The impact of skin barrier cream on variation in sub-epidermal moisture readings

KEY WORDS
- Barrier cream
- Pressure ulcers
- Prevention
- SEM Scanner 200
- Subepidermal moisture

Background: The costs to healthcare systems of pressure ulcer (PU) prevention and management programmes remain high, and although PU risk assessment tools exist, they generally have poor predictive value. It has been demonstrated that PU are preceded by subtle tissue changes that are invisible to the naked eye before skin breakdown occurs. One such change is an increase in sub-epidermal moisture (SEM) which can be identified by biocapacitance. **Aim:** To investigate the effect of skin barrier cream on biocapacitance readings made with the SEM Scanner 200 (BBI LLC (CA, USA). **Methods:** SEM Scanner 200 delta readings were recorded on the heels and sacrums of healthy volunteers with and without barrier cream. This was a two part investigation. In part one participants had barrier cream applied to one heel (right) and not to the other (left). In part two participants were allocated into one of two groups- full application or partial application of barrier cream. **Results:** No difference in SEM delta values was observed in participants between the right and left heel. With sacral application there was a significant rise in SEM Scanner 200 readings when barrier cream was only applied to a small area compared to those with full coverage though this rapidly resolved with time and skin cleaning. **Conclusions:** Even distribution of barrier creams over scanned areas did not affect SEM readings though uneven application might adversely affect readings.

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A pressure ulcer (PU) is defined as 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 (National Pressure Ulcer Advisory Panel [NPUAP], European Pressure Ulcer Advisory Panel [EPUAP] and Pan Pacific Pressure Injury Alliance [PPPIA], 2014). Despite considerable attention being focused on reducing incidence, they remain relatively common with a mean incidence of 17.6% in acute care and 6.63% in long-term care settings (Moore et al, 2013; Nguyen et al, 2015; Norton et al, 2018). Therefore, they continue to cause a significant burden to patients and healthcare systems (Whitlock, 2013). In the UK, the mean annual NHS expenditure per PU, at 2015/2016 healthcare costs, was estimated to be £8,720 (Guest et al 2018). Costs increase with the severity of the PU and are similarly high in other healthcare systems (Chan et al, 2017; White et al, 2017; Dreyfus et al, 2018). Therefore, there is a strong emphasis on preventing PUs developing to reduce overall clinical management costs and to provide a indicator of the quality of patient care (Black et al 2011).

Best practice guidance for PU prevention combines both clinical assessment of the patient and risk assessment of PU development (NPUAP/EPUAP/PPPIA, 2014; National Institute for Health and Care Excellence [NICE], 2017), with all patients being considered at risk of developing a PU until determined otherwise. Numerous tools have been developed to guide PU risk assessment, and several factors have been demonstrated to be strongly associated with PU development (Schoonhoven et al, 2006; Moore and Cowman, 2014). However, the predictive value of existing risk assessment tools is low, leading to problems with under- and over-estimating risk of injury (Moore and Cowman, 2014; Chen et al, 2016; Fletcher, 2017). Clinical assessment is based on visual skin inspection and assessment of factors such as, comorbidities, mobility, nutritional status and tissue perfusion using semi-quantitative scales and subjective clinical assessment (O'Tuathail and Taqi, 2011; NPUAP/EPUAP/PPPIA, 2014). However, there are several problems with visual skin assessment making it unreliable, particularly in

individuals with dark skin tones (Baumgarten et al, 2004) and the fact that by the time changes are visible on the skin surface, the damage has already occurred.

Whilst the aetiology of PUs is complex, it is now commonly accepted that several pathophysiological factors contribute to their formation. Tissue ischaemia, reperfusion injury, cellular deformation and probable lymphatic dysfunction, disrupts cellular processes leading to cell death and the initiation of an inflammatory response (Oomens et al, 2015; Moore et al, 2016; Gray et al, 2016). Inflammation causes the leakage of fluid into the extravascular tissue, leading to an increase in interstitial fluid (also known as subepidermal moisture [SEM]) and increase in tissue capacitance. This can be measured by bioimpedance, or biocapacitance, which are well-established techniques used in physiological measurement (Martinsen and Grimnes, 2011). The hand-held SEM Scanner 200 (BBI LLC, CA, USA) uses biocapacitance to identify SEM at a number of locations and has been more fully described by Moore et al (2017) and Gefen and Gershon (2018). The difference (delta or Δ) in the readings across a site has been shown to identify increased risk of PU up to a median five days before visual skin inspection (Okonkwo et al 2018). However, the effects of barrier creams, which are often part of standard nursing care, on SEM scanner readings are unclear.

