Journal of Tissue Viability (2015) **24**, 17–23

JOURNAL OF tissueviability

www.elsevier.com/locate/jtv

Clinical study

Inter-operator and inter-device agreement and reliability of the SEM Scanner

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KEYWORDS
Pressure ulcer;
Reproducibility;
Medical device

Abstract *Objective:* The SEM Scanner is a medical device designed for use by healthcare providers as part of pressure ulcer prevention programs. The objective of this study was to evaluate the inter-rater and inter-device agreement and reliability of the SEM Scanner.
Methods: Thirty-one (31) volunteers free of pressure ulcers or broken skin at the sternum, sacrum, and heels were assessed with the SEM Scanner. Each of three operators utilized each of three devices to collect readings from four anatomical sites (sternum, sacrum, left and right heels) on each subject for a total of 108 readings per subject collected over approximately 30 min. For each combination of operator-device-anatomical site, three SEM readings were collected. Inter-operator and inter-device agreement and reliability were estimated.
Results: Over the course of this study, more than 3000 SEM Scanner readings were collected. Agreement between operators was good with mean differences ranging from −0.01 to 0.11. Inter-operator and inter-device reliability exceeded 0.80 at all anatomical sites assessed.
Conclusion: The results of this study demonstrate the high reliability and good agreement of the SEM Scanner across different operators and different devices. Given the limitations of current methods to prevent and detect pressure ulcers, the SEM Scanner shows promise as an objective, reliable tool for assessing the presence or absence of pressure-induced tissue damage such as pressure ulcers.

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http://dx.doi.org/10.1016/j.jtv.2015.01.003

Introduction

Pressure ulcers (PUs) represent a serious health problem to patients impacting up to 25% of patients across acute and long-term care settings in Western Europe and the US [1,2]. Pressure ulcers are a chronic condition that can be extremely painful, and sometimes fatal — approximately 60,000 patients die per year in the US due to infection and other complications from PUs [3]. Pressure ulcers also result in significant financial burden — on average, a pressure ulcer can result in 6—10 additional hospital days and €10,500 indirect costs per patient episode [4]. Treatment costs rise materially once the skin has broken (Stages II—IV and unstageable) [5—7]. Most PUs are considered preventable [8] and reversible if identified in the early stage of ulceration [9].

The 2014 NPUAP/EPUAP/PPPIA Pressure Ulcer Guidelines [10] recommend a structured risk assessment and comprehensive skin assessment for each patient. However, existing tools pose significant limitations. One systematic review of the EPUAP and NPUAP PU classification systems [11] found highly variable inter-rater reliability (κ = 0.31—0.97) and highly variable agreement (58%—100%), respectively. A second review article [12] concluded that reliability and agreement of PU classification was dependent on the individual assessing the PU. Similarly, the three most common risk assessment tools (Braden, Norton, and Waterlow scales) are subjective and offer highly variable reliability and accuracy [13—16], depending on the experience of the clinician. Last, visual skin assessment (VSA) for the identification of PUs poses similar challenges [16—19] with particular limitation around accurate detection of Stage I PUs and suspected deep tissue injury (sDTI) in dark skin-toned patients [10,20,21].

Subepidermal moisture (SEM), a measure of localized edema, has been previously investigated (i) for association with erythema, Stage I, and Stage II PUs [22—25], (ii) for its ability to differentiate between healthy skin and skin with pressure-induced tissue damage [26] and (iii) as a predictor of imminent ulceration (PUs, sDTIs) in various populations [22,23,27]. These studies suggest that changes in measures of SEM could be utilized for both prevention and detection of PUs. The addition of an objective biophysical measure, such as SEM, to VSA could address existing challenges of objectivity and reliability.

The SEM Scanner has been designed to overcome these limitations, by offering an objective and reliable method to assess SEM and therefore tissue damage and/or risk of PUs, with the hope that this could lead to interventional efforts that would prevent further damage. The objective of this study was to evaluate the inter-rater and inter-device agreement and reliability of the SEM Scanner.

Methods

Study procedures were approved by an Institutional Review Board and all subjects provided informed consent.

Devices

The SEM Scanner Model 200 is a cordless, hand-held portable device that consists of a single circular coaxial electrode, an integrated pressure sensor, and the hardware and software to run a user interface device screen that displays the device status, battery status, and SEM readings. When pressed against an area on the skin with appropriate pressure for at least 1 second, the SEM Scanner measures subepidermal electrical capacitance by applying low frequency (kHz) signal to the electrode, recording the reflected signal, and processing the signal into an unitless SEM Reading. The dimensionless values displayed on the SEM Scanner are a relative measure of the free and bound water in the subepidermal tissue. The values are intended as a comparative measure to adjacent tissues, not as absolute values. The recorded values can also be compared to readings on the same patient area measured at another time.

