LITERATURE REVIEW

Moisture accumulation detection technologies for identifying pressure injuries: a literature review

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Abstract

Background Recent prevalence rates of 9% in Australia indicate that pressure injury (PI) remains a significant problem. The current methods used to detect PI are limited and can be imprecise and subjective. More recently, technology has been used in clinical practice to aid in detecting PIs.

Aim The purpose of this literature review was to describe the effectiveness of two moisture accumulation detection technologies – ultrasound imaging and subepidermal moisture (SEM) – for identifying the early development of PI in comparison to the standard visual skin assessment (VSA).

Methods A systematic search of MEDLINE, CINAHL and Embase databases was undertaken using MeSH terms. The quality of the research was evaluated using a Mixed Method Appraisal Tool (MMAT).

Results We identified five SEM and two ultrasound studies. Our findings suggest that both bedside technologies can be effective for identifying and preventing PI. However, the SEM scanner identified abnormal tissue pathology 2 days before ultrasound indicated signs of PI.

Conclusion The evidence suggests that the use of the SEM scanner may lead to a reduction of PI and a decrease in PI progression. However, there is a need for wider testing of the SEM scanner to establish optimal protocols for use in practice.

Keywords early wound detection, point of care technologies, pressure ulcer, prevention

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Introduction

Pressure injuries (PI) carry a heavy burden on the healthcare system and on the psychological wellbeing of the patients who experience them[1]. The direct costs of treating PI in the Australian public hospital system in 2020 was reported at A$9.11 billion per annum[2] and, for the individual, the development of a PI can contribute to significant psychological stress and lower health-related quality of life (HRQoL)[3]. Highlighting the severity of this issue, the most recent worldwide prevalence rates of hospital-acquired PIs ranges from 6.0–18.5%[1]. Of these, the sacrum (37.3%) was the most common anatomical location for PI development, followed by heels (29.5%) and hips (7.8%)[4].

There are four classifications for PIs: Stage I (non-blanchable erythema of the skin), Stage II (partial thickness loss of skin), Stage III (full thickness loss of skin) and Stage IV (full thickness skin and tissue loss with exposure of bone, tendons and muscles)[5,6]. Overall, there is no single risk factor that can explain why some individuals are at higher risk of PI development. Rather, there are a combination of potential aspects of an individual's context that can result in the development of PI[7]. Some of these include mobility, perfusion status, malnutrition, BMI and changes in skin characteristics and cellular regeneration that occur more commonly in older patients[7].

PI are the result of external mechanical loading leading to cellular hypoxia and eventually tissue death[8]. The aetiology of PI development has become better understood in recent years. As a cell becomes deformed, intracellular fluid leaks into the interstitial space, changing the pH of the tissue, leading to tissue death[9]. This physiological process occurs often before visual or tactile changes are visible on the skin[10]. In clinical practice, the current 'gold-standard' for detecting tissue damage relies on visual skin assessments (VSA), a method that is criticised for being subjective and qualitative, adding to its lack of precision[11]. Technologies that can identify tissue damage under the skin prior to visual changes may potentially fill this gap in practice[12]. Over the past decade, there is an emerging market for bedside technology which offers point of care clinicians a quantitative biomarker for potential tissue damage[13]. These technologies could be used as an adjunct tool that provides clinicians with a quantitative value to prospectively assess the potential of PI development[12]. This review of the published literature examines two non-invasive bedside technological methods for identifying impending tissue damage – SEM and ultrasound imaging.