The objective of this study was to investigate whether the use of skin barrier products used as part of a standard skin care protocol would interfere with SEM Scanner 200 delta readings.

MATERIALS AND METHODS

Setting, participants and ethics

Following approval by the University of Southampton, Faculty of Health Sciences Ethics Committee (REC Ref 25037), 22 healthy participants aged 18–65 were recruited from the staff and student population of the University of Southampton. Exclusion criteria for the study were active inflammatory skin disease, skin infection, open wounds or scarring affecting the proposed measuring areas. Participants attended for a single visit and the study was conducted within dedicated clinical research facilities. Environmental temperature at 21 ± 2°C and humidity was maintained at 55 ± 2%. Prior to commencing any measurements, participants rested comfortably in semi-recumbent position on a bed for a period of 20 minutes to acclimatise to the ambient environment. All participants were reimbursed for their time and expenses.

Study design

An exploratory, unblinded, prospective, cohort design was used in this study, with participants acting as their own controls. This study investigated the effect of barrier cream application versus non-application on SEM scanner delta values on directly comparable sites, e.g. heels and sacrum, and the effect of full versus partial barrier cream application on delta values on the sacrum. Participant skin type was self-assessed using the Fitzpatrick Scale (Fitzpatrick, 1988), and PU risk assessed by calculating the Waterlow score. The study team was trained by the manufacturer before commencement of the study to ensure validity of SEM measurements. Standard hospital pillows and bed sheets were used on hospital mattresses (NP100, Hill-Rom or AtmosAir™, Arjo-Huntleigh).

Interventions

The skin care products used were in accordance with the researcher's hospital policy. Skin cleansing utilised Senset® foam (Vernacare, UK) and the barrier product used was Medi Derma-S (Medicareplus, UK). SEM scans were performed using a SEM Scanner 200 (Bruin Biometrics LLC, Los Angeles, CA) and readings obtained according to the manufacturer's instructions at 6 points on the sacrum (landmarked using manufacturers template) and 4 on the heel (anatomically landmarked). Baseline scans were taken before the study commenced (T=0).

Study 1. Effect of application versus non-application of cream on SEM delta values on comparable sites (heels)

Participants lay supine with heels elevated using a pillow under the calf. Whilst this method does not represent local standard practice for offloading the heels, it was used to ensure methodological consistency during the study. Derma S was applied evenly to all scan points on the right heel. SEM readings were taken from both heels 5 minutes later (T+5), and the right heel was cleaned with Senset® foam. Reading, cleaning and scanning were repeated every 5 minutes over 25 minutes (T+10, +15, +20, +25).

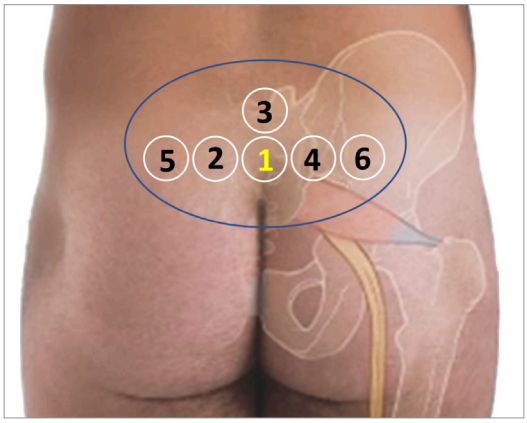

Figure 1. Sacral scan points, as advised by manufacturer, overlayed on the sacrum. In study 2, participants in the 'partial application' group had barrier cream applied to point 1 only, whereas those in the 'full application' group had barrier cream applied over all sacral scan points (1–6).