The principles of measuring dielectric properties of tissue, including capacitance, with a coaxial electrode are well understood [28,29]. Briefly, a signal is generated by the device and transmitted to the tissue through the sensor. The signal response is affected by dielectric characteristics of the subepidermal tissue and the amount of free and bound water in the tissue, which is compared to internal reference values. The depth of the transmitted signal, and hence the depth of measurement, is dependent upon the size of the probe and the applied signal frequency. The SEM Scanner has been designed to measure the water content of the extracellular space below the surface of the tissue.

The SEM Scanner is intended for use by healthcare professionals.

Subjects and operators

A total of thirty-one (31) volunteers from the Los Angeles, CA, US region participated in the study.

Subjects were ≥18 years of age, free of pressure ulcers or broken skin at the assessment sites, and were willing and able to undergo all study assessments. Subjects were 45% female, 65% non-Hispanic Caucasian, and 29.8 years of age on average (Supplemental Table 1). There were no reported prescriptions for diuretics or comorbidities potentially relevant to the study measures (e.g. chronic edema, diabetes, vascular disease).

Three research assistants (A, B, C) were trained on proper use of the device according to the Instructions for Use and performed all evaluations as the operators. Two of three research assistants had prior experience in a hospital setting.

Procedures

Each participant remained in a supine position for 15 min prior to the collection of SEM Scanner readings. Each operator (A, B, C) utilized three devices (001, 002, 003) to collect readings from four anatomical sites (sternum, sacrum, left and right heels) per subject for a total of 108 readings per subject collected over approximately 30 min. The sternum was included as an anatomical site unlikely to develop a pressure ulcer and the sacrum and heels were included to represent the most common pressure ulcer sites [20]. For each combination of operator-device-anatomical site, three SEM readings were collected (e.g., three readings were recorded for Operator A with Device 001 at the sacrum of subject 1001). A single reading consisted of the average of three measurements; one each collected directly over the bony prominence, 1 cm to the left of the bony prominence, and 1 cm to the right of the bony prominence of the anatomical site. The reading is the primary unit of analysis in the study. Operators performed measurements independent of each other and were not blinded.

Statistical methods & analyses

The following analyses were performed:

1. *Anatomical Differences* in SEM readings were compared using a mixed effects model with location as the fixed effect and operator, device, and subject as random effects with Tukey–Kramer adjustment for multiple comparison [30,31].
2. *Inter-Operator and Inter-Device Agreement*, how similar the readings collected by different operators and different devices were to each other, was assessed by the mean differences between each pair of operators and each pair of devices for each anatomical site, presented in Bland–Altman plots with 95% bounds on the differences [32].
3. *Inter-Operator and Inter-Device Reliability*, how much of the observed variation is due to between-subject variation as opposed to between-operator or between-device variation, was assessed by calculating the (2,1) intraclass correlation coefficients [33] at each anatomical location using repeated measure models with compound symmetry covariance structure and Kenward-Roger degrees of freedom estimation.

An alpha level of 0.05 was considered statistically significant. Analyses were conducted in SAS 9.4 (SAS Institute, Cary, NC, USA).

Results

Over the course of this study, more than 3000 SEM Scanner readings were collected by three trained operators using three independent devices at four different anatomical sites on 31 subjects. The mean SEM reading across all anatomical sites, operators, and devices was 2.60 (range 0.5–4.4) and the median reading was 2.7.

Anatomical differences

Readings varied by anatomical site (Table 1) with the sternum having higher SEM readings than other anatomical sites, the sacrum having lower SEM readings than other sites, and the heels having statistically similar SEM readings. The distributions of SEM readings at the sacrum and heels were approximately normally distributed; readings at the sternum were bimodal and approximately normally distributed once stratified by gender. SEM readings by device, operator, and anatomical location are summarized in Supplemental Table 2.

Inter-operator and inter-device agreement

Mean differences between devices ranged from −0.21 to 0.10 and mean differences between operators ranged from −0.01 to 0.11 (Table 2). Differences that fell outside the 95% bounds on the differences (Fig. 1a–d and Supplemental Figures 1–3) were observed across the range of SEM readings suggesting that the agreement between readings is not influenced by having a higher or lower reading. While the mean differences

Table 1 Summary statistics for SEM readings by anatomical site.