The Bruin Biometrics subepidermal moisture (SEM) scanner device – the Provizio® SEM Scanner – is the first Food and Drug Administration (FDA)-authorised risk assessment device for PI prevention[14]. The SEM scanner utilises electromagnetism to quantitatively measure the biocapacitance of tissue in the subepidermal layer[10]. Biocapacitance refers to the level of ease an electrical current can pass through the cell membrane and into the intracellular space[15]. The SEM scanner reports the individual biocapacitance of the subepidermal tissue as a unitless value[16]. The SEM value is a quantitative reading that indicates the degree of localised oedema and potential tissue damage expected at the scanned site in comparison to healthy tissue[13]. While the SEM scanner utilises biocapacitance to detect localised oedema in the subepidermal tissue[17], ultrasound imaging uses high frequency sound waves to identify abnormalities in the soft tissue[12]. High frequency ultrasound imaging refers to ultrasound probe frequency above 10 MHz[12]. Ultrasound imaging of this frequency is used to identify abnormalities in the underlying dermal structures[12]. The review aims to evaluate ultrasound imaging and SEM for identifying the incidence of PI in comparison to the standard VSA.

Methods

The quality of a literature review depends on the rigour and consistency of the systematic methods used to execute database searches, data extraction, synthesis and quality appraisal[18]. The 2020 Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines were used to guide this review (Figure 1) and facilitated the transparent reporting of what and how the studies were identified and selected[19]. Full text articles were critically appraised with a structured approach using a Mixed Method Appraisal Tool (MMAT)[20]. We used a narrative approach to summarise the existing literature on two bedside technologies currently used to detect PI. The rigour of this review is reflected in the detailed research strategy and the transparency of the methodology.

Problem identification

The clinical problems that guided this review include: (1) tissue damage, as a result of prolonged pressure, occurring on a cellular level prior to visible changes being seen on the skin, and (2) the subjectivity of VSA in recognising the early stages of a pressure injury. These problems shaped the following research question: *What is the most accurate method for detecting incidence of PI in adults in comparison to visual skin assessments?*

Search strategy

With the assistance of a health librarian, a search of the literature was carried out in September 2021 using the three following databases – Medical Literature Analysis and Retrieval System Online (MEDLINE), Cumulative Index of Nursing and Allied Health Literature (CINAHL) and Embase. Medical Subject Heading (MeSH) terms and key words were used in conjunction with Boolean operators (AND, OR) to identify relevant literature. The search terms used are presented in Table 1.

Studies published from 2011 onwards were included if they satisfied the following inclusion criteria:

- Peer-reviewed research.
- Primary quantitative studies, including pilot studies.
- Primary research published in English.
- Published between 2011 and 2021.
- Adult patients ≥18 years in acute medical/surgical and aged care facilities.
- Used bedside PI detection technologies based on quantification of moisture accumulation or oedema, i.e., SEM and ultrasound, any brand or device.

Studies were excluded based on the following criteria:

- Reviews, editorials, letters, posters, conference presentations and clinical practice guidelines.
- Patients with existing PI.
- Community settings.
- Pregnant women.
- Alternate bedside PI detection technologies (i.e., thermography, alternative light sources, spectrophotometry) were excluded because they do not detect PI using moisture accumulation or oedema.

Selection of studies

Using Rayyan, a reference management tool, the primary author (MB) imported all references and removed duplicates. Following this process, two researchers (MB, BG) independently screened titles and, where available, abstracts, and excluded articles if they did not contain

relevant data. A third researcher (SL) was available to assist adjudicating any differences of opinion. Full text versions of potentially relevant articles were screened against the inclusion criteria.

Data extraction and presentation

Data extraction of eligible studies was first undertaken independently by two researchers (MB, SL), with the information compared to ensure accuracy and completeness. A third researcher (BG) reviewed the data extraction for accuracy. Included studies were classified into two categories based on the method of PI detection: (1) Ultrasound imaging and (2) SEM scanner. Key items for data extraction were guided by the proposed research question and presented in tabular form. A data extraction table collated the date of publication, authors' names, study aim(s), design, setting, sample size, PI identification procedure, and main findings.

Quality appraisal

A structured Mixed Methods Appraisal Tool (MMAT)[20] was used to assess the methodological quality of the included studies. The MMAT checklist was chosen to evaluate the methodological strengths and limitations of the individual studies[20]. The MMAT allows qualitative, quantitative and mixed methods studies to be appraised with one checklist[20]. Each study was rated 'Yes' or 'No' using the questions in the appropriate study design category. If information was not reported, the 'Can't tell' response was given[20]. As with any appraisal tool, the subjective nature of decision-making can affect validity[21]. Therefore, to improve the objectivity in assessment and inter-rater reliability of the MMAT checklist, two researchers independently rated the studies (MB, SL).