Study 2. Effect of even and uneven application of cream on SEM delta values on the sacrum

Participants were allocated to one of two groups according to order of arrival. Participants lay supine for one hour, then rolled onto their right side and were offloaded for 20 minutes. Following offloading, one group (N=11) had 0.2 ml of Derma S applied to sacral point one only *(Figure 1)*. The other group (N=11) had Derma S applied evenly on all scan sites. Readings were taken every 5 minutes (T+5) for 55 minutes (T+55). Once the SEM delta had been recorded the area was cleaned with Senset® foam.

Outcome measures

The main outcome measure for this study was the difference (delta/Δ) between the minimum and maximum SEM scanner readings at each time point. A delta ≥0.6 has been determined by the SEM Scanner 200 manufacturer to indicate increased risk of pressure ulceration earlier than visual skin assessment.

Data analysis:

Data were anonymised and participants identified by a study number allocated on recruitment. Normality of data was assessed by the Shapiro-Wilk test. Results were expressed as mean ± standard deviation (SD) for parametric values and median and interquartile range (IQR) for non-parametric data. Within individuals, between scan site differences were tested using a paired t-test (normal distribution) or a Wilcoxon test (non-normal distribution). Between group differences were investigated using a two sample t-test (for normal data) or a Mann Whitney test (non-normal). The effects of confounding variables (age, sex, and identified extraneous variables) were controlled for using a linear or logistic regression model. Differences were considered statistically significant at the 5% level ($p<0.05$). Statistical analysis was performed using SPSS version 25 (IBM).

RESULTS

Participants

Twenty-two participants (13 females and 9 males) mean age ± SD 36.6 ± 11.6 years were recruited and completed the study. Bodyweight was between 55 kg and 104 kg. Of the participants, 41% had a

Table 1. Results of Wilcoxon signed rank test between left and right heels

	Right heel (barrier cream)				Left heel (no barrier cream)				z-value	Asymp Sig (2-tailed)
	N	Min	Max	Mean (SD)	N	Min	Max	Mean (SD)		
SEM Δ Baseline	20	0.3	1.2	0.575 (0.269)	20	0.2	1.4	0.610 (0.316)	-0.602	0.547
SEM Δ +5 minutes	20	0.2	1.3	0.625 (0.304)	20	0.2	1.7	0.795 (0.355)	-1.823	0.068
SEM Δ +10 minutes	19	0.4	1.4	0.774 (0.323)	19	0.3	1.8	0.700 (0.353)	-0.522	0.602
SEM Δ + 15 minutes	19	0.3	1.5	0.784 (0.287)	19	0.3	1.7	0.763 (0.355)	-0.153	0.878
SEM Δ + 20 minutes	19	0.3	1.1	0.647 (0.222)	19	0.4	1.4	0.779 (0.272)	-1.907	0.56
SEM Δ +25 minutes	19	0.2	1.5	0.753 (0.313)	19	0.3	1.6	0.768 (0.325)	0.208	0.835

