not reported
Kim et al.[29]	Not reported	Not reported	Not reported
Gefen and Gershon[30]	2 days	Day 3	Day 1
Park et al.[31]	Not reported	Not reported	Not reported
O'Brien et al.[32]	4 days	5.5±2.5 days	1.5±1.4 days
Raizman et al.[33]	Not reported	Not reported	Not reported
Bates-Jensen et al.[34]	Not reported	Not reported	Not reported
Smith[35]	Not applicable	Not applicable	Not applicable
Okonkwo et al.[9]*	4.9±2.54 days	7.14 days (min: 3 days, max: 13 days; SD: 2.27 days)	2.24 days (min: 1 day, max: 10 days; SD: 2.15 days)
Gershon[21]	Not applicable	Not applicable	Not applicable
Moda Vitoriano Budri et al.[22]	8 days	14.4 days (min: 3 days, max: 20 days; SD: 5.8 days)	8.2 days (min: 1 day, max: 18 days; SD: 6.3 days)
Bates-Jensen et al.[23]	Not reported	Not reported	Not reported

SEM—subepidermal moisture; VSA—visual skin assessment; PU—pressure ulcer; *Not reported in paper. The author was contacted and results provided; min—minimum; max—maximum; SD—standard deviation

48.3% (left heel DTI) to 60.8% (left heel Grade 1 PU). O'Brien et al.[32] and Moda Vitoriano Budri et al.[22] reported 100% sensitivity of SEM measurements in predicting PU development. Okonkwo et al.[9] reported a sensitivity of 87.5% (95% CI: 74.8–95.3%). Across these four studies the mean sensitivity was 72.07±23.05%; minimum (min)=48%; maximum (max)=100% (Table 7).

The specificity of SEM measurements was reported in four studies.[9,22,32,34] O'Brien et al.[32] reported a specificity of 83% (95% CI: 75.44–89.51%), whereas Bates-Jensen et al.[34] reported specificity ranging from 47.2% (right heel Grade 1 PU) to 65% (DTI right heel). Okonkwo et al.[9] reported a specificity of 33% (95% CI: 28.3–37.8%), whereas Moda Vitoriano Budri et al.[22] reported a specificity of 24.4%. Across the four studies the mean specificity was 51.96±20.20%; min=24.40%; max=83.33% (Table 7).

Impact of SEM assessment on PU prevention: one study reported the impact of measuring SEM on PU rates (Table 8).[33] In Phase 1, patients received a SoC risk assessment and interventions. The patients were also scanned with the SEM scanner; however, the resulting SEM scanner scores were not used to determine interventions. In Phase 2, patients received the same care as outlined in Phase 1; however, the resulting SEM scores were used in conjunction with risk assessment scores to inform care. In Phase 1, 12 of the 89 subjects (13.5%) developed a visible PU. In Phase 2, two of the 195 subjects (1.0%) developed visible PUs. The use of the SEM scanner resulted in a 93% decrease in PU rates. It is important to consider PU risk between these groups under investigation in Phase 1 versus Phase 2. While the breakdown of PU risk assessment score is not given in this paper, the authors have stated that as a group, the patients in Phase 2 were at higher risk for PU development than the Phase 1 group; however, fewer patients in Phase 2 developed a PU compared with patients in Phase 1.

Discussion

SEM and VSA measure two separate processes. SEM is a biophysical marker and is a product of plasma leak after the inflammation process increases local vasculature permeability.[36,37] When tissue damage progresses to a greater number of cells, the inflammatory markers increase along with the plasma leakage through the blood vessels. SEM, that started as microscopic oedema, grows to a macroscopic level and becomes detectable on imaging and later by visual observation. Evidence from