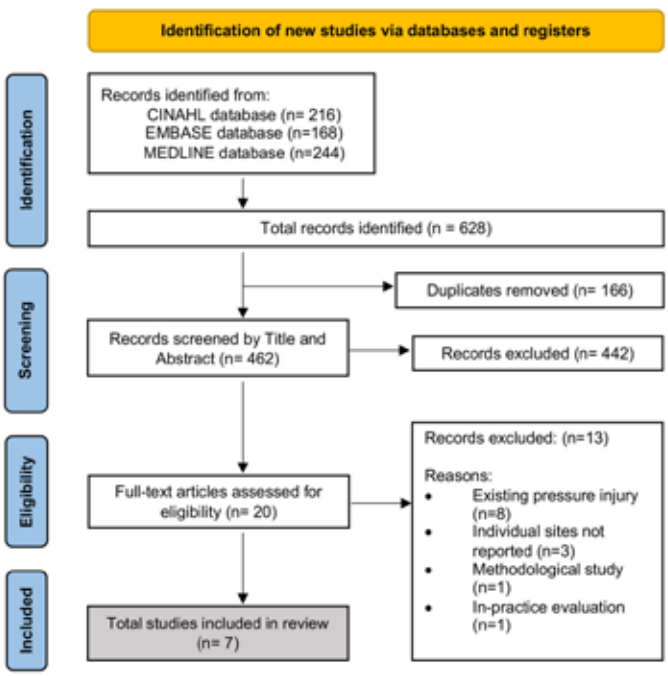

Figure 1. PRISMA flow diagram of search outcomes[19]

Results

The initial database search identified 628 articles (Figure 1). After removing duplicates (n=166) and assessing records for eligibility, seven articles met the inclusion criteria (Figure 1)[22–27]. These studies compared the use of the SEM scanner (n=5)[23–25,27,28] and/or ultrasound devices (n=2)[22,26] to standard VSA for identifying early signs of tissue damage and were accessible for bedside use. Figure 1 presents the PRISMA flow diagram.

Study characteristics

Of the included studies, six were observational[22–24,26–28] and one was a non-randomised controlled study[25]. Most studies were conducted in long-term care facilities[27,28] or acute hospital settings[22–25]. The mean sample size was 102 participants (range: 9–284)[22–27]. Most studies were conducted in Ireland[23,28] and the United States of America[22,24]. In the six studies that reported patient socio-demographics, the average age was 76.7 years, with the majority of patients being female (n=291, 67%)[22–24,26–28].

Category 1: ultrasound imaging

Ultrasound uses a transducer to emit and detect high frequency sound waves[12]. The sound waves can identify tissue boundaries and produce a two-dimensional image used for diagnosing soft tissue abnormalities[12]. Of the two studies

Table 1. Search strategy: keywords and MeSH terms used for literature review

Concept / keywords†	MeSH terms¥
Pressure ulcer	
• Pressure adj (ulcer* OR injur* OR sore*) • Pressure injur* • Pressure ulcer* • PI OR PU • Bedsore* OR "bed sore*" • Decubitus adj (ulcer* OR sore*)	Pressure Ulcer (Subject Heading) exp
Diagnostic tool	
• SEM • Subepidermal moisture • Sub-epidermal moisture • Sub epidermal moisture • SEM scan* • SEM device* • Bioimpedance • Ultrason* • Ultrason* image* • Visual skin assessment • VSA	Ultrasonography (Subject Heading) exp

† used in MEDLINE, CINAHL and Embase Library
¥ used in MEDLINE
* truncation symbol

Table 2. Included ultrasound studies (n=2)