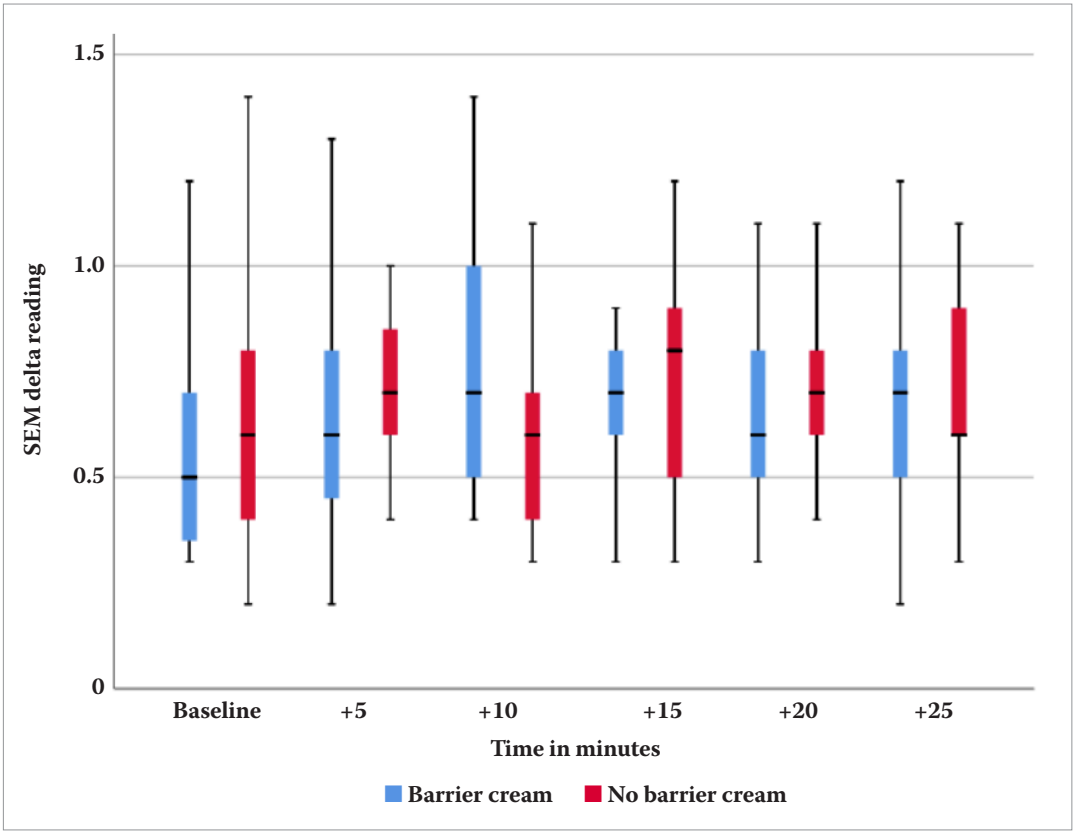

Figure 2. Graphic representation of median and interquartile ranges of SEM delta results. Results divided into application and non-application on heels with participants acting as their own controls

healthy BMI; 45% were overweight; 14% were obese. Fitzpatrick scores were type 2 ('fair skin': 9% N=2), type 3 ('darker white skin': 41% N=9), type 4 ('light brown skin': 41% N=9) and type 5 ('brown skin': 9% N=2). No participant was calculated to be at risk by Waterlow score.

Study 1. Effect of barrier cream on SEM delta values on the heels.

A full set of SEM readings were obtained in 19 of 22 participants. Two participants had no data due to a technical problem and one had only T=0 and T=5 minute readings recorded as they had to leave before the study concluded. No statistically significant differences were observed between delta values for the left (no barrier cream) and right heels (barrier cream applied) at any timepoint as shown in *Table 1*. There was significant fluctuation in delta values on both heels and at all time points with a proportion of SEM delta values being ≥0.6 (at risk of tissue damage) despite elevation of heels throughout the study as shown in *Figure 2*.

No significant relationship was demonstrated between gender despite males having a greater median SEM delta in both heels than women.

Where variation was seen in the sub-group analysis according to BMI, smoking or Fitzpatrick score, it was demonstrated to be non-significant. This may be due to low representation of the sub groups (Smokers=3(13.6%), Obese=3(13.6), Fitzpatrick 1=2 (9.1%) and Fitzpatrick 4 =2(9.1%)) and further investigation should be considered.

Study 2. Effect of barrier cream on sacral SEM delta values

In this part of the study, a full set of SEM readings were obtained in 20 of 22 participants. One participant had to leave before completion of the study and so no readings were obtained at 45 and 55 minutes, and for another a technical problem meant that no readings were recorded at 55 minutes. A significant difference in SEM delta readings was seen at 5 minutes (p=0.044, Kruskal-Wallis test for independent sample [*Figure 3*]). This indicates that although the delta was elevated at 5 minutes in participants with partial barrier cream coverage, the delta after cleansing at subsequent time points was not elevated compared with deltas from participants

