SEM Scanner made easy

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Introduction

Pressure injuries or pressure ulcers (PIs/PUs) pose a considerable humanistic and economic burden to global healthcare systems, and are an underappreciated public health issue in the US where PIs/PUs results in as many deaths per year as influenza and gun-related deaths combined[1]. It is well documented that with early diagnosis and intervention, PI/PU prevention is not only possible but also significantly less costly than treatment. This article discusses the SEM Scanner (Bruin Biometrics) a revolutionary device that allows the user to 'visualise pathology' beneath the skin surface before the naked eye can detect a problem, allowing clinicians to put in place interventions to reverse or prevent further damage.

Authors: Prof. Zena Moore, Dr. Steven Gershon M.D., Jacqui Fletcher. Full details on page 6.

The case for early detection of PIs/PUs

Pressure-induced tissue damage (i.e. PIs/PUs/deep tissue injuries) results from degeneration of the skin and underlying tissues, usually over bony prominences (e.g. sacrum, coccyx, ischial tuberosities, trochanters, heels) due to sustained mechanical loading for prolonged periods, such as in patients who are bedridden or confined to wheelchairs[2]. Regular/frequent unloading the tissue to restore oxygen and nutrient supply and remove waste products can return the system to normal homeostasis[3]; this can be achieved via appropriate use of pressure-redistributing support surfaces or using a repositioning regimen[4].

Evidence has shown that PI/PU damage is reversible if it is identified early and appropriate interventions are put in place[3]. An alternative to current methods of diagnosis is needed that offers early detection and more certainty than visual assessment and risk assessment tools, which will allow clinicians to focus their prevention efforts. One example of such a tool is the SEM Scanner, an innovative tool that:

- **Is grounded in advanced scientific understanding of pressure-induced skin damage and deep tissue injury**
- **Provides a method to identify patients with pressure-induced skin damage days earlier than visual assessment and with greater certainty than either risk assessment scales or visual assessment[5]**
- **Allows clinicians to focus prevention resources, targeting interventions to patients for whom damage has already begun versus those who are still just 'at-risk', leading to more cost-effective utilisation of healthcare resources.**

Why should we focus on PI/PU prevention?

PIs/PUs are a widespread issue in healthcare facilities, incurring high treatment costs and leading to extended hospital stays[6]. In the UK, 700,000 people are affected by PI/PU each year[7] and using 2013/2014 prices, the cost of managing PIs/PUs in the UK was estimated to be £1.4–2.1 billion annually[8]. In the US, the national cost of hospital-acquired PIs/PUs is estimated at $11 billion per year among an estimated 3 million adults, and the cost per patient can range from $500–70,000 per patient (using 2009 data)[9–12]. Additionally, 60,000 patients in the US die each year from complications of PIs/PUs, such as sepsis[13], which is similar to the number of opioid overdose deaths (*n*=63,000) in 2016[14].

Evidence has demonstrated that between 20–25% of beds are occupied by patients with a PI/PU, with about 60–80% acquired post-admission[15]. PIs/PUs tend to develop relatively early after admission, often within the first 2 weeks[16]. Research has shown that 15% of elderly patients develop a PI/PU in hospital within the first week[17], and that elderly patients in long-term care are most likely to develop a PI/PU within the first 4 weeks of admission[18]. Intensive care units have the highest prevalence of PIs/PUs[19] (estimated 2.5 million patients in the US[13]). Despite initial improvements with management efforts, incidence rates of healthcare-acquired PIs/PUs remain high, especially in nursing homes (a mean incidence of 17.6% has been reported [range 1.4% – 49%], with 6.63% estimated in the long-stay setting [range 3.1% – 8.4%])[20].

Given that the cost of treating a PI/PU is approximately 2.5 times the cost of prevention, it is critical that prevention efforts — undertaken as soon as possible after admission — are the focus of any management programme[21,22]. Indeed, analyses have confirmed that taking preventative action against hospital-acquired PIs/PUs is cost-saving[6,23] and has greater expected effectiveness (measured in quality-adjusted life-years; QALYs) compared with the cost of treatment[23]:

- **Prevention:**
  - **$7276 (USD) per patient hospitalisation and an expected effectiveness of 11.24 QALYs[23]**
  - **€2.65–87.57 per patient per day[6]**
- **Treatment:**
  - **$10,053 (USD) per patient hospitalisation and an expected effectiveness of 9.34 QALYs[23]**
  - **€1.71–470.49 per patient per day[6]**

The economic impact of PIs/PUs is clear, but the emotional, physical, mental and social aspects of patients' quality of life impact must also be considered. Patients who experience a PI/PU may be negatively affected by its appearance, pain, malodour, or excess exudate production. PIs/PUs may also negatively affect a hospital's quality rating, potentially resulting in lower levels of