Study aim	Design	Sample & setting	Brand of device used	PI identification procedure	Anatomical sites	Main findings
Gefen & Gershon, 2018[22] • United States of America						
To evaluate consistency between SEM and ultrasound examinations of sDTI	Single centre, observational, prospective cohort pilot study	n=15 (males=5, females=10). Age: mean 74 years (±10.9 years); post-acute care setting	Mindray M7 Ultrasound and Bruin Biometrics SEM Scanner 200 device	VSA, SEM and ultrasound assessments were performed daily for a minimum of 3 and maximum of 10 consecutive days. SEM readings of Δ≥0.6 over 2 consecutive days were considered abnormal	Left/right heel, sacrum	• One patient developed a heel sDTI, with abnormal SEM readings recorded 2 days prior to visible tissue damage and 3 days before a hypoechoic lesion was detected using ultrasound • 100% agreement rate on ultrasound and SEM measurements of all subepidermal lesions
Schäfer et al, 2015[26] • Germany						
To assess whether ultrasound elastography can measure changes in dermal and subcutaneous tissue stiffness during prolonged loading	Exploratory, observational study	n=9 (females). Age: mean 70.1 years (±4.8 years); dermatology clinic	ACUSON S2000 Ultrasound	A standardised lying protocol was followed. Ultrasound measurements were taken at baseline, after 90 minutes, and after 150 minutes of continuous supine positioning	Lateral heel over the calcaneus, sacrum, and upper back area	• Baseline skin and subcutaneous tissue stiffness was highest in the heel (2.7m/s) respectively and lowest in the upper back skin (1.9m/s) and tissue (1.3m/s) • After 90 and 150 minutes of loading there was a mean stiffness increase of the heel skin (p=.431) and a stiffness decrease of heel tissue (p=.140)

evaluating the effectiveness of ultrasound imaging for detecting changes in the subepidermal layer in comparison to VSA (Table 2), both reported tissue property changes[22,26]. Ultrasound imaging was performed by a trained technician in both studies on the sacrum and left and right heels; Schäfer et al[26] included scans from the upper back.

One study used a female-only sample. Sample sizes were small in both studies (range: 9–15 participants) and only the study by Gefen and Gershon[22] collected participant demographics and reported findings based on ethnicity/skin tone. Schäfer et al[26] noted statistically significant (p=.046) differences in the stiffness of the heel skin and subcutaneous tissues after a period of continuous loading (pressure). In the pilot study conducted by Gefen and Gershon[22], ultrasound imaging identified hypoechoic lesions in the tissue, indicating suspected deep tissue injury (sDTI) prior to skin erythema. Additionally, the authors noted a 100% agreement rate on ultrasound imaging and SEM readings for identifying sDTI.

Category 2: SEM scanner

The SEM scanner uses electromagnetism to quantitatively measure the microscopic build-up of fluid in the interstitial spaces of the tissue[10]. Vascular permeability and interstitial fluid collection can immediately be detected through the measurement of biocapacitance[13]. As such, the initial phase of tissue damage can be identified at the microscopic level prior to the development of visible changes in the skin[10].

As illustrated in Table 3, all five studies included in this category evaluated SEM scanner readings as an indicator of potential tissue damage and compared this to VSA[23–25,27,28]. Overall, findings suggest the SEM scanner was an effective adjunct tool for identifying PI earlier than VSA[23,24,27,28]. Four of the five studies used the Bruin Biometrics SEM Scanner 200[23–25,28]. Most studies collected SEM scanner readings on the sacral, and left and right heels[23–25,28]. The sample size was varied (range: 29–195 participants) and there were fewer than 50 participants in three out of five studies.

One non-randomised controlled study[25] compared the effectiveness of the SEM Scanner compared to standard VSA using control and intervention groups. The study reported a 93% decrease in PI in the SEM Scanner intervention group[25]. The number of days SEM readings in this study were taken ranged from 7–30 days. Most studies conducted SEM scanner data collection within 30 days of study commencement. One study extended the length of daily SEM scanner

assessments to 12 weeks[27]. In two studies comparing SEM readings to VSA for identifying signs of tissue damage, findings suggest SEM readings indicated a PI on average 4 days earlier than VSA[23,24]. However, the study by Moda Vitoriano Budri et al[28] found that PI detection using the SEM Scanner was on average 8.2 days before VSA.