Anatomical site	N	Mean (SD)	Median	Range	p-value[a] for comparison to		
					Sternum	Sacrum	Right heel
Sternum	735	2.73 (0.95)	3.1	0.5–4.0	n.a.	n.a.	n.a.
Sacrum	810	2.46 (0.58)	2.6	0.7–3.9	<0.001	n.a.	n.a.
Right heel	810	2.58 (0.61)	2.6	0.7–4.4	<0.001	0.007	n.a.
Left heel	810	2.64 (0.59)	2.7	0.9–4.4	0.072	<0.001	0.212

Abbreviations: N, number of readings; SD, standard deviation; n.a., not applicable.
[a] p-value adjusted for multiple comparison according to Tukey–Kramer.

between devices suggest that device 001 recorded lower SEM readings than devices 002 and 003 (Table 2), mean difference between operators were similar to each other.

Inter-operator and inter-device reliability

Intraclass correlation coefficients (ICCs) and 95% confidence intervals are presented in Table 3. ICCs for both operators and devices exceeded 0.80 suggesting that over 80% of the observed variation in SEM readings is due to between-subject variability, i.e., natural population variation not attributable to the device or the operator.

Discussion

The results of this study in healthy individuals indicate that the SEM Scanner demonstrates high reliability indicative of a good quality assessment tool that will provide reproducible results regardless of the device or the operator. The intraclass correlation coefficients (ICCs), a measure of reliability, exceeded 0.80 at all anatomical sites, meeting or surpassing the levels deemed acceptable for many clinical situations [34,35]. The analysis of agreement showed that device unit 001 consistently recorded lower SEM Scanner readings compared to the other two devices, however this would likely disappear upon recalibration of the device. Future clinical studies to determine clinically relevant variation in SEM readings would be desirable for informing clinically relevant limits of agreement. Early research with the device suggests that a change in SEM Scanner reading exceeding 0.5 might be clinically relevant for differentiating between damaged and undamaged tissue in subjects at risk for pressure ulcers [36]. If such is found to be the case in future studies, then the observed differences in healthy participants, of which fewer than 5% on average are greater than 0.5, suggest good agreement.

The SEM Scanner shows promise as a tool for reliable assessment of subepidermal moisture, a biophysical measure that has been previously reported as an indicator of tissue damage [22–27] and risk of PUs [22,23,27]. There are no known publications reporting on reliability for assessment of SEM by a device in healthy or PU-affected individuals, but to be clinically relevant the SEM Scanner should have comparable or superior reliability to current methods of detection or risk prediction. ICCs for the three most common risk scales range from 0.36 to 1.0 [15,16,37–41] and have considerable measurement error on individual subscales [39,42] which may be related to experience or knowledge of the raters [15,43] as compared to the SEM Scanner with ICCs which ranged from 0.83 to 0.96. Similarly, inter-rater reliability for classification systems has a wide range [11] and is dependent upon the individual performing the assessment [12]. The SEM Scanner, as an objective and reliable method to detect tissue damage and/or risk of PUs through assessment of SEM, has been designed to augment existing tools so as to address these limitations.

Table 2 Mean differences between devices and between operators by anatomical site.

Anatomical site	Device comparisons			Operator comparisons		
	001 vs. 002	001 vs. 003	002 vs. 003	A vs. B	A vs. C	B vs. C
Sternum	−0.17	−0.17	0.01	0.10	0.11	0.02
Sacrum	−0.14	−0.13	0.10	0.02	0.09	0.06
Left heel	−0.21	−0.16	0.05	−0.01	0.03	0.05
Right heel	−0.21	−0.17	0.04	−0.01	0.06	0.07