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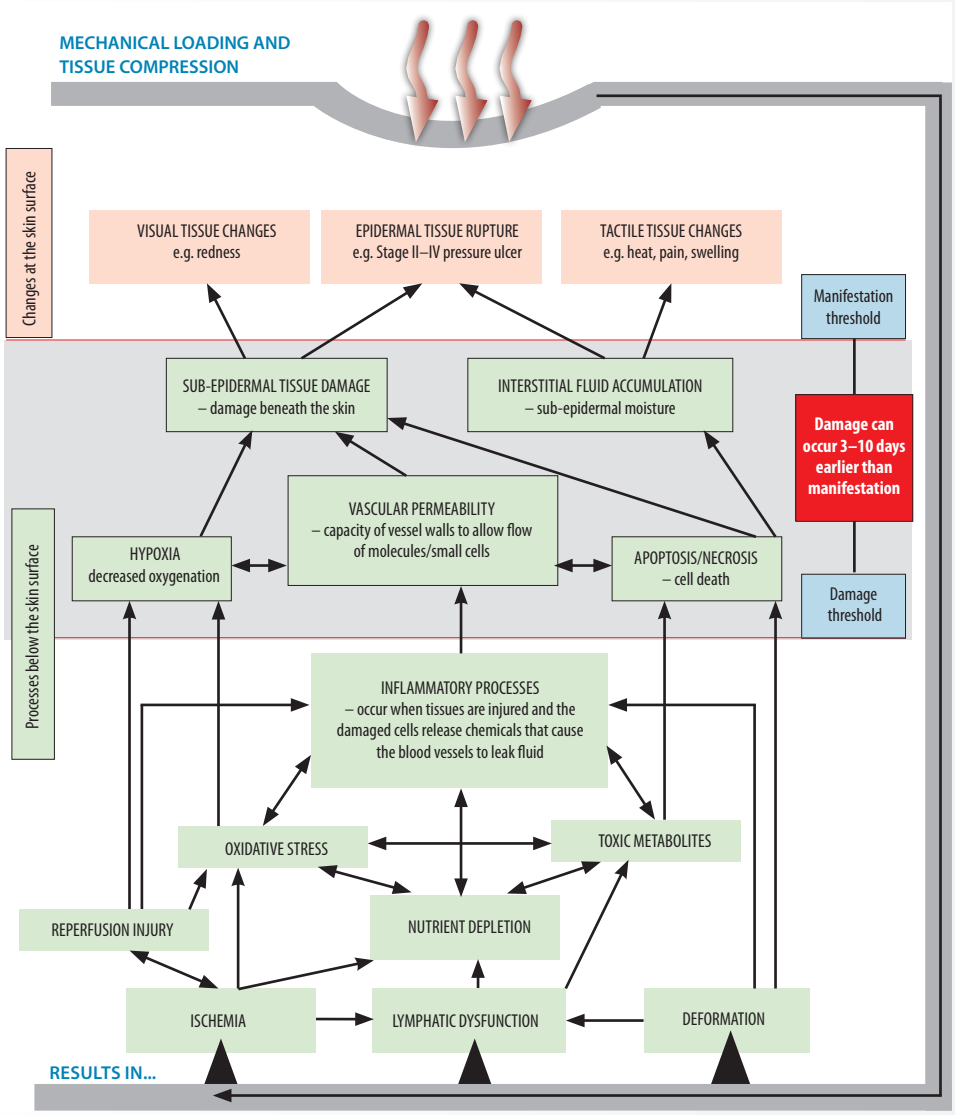

Figure 1: Biological processes that lead to tissue damage (Adapted from[20])

reimbursement[24]. For these reasons, the prevention of pressure damage represents a marker of good quality patient care. Vigilant care is required to ensure the majority of instances of pressure-induced tissue injury are prevented, with the aim of protecting and safeguarding patients[25].

How do PIs/PUs develop?

It is irrefutable that even small amounts of pressure and shear can result in partial occlusion of blood vessels, which limits perfusion. Sustained, unrelieved pressure and shear causes cell deformation, which can quickly advance to complete cell destruction. This also results in an inflammatory processes synonymous with cell damage[3].

Figure 1 illustrates the biological processes that lead to PI/PU development, showing the point at which an objective test may detect early physiological changes below the skin (damage threshold), and the point at which pressure damage becomes apparent at the skin (manifestation threshold), which can be 3 to 10 days later. This figure demonstrates the importance of using this window of opportunity to detect damage, rather than waiting to react to visual cues at the skin surface after it is too late.