Assessment of methodological quality

All studies included in the review were quantitative studies and were assessed using the quantitative descriptive category of the MMAT[20] (Table 4). Overall, the methodological quality of included studies varied. Most studies were observational in design. More than half of the studies provided sufficient methodological details to meet all five of the criteria in the MMAT checklist[20]. Due to limited methodological details reported in some studies, the 'Can't tell' response was used. Only three studies reported blinding of the clinician performing data collection[22–24]. Most studies used convenience sampling, subjecting them to possible selection bias. Additionally, all but two of the studies were single site, inherently limiting generalisability.

Discussion

Oedema accumulation in the subepidermal layer is known to be a prognostic factor in PI development[29], which highlights the imperative for early implementation of preventative strategies[30]. This review synthesised evidence from five studies relating to the SEM scanner and two studies using ultrasound imaging.

There is a consensus that early PI detection technologies are beneficial for patients at risk of developing PI, in comparison to using standard VSA alone[23–25,27,28]. The review findings suggest the use of the SEM scanner is a more accurate and consistent method for detecting early signs of tissue damage in patients compared to standard VSA. Findings are similar to previous systematic reviews[12,29] which support the use of SEM scanner measurements for the early identification of PI. Previous research by Oomens and Bader[9] suggests the first event of cellular deformation occurs at the molecular level, when accumulation of interstitial fluid is irreversible and initiates cell death. The rise in interstitial fluid volume presents as localised oedema within the tissue which is not yet visible on the skin[13]. Using biocapacitance, the SEM scanner can detect microscopic pockets of fluid within the tissue and reflect this inflammation as an elevated SEM reading[10]. As the inflammatory process cascades, the injury progresses from the microscopic level to the macroscopic level[10]. It is only at this macroscopic level of fluid collection that ultrasound imaging can detect abnormal tissue pathology[22].

The ultrasound imaging study by Gefen and Gershon[22] reported meaningful results with ultrasound imaging; however, notably, the SEM Scanner identified abnormal tissue pathology 2 days before the ultrasound clearly indicated signs of a PI. Further, the ultrasound device is limited by its requirement to be operated and interpreted by a trained technician[22]. This restricts the convenience and cost-effectiveness of earlier PI detection due to the lack of accessibility of ultrasound technicians. Additionally, the small sample size of the included ultrasound studies suggests that the ultrasound device needs further evaluation. It is clear that the earlier the detection of tissue damage is identified, the increased likelihood of the body self-repairing the injury[13]. Thus, it is imperative to adopt a technology that can detect early tissue changes after death of the first cells[9].

Evidence from the included studies suggest elevated SEM readings were able to identify areas of tissue damage up to 4.7 days earlier than VSA[24]. Study results indicate the high sensitivity of the SEM Scanner contributes to the high success rate of identifying PI[23]. The SEM sensitivity of >80% reported in the studies[23,24,28] is in stark contrast to the reported 50% sensitivity of VSA for PI detection[23,24]. VSA relies heavily on the nurse's clinical judgement which can have poor predictive validity and inter-rater reliability[24]. In addition, although the included studies did not calculate associated cost savings with the SEM scanner, the reduced rates of PIs and reduced need for physical resources may equate to direct cost savings. Further, evidence from this review found the implementation of the SEM scanner into standard of care PI prevention was well received by the nursing staff. There was a sense of increased confidence and skill acquisition for the nurses that incorporated the device into their standard PI prevention assessments[25].