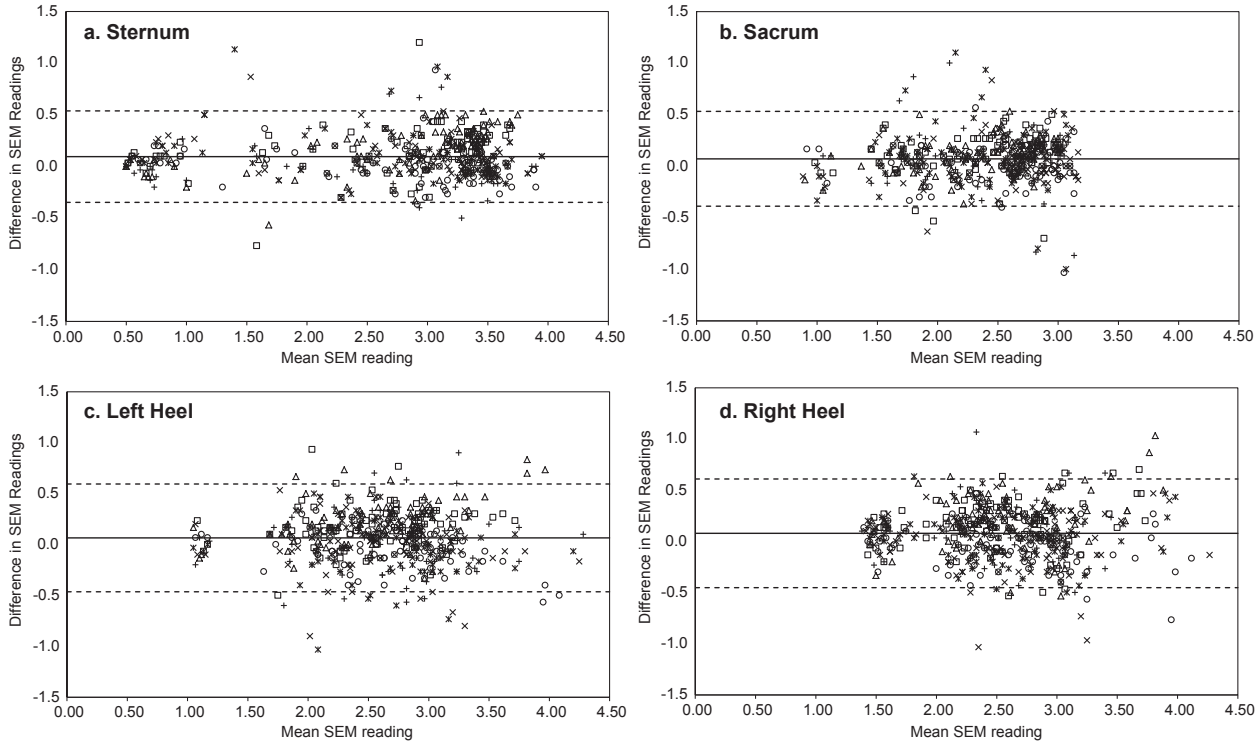

Fig. 1 a–d. Bland–Altman plots of the differences between each pair of operators and each pair of devices against their means for all four anatomical sites. Operator-specific Bland–Altman plots are presented in Supplemental Figures 1–3. Comparisons: device 001 vs. 002 (○), device 001 vs. 003 (□), device 002 vs. 003 (△), operator A vs. B (×), operator A vs. C (✳), and operator B vs. C (+). The *solid horizontal line* represents the mean difference and the *dotted horizontal lines* represent the 95% bounds on the differences (1.96*SD).

There were two main limitations in this study. First, the study population was not representative of the population in which the device will ultimately be utilized; this population was relatively young (mean age, 29.8), ambulatory, and otherwise not at risk for developing a pressure ulcer. The healthcare provider's ability to operate the device and the capability of different device units to obtain consistent readings is likely to be similar in the two populations, and thus unlikely to influence the estimates of reliability and agreement. Second, the operators in this study had minimal or no clinical training unlike the target users (e.g., healthcare providers). Due to the ease of use of the SEM Scanner, it is unlikely that differences in characteristics of the operators would materially impact reliability. Regardless of the study design limitations, this study provides evidence that multiple SEM Scanner units can reliably be used by multiple users to obtain consistent results.

Table 3 Inter-operator and inter-device reliability by anatomical site.

Anatomical site	Operator		Device	
	ICC	95% CI	ICC	95% CI
Sternum	0.961	0.955–0.967	0.957	0.950–0.963
Sacrum	0.886	0.870–0.900	0.879	0.862–0.894
Left heel	0.848	0.827–0.867	0.828	0.805–0.850
Right heel	0.854	0.834–0.872	0.837	0.814–0.857

Abbreviations: ICC, intraclass correlation coefficient; CI, confidence interval.

Conclusion

The SEM Scanner demonstrates good inter-operator and inter-device reliability with all ICCs exceeding 0.80. Given the limitations of current methods to prevent and detect pressure ulcers, the SEM Scanner shows promise as an objective, reliable tool for assessing the presence or absence of pressure-induced tissue damage such as pressure ulcers.

Conflicts of interest

None.

Acknowledgments

This study was funded by Bruin Biometrics, LLC.

Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jtv.2015.01.003.

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