Table 7. Sensitivity and specificity of SEM

Study	Sensitivity	Specificity
Bates-Jensen et al.[20]	Not reported	Not reported
Bates-Jensen et al.[24]	Not reported	Not reported
Bates-Jensen et al.[25]	Not reported	Not reported
Guihan et al.[26]	Not reported	Not reported
Harrow and Mayrovitz[27]	Not reported	Not reported
Bates-Jensen et al.[28]	Not reported	Not reported
Kim et al.[29]	Not reported	Not reported
Gefen and Gershon[30]	Not reported	Not reported
Park et al.[31]	Not reported	Not reported
O'Brien et al.[32]	100.00% (95% CI: 83.89–100.00%)	83.33% (95% CI: 75.44–89.51%)
Raizman et al.[33]	Not reported	Not reported
Bates-Jensen et al.[34]	• Right heel Stage 1 PU sensitivity of 58.6% • Left heel Stage 1 PU sensitivity of 60.8% • DTI right heel sensitivity of 49.3% • Left heel DTI sensitivity was 48.3%	• Right heel Stage 1 PU specificity of 47.2% • Left heel Stage 1 PU • Specificity of 47.5% • DTI right heel specificity of 65% • Left heel DTI specificity of 63.4%
Smith[35]	Not reported	Not reported
Okonkwo et al.[9]	87.5% (95% CI: 74.8–95.3%)	32.9% (95% CI: 28.3–37.8%)
Gershon[21]	Not reported	Not reported
Moda Vitoriano Budri et al.[22]	100%	24.4%
Bates-Jensen et al.[23]	Not reported	Not reported

SEM—subepidermal moisture; CI—confidence interval; PU—pressure ulcer; DTI—deep tissue injury

this current review supports the use of SEM measurement in the early detection of unseen PUs. SEM measurement can detect PUs up to eight days before visible pressure ulceration appears.

In order to assess the ability of SEM measurement as a tool to determine PU development, sensitivity and specificity values were reported in this review. Sensitivity scores varied from 48.3%[34] to 100%.[32] Specificity scores ranged from 24.4%[22] to 83%.[32] These findings further support the idea that SEM measurements can be used as a biophysical marker of early pressure ulceration.

The sensitivity and specificity data presented in four studies lends itself to this discussion.[9,22,32,34] It has been suggested that a true-positive occurs when there is an elevated SEM measurement combined with a visible PU, meanwhile, a false-positive is said to occur when there is an elevated SEM measurement without visible PU development.[9,32] A key question arising from this review, is whether an elevated SEM in isolation, without the presence of a visual PU, is in fact a false-positive. Both sensitivity and specificity are influenced by preventive measures. It could, therefore, be suggested that there is a need for further randomised controlled trials that prospectively examine groups of patients over a period of time. While one of the included studies in this review evaluated the clinical utility of SEM measurement among patients in two phases, there was no randomisation process, which is a limitation.[33]

Methodological quality

The EBL Appraisal checklist was used to evaluate the methodological quality of the included studies.[15] All studies employed an observational design. Participants were selected conveniently, exposing the potential for selection bias, meaning that there was a risk that participants in the studies did not fully represent all populations at risk of PU development.[38] Furthermore, the observational nature of the data collection lends itself to bias in outcome assessment. The challenge here is that there can be over- or underestimation of the effect size.[39] Furthermore, the instruments used were not homogenous, and thus, there was also inconsistency in how the outcomes were measured which challenged the ability to synthesise the data.

Limitations

The main limitation of this systematic review was the broad methodological heterogeneity of the studies, which prevented comparison between studies. Furthermore, this heterogeneity meant that

Table 8. The difference in pressure ulcer (PUs) grades from Phase 1 to Phase 2

Number of PUs	Phase 1	Phase 2
Grade 1	4	1
Grade 2	6	1
Grade 3	1	0
Grade 4	0	0
Deep tissue injury	1	0

meta-analysis could not be completed for all of the outcomes of interest. Different devices exist to measure SEM and, in this review, three devices were used. This made it difficult to synthesise the data and make comparisons between studies. Furthermore, SEM cut-off values differed between studies making it difficult to comparatively assess results between studies.

Conclusion

The purpose of this study was to determine if measuring SEM enables the detection of early non-visible PU development. This review incorporated 17 studies, thus adding to the existing knowledge available to further compound the validity of SEM measurements as a method of detection for early non-visible PU development. Intervening when abnormal SEM deltas are identified, yielding clinical benefit in terms of PU reduction, was demonstrated by one study. Despite this positive outcome, it is necessary to complete further clinical studies on the measurement of SEM alongside enhanced skincare interventions, to further validate if SEM measurement can impact PU development. **JWC**

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Reflective questions

- What is the role of subepidermal moisture (SEM) in the development of pressure ulcers (PU)?
- What do you think are the limitations associated with current methods of PU detection in the clinical setting?
- Would you consider using SEM as a tool to predict PUs in the clinical setting?

notes