The results of our review suggest that bedside technologies can be effective for identifying and preventing PI in patients. As such, it may be appropriate to supplement VSA with the more objective approach of PI detection technologies. Further studies with larger samples are needed to improve the rigour and generalisability of this body of research. Strengthening the methodological rigour in future SEM research may inform its implementation as an evidence-based technology to real world practice. Lastly, although the current state of literature in the field of SEM is expanding, our results indicate that research examining longitudinal changes over a fixed period of time in SEM readings in healthy adults is lacking.

Limitations

We note several limitations to this systematic review. First, despite undertaking a comprehensive search across large healthcare-specific databases (CINAHL, Embase, MEDLINE), it is possible that we missed relevant published research. Secondly, as the review exclusively included studies published in English, we cannot rule out language bias. We also acknowledge that pragmatically restricting the search criteria to English-only studies limits exposure to potentially relevant non-English studies. Furthermore, five of the included studies were single-centre studies. Thus, the generalisability of the findings may be limited to the study settings. Finally, although a rigorous quality appraisal tool was used, some included studies were rated 'Can't tell',

Table 3. Included SEM scanner studies (n=5)

Study aim	Design	Sample & setting	Brand of device used	PI identification procedure	Anatomical sites	Main findings
Moda Vitoriano Budri et al, 2020[28] • Ireland						
To identify how a patient's movement leads to pressure ulcer development	Multi-centre, observational, prospective study	n=150 (males=39, females=111). Age: mean 84.3 years (±8.2 years); two long-term care facilities	Bruin Biometrics SEM Scanner 200 device	VSA and SEM assessments were performed daily for 20 days. Movement was measured using the Braden subscale and a continuous motion sensor which provided a "movement score"	Left/right heel, sacrum, anterior part of the head of the humerus	• PI identification with VSA was 12.7% compared to 78.7% using the SEM Scanner • The SEM Scanner detected PI on average 8.2 days before VSA. Of the 19 PI detected, 53% (n=10) occurred among participants classified as low movers, and 47% (n=9) occurred among the high movers
Kim et al, 2018[27] • Korea						
To examine the relationship between SEM readings and early PI detection in elderly Korean patients	Single centre longitudinal observational study	n=29 (males=4, females=25). Age: mean 81.2 years (±7.5 years); one long-term care facility	NOVA Petite dermal phase meter	VSA and SEM assessments were performed on eight sites of each participant once a week for 12 weeks. A 20 unit increase of SEM value from the participants previous values were considered abnormal	Left/right buttocks, left/right ischia, left/right trochanters, sacrum, coccyx	• Six residents developed PI; the SEM value of a Stage I PI was significantly higher than that of no injury • Mean SEM values of normal skin were 216.3 dermal phase units (DPU) compared to mean SEM values of Stage I PI which were 387.6DPU (p=.013)
O'Brien at al, 2018[23] • Ireland						
To explore the relationship between nurses' VSA of early PI detection and assessment using SEM measurements	Descriptive prospective observational study	n=47 (males=18, females=29). Age: mean 74.7 years (±14 years); acute care facility	Bruin Biometrics SEM Scanner 200 device	VSA and SEM assessments were performed daily for 4 weeks. SEM readings of $\Delta \geq 0.5$ over 3 days or more were considered abnormal	Left/right heels, sacrum	• 19 patients developed PI; the SEM values remained elevated before VSA detected the PI. • The mean number of days for VSA detect a PI was 5.5 compared to 1.5 days for SEM readings. SEM measurement identified tissue damage 4 days before the nurses' VSA
Okonkwo et al, 2020[24] • United States of America						
To evaluate the sensitivity and specificity of SEM for early PI detection compared to VSA	Multi-site, blinded, prospective, longitudinal study	n=182 (males=85, females=97). Age: mean 76 years (±11 years); acute and post-acute facility	Bruin Biometrics SEM Scanner 200 device	VSA and SEM assessments were performed daily for a minimum of 6 days. SEM readings of $\Delta \geq 0.6$ for 3 days of device measurements with no more than 1 day missing was considered abnormal	Left/right heels, sacrum	• 48 patients developed PI; the SEM values detected tissue damage • 4.7 (±2.4 days) earlier than diagnosis of a PI via VSA