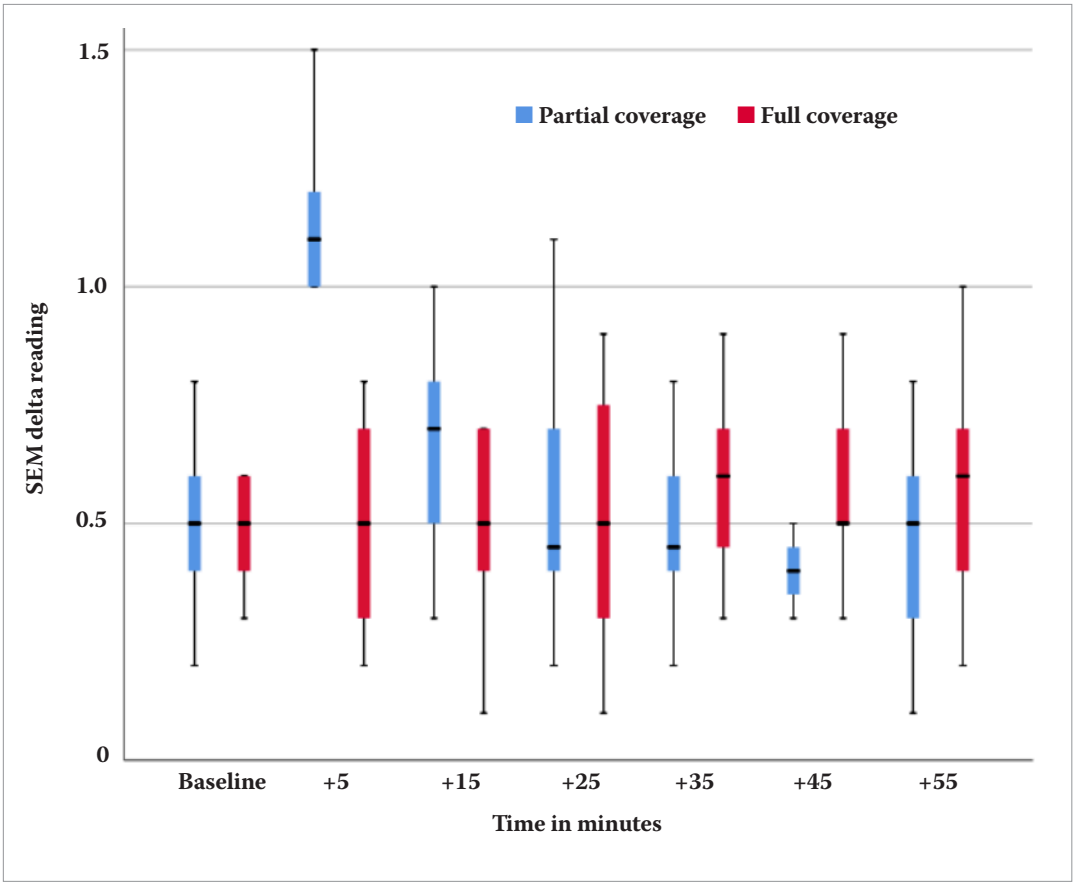

Figure 3. Graphic representation of median and interquartile ranges of SEM Δ. Results divided in to full sacral application (full coverage of barrier cream) and partial sacral application (barrier cream applied only to point as per *Figure 1*) groups over time.

with full barrier cream coverage. No statistical differences in delta values by Fitzpatrick scores, BMI group, age or sex were observed.

DISCUSSION

This exploratory study is believed to be the first to investigate whether the use of skin barrier products affects the reliability of SEM scanner readings. Twenty-two healthy volunteers had repeated SEM scanner readings recorded from their heels and sacrum with and without the presence of a topically applied skin barrier cream.

From the similarities between individual heel delta values it appears that neither barrier cream or skin cleaning seems to effect the SEM delta readings when applied across the whole scan area. If applied to only one part of the scan area these results suggest that it is possible to falsely elevate the SEM delta. This effect was observed to diminish with time/cleaning of the area. Ten minutes after application and following one clean with Senset foam, the SEM delta was not statistically different between application and partial application groups.