Study aim	Design	Sample & setting	Brand of device used	PI identification procedure	Anatomical sites	Main findings
Raizman et al. 2018[25] • Canada						
To evaluate the clinical impact of the SEM device as measured by reductions in PI in hospitalised patients	Prospective non-randomised controlled study	Phase 1: n=89; stroke unit. Phase 2: n=195; (n=166 emergency room), (n=29) medical unit; acute facility	Bruin Biometrics SEM Scanner 200 device	Phase 1: SEM scans were performed 5 times per week for 1 month or until discharge. SEM delta value was recorded, but interventions were based on the site's standard VSA protocols Phase 2: SEM scans were performed 5 times per week for a minimum of 7 or 14 days or until discharge. Examiners were aware that Δ≥0.6 were indicators of tissue damage and increased interventions	Left/right heels, sacrum	• In Phase 1 with no intervention from the SEM readings, 12 of the 89 participants (13.5%) developed PI. • In Phase 2, with the examiner's knowledge of the meaning of the SEM readings, two of the 195 participants (1.0%) developed PI. The SEM Scanner alerted clinicians to potential tissue damage and implement stronger prevention strategies.

indicating some ambiguity. We did not contact the authors to ask for more information, which may have allowed a more complete quality assessment of all aspects of the methodology.

Conclusions

There have been notable advancements in the field of early PI detection technologies. As the aetiology of PIs are better understood, the need for early detection is essential. The evidence available suggests that the use of the SEM scanner may lead to a reduction of PI and a decrease in PI progression. To date, it is not clear how this technology will be implemented in standard practice in the clinical setting. There is a need for well-designed studies to establish optimal protocols for implementing the SEM scanner.

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Conflict of interest

No conflicts of interest.

Ethics statement

An ethics statement is not applicable.

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Author contribution

The guiding concepts of the review were framed by MB, BG, SL and RW, and MB analysed the literature under the regular supervision of all other co-authors. All authors read and approved the final manuscript.

Table 4. Results of the MMAT for the included studies

Quantitative descriptive study	Is the sampling strategy relevant to address the research question?	Is the sample representative of the target population?	Are the measurements appropriate?	Is the risk of non-response bias low?	Is the statistical analysis appropriate to answer the research question?	Limitations/comments
Moda Vitoriano Budri et al, 2020[28]	Yes	Yes	Yes	Yes	Yes	• The two study sites did not have the same protocols for PI prevention • Specific population limits generalisation to other populations • All participants had light skin tone • Wide confidence intervals (CI) indicate imprecision and may indicate mobility variations in recruited participants
Gefen & Gershon, 2018[22]	Yes	Yes	Yes	Yes	Yes	• Single site pilot study with small cohort limits generalisability • Convenience sampling, possible selection bias • Study not powered for validity/reliability; inconsistency between SEM and ultrasound where VSA determined sDTI
Kim et al, 2018[27]	Yes	Yes	Can't tell	Can't tell	Can't tell	• Single nursing home site • Convenience sampling, possible selection bias • 13.8% participants had history of PI, so were possibly at higher risk of developing PI
O'Brien at al, 2018[23]	Yes	Yes	Yes	Yes	Yes	• Single hospital site • Convenience sampling, possible selection bias • No details on participants' skin tone
Okonkwo et al, 2020[24]	Yes	Yes	Yes	Yes	Yes	• Convenience sampling, possible selection bias • Possible variability amongst observers
Raizman et al, 2018[25]	Yes	Yes	Can't tell	Can't tell	Can't tell	• Participants included in Phase 2 of the study were at higher risk of developing PI • Lack of inferential testing to determine if study sufficiently powered to confirm effect • Convenience sampling, possible selection bias • No details on skin tone
Schäfer et al, 2015[26]	Yes	Yes	Yes	Yes	Yes	• Small cohort limits representation and threatens internal and external validity • Female only cohort, lacks generalisability

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