Although participants were low-risk volunteers and their heels were not subject to a degree of pressure associated with tissue damage, considerable variability in the median deltas recorded was observed, with some values suggesting tissue damage was likely. The heel study lasted 25 minutes following elevation, application of barrier cream and a 5-minute interval before scanning. The mechanism for the elevated values is not fully understood. Some sacral delta values in study 2 were also elevated. One hour of direct pressure before scanning may have increased SEM, but we consider this unlikely because tissue was off-loaded for 20 minutes before scanning. The high median delta for the sacrum in study 2 can be explained by a single, high SEM reading from point 1 (covered by barrier cream). In normal clinical practice such variation would trigger repeat scanning. However, in this study we recorded the deltas from single sets of readings and did not repeat readings where possible discrepancies were noticed to reduce the time burden of participants. The number of participants in this evaluation was relatively small and after stratification by BMI, only three participants

were classified as obese. This sub group returned deltas higher than participants with lower BMIs. However, the small number means that the outcome in obese participants is uncertain, requiring further investigation.

The variation in delta values in the heels may be artefact related to the technical challenges experienced in scanning heels. The SEM Scanner 200 sensor is 25 mm in diameter and must be in complete contact with the skin during scanning. Heels have a small radii of curvature. Landmarking the heel for measurement, placing the sensor, and making SEM readings in this area proved challenging, probably contributing to the variation in delta values seen. The sacrum was not affected by curvature of skin to the same extent, and thus variation in sacral deltas was correspondingly lower with fewer delta values ≥0.6. The manufacturer is investigating the potential to reduce the sensor size to reduce variation from curvature. Previous studies with the SEM Scanner 200 have demonstrated low variability between operators and devices in all anatomic sites (Clendenin et al, 2015). In clinical studies, the SEM Scanner 200 has been reported to distinguish tissue damage with positive and negative predictive values of 90.9% and 86% respectively for the sacrum and 82.5% and 90% for the heel (Gershon et al 2014) and identifies potentially damaged tissue more reliably than visual inspection alone (Bates-Jensen et al, 2008; Harrow and Mayrovitz, 2014; Swisher et a,l 2015). Whilst this study did not achieve these levels of accuracy, it is important to note that all the previous work has been focused on an older population with a mean age >60 years (Bates-Jensen et al, 2007; 2008; 2009; 2017; 2018; Guihan e tal, 2012; Gefen amd Gerson, 2018; Harrow and Mayrovitz, 2014, Kim et al, 2018; O'Brian et al, 2018). Therefore, it may be that the skin changes associated with aging both increases the accuracy of results and reduces the false positive rates seen in this study.

As current PU risk assessment tools are not highly predictive (Moore and Cowman, 2014; Chen et al, 2016; Fletcher, 2017) and require clinical judgement (O'Tathall and Taqi, 2011), they lack objectivity. Consequently, risk assessment does not necessarily lead to better treatment planning (Johansen et al, 2014). The additional discrimination and early identification of increased risk of PU using SEM compared with ultrasound or visual inspection potentially delivers significant advantages in PU prevention (Moore et al, 2016; Gefen and Gershon, 2018).

There are a number of limitations to this study which need to be recognised. As this study was conducted in a group of young, healthy volunteers, with no comorbidities, the findings cannot be generalised to the whole population. The small sample size, particularly after stratification for confounding variables limits the validity of the sub-group analysis. Also, as it was not conducted in normal clinical setting with the associated time pressures and number of patients, replication is needed in a 'real-world' setting. However, conducting this in a controlled environment enabled researchers to focus entirely on the study and preciseness in measurements. The controlled nature of the study also ensured methodological consistency. Variability between subjects was controlled by using the same participants for both studies. Thus, overall, the design of the study enabled the original research question to be answered.

CONCLUSIONS

The use of skin barrier cream does not appear to adversely effect SEM scanner readings, providing it is applied evenly and in accordance with the manufacturer's instructions. However, uneven application of barrier cream can affect the SEM delta, though this risk appears to reduce with time and regular skin cleaning. This suggests that adherence to skin care protocols and staff education are additional factors to consider when using the SEM scanner. Further work is required to corroborate these findings in a clinical setting. WUK

DECLARATION OF INTEREST

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