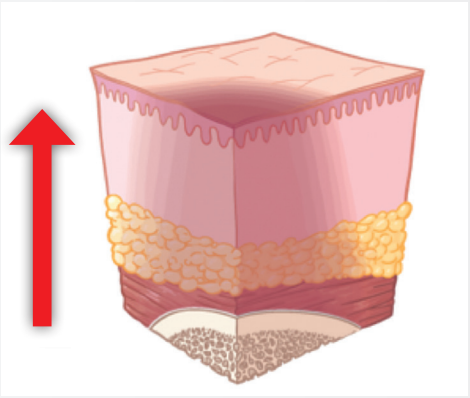

Figure 2: PIs/PUs develop from the inside out

What is the 'inside out' phenomenon?

Although current methods of detection for PIs/PUs tend to rely on changes at the skin surface, physiological changes below the skin can precede these changes by 3 to 10 days[20] (Figure 2).

When a person is lying or sitting, pressure is transferred from the external surface through to the underlying bone; the intermediate layers are compressed between the bone and the external surface, resulting in a cone-shaped pressure gradient (otherwise known as the 'cone of pressure'). This gradient means that pressure exerted on the deeper tissues is far greater than at the surface of the skin[26].

This 'inside out' phenomenon can also be seen in Figure 1, which shows:

- **The damage threshold: the point at which an objective test may detect early physiological changes below the skin**
- **The manifestation threshold: where pressure damage becomes apparent at the skin.**

Table 1: Comparison of current risk assessment and detection methods[19; 27–32; 33–35]				
Assessment tool	**Sensitivity**	**Specificity**	**Odds ratio**	**95% Confidence Interval**
Braden scale	57.1%	67.5%	4.08	2.56–6.48
Norton scale	46.8%	61.8%	2.16	1.03–4.54
Waterlow scale	75.8%	27.4%	2.05	1.11–3.76
Clinical judgement	50.6%	60.1%	1.69	0.76–3.75

Are existing methods for PI/PU risk assessment and diagnosis effective?

International recommendations state that a risk assessment should be completed within 8 hours of admission to healthcare facility[4]. As risk assessment tools identify multiple known risk factors and are not exact predictors of PI/PU development, it is important to understand their limitations and use risk assessment tools to provide corroboration for clinical judgement[25]. Examples include the Braden scale, the Norton scale and the Waterlow scales (Table 1). These tools are widely used, but their scoring systems are subjective and questions have been raised about their reliability and validity[36].

It is recommended in various guidelines, including those of the NPUAP/EPUAP/PPPIA[4], that nurses also use their clinical judgement during assessment, which may override the results of the risk assessment 'score'. Since visual inspection is largely dependent on caregiver skill, a wide variation in results can be seen. The PI/PU must be at or close to the skin surface and skin colour may affect diagnosis, since redness can be harder to see in darker-skinned patients. In addition, PIs/PUs may occur suddenly without visual clues (i.e. in deep tissue injury)[36].

A Cochrane review of risk assessment tools[37] concluded that there is no reliable evidence demonstrating that use of structured PI/PU risk assessment actually reduces incidence, and their systematic use may not be the best use of nurses' valuable time[38]. While a number of different risk assessment tools exist, is seems that none is universally effective or reliable and there is a missing link between assessment, care planning and preventative action[39].

Table 1 outlines the comparative sensitivity (the proportion of positives correctly identified as such) and specificity (the proportion of negatives correctly identified as such) of PI detection methods, showing that they are largely insufficient.

What is sub-epidermal moisture?

Sub-epidermal moisture (SEM) is a biophysical indicator associated with localised oedema in the inflammatory phase. Inflammatory changes and tissue oedema as a result of pressure injury have been shown to occur in the 3 to 10 days before skin breakdown. An integral part of the tissue damage process during prolonged periods of mechanical loading is an increase in SEM – or water present in the tissues below the skin's surface – which occurs as blood and lymph vessels are blocked and waste products accumulate in the cell niche and interstitial space[3].

What is the SEM Scanner?

The SEM Scanner is a simple, non-invasive, hand-held device for the identification of early-stage PIs/PUs. The SEM Scanner uses capacitance technology to assess macroscopic changes in moisture as skin and tissue progressively change (Figure 1). The SEM Scanner detects these changes beneath the surface of the skin using an integrated electrode sensor. The SEM Scanner works by directly measuring the capacitance (i.e.the ability to store an electric charge) between two insulated electrodes placed on the skin to assess changes in SEM. The SEM Scanner does not emit any radiofrequency energy and there is no current passing through the body between the electrodes. The SEM Scanner is indicated as an adjunct to current clinical judgment for early detection of PIs/PUs in the heel and sacrum. A series of recent papers have explored the use of SEM to predict PI/PU risk, with the intention of showing that such a device could detect the presence of early pressure damage, allowing interventions to be put in place to prevent more serious pressure damage:

- **Bates-Jensen et al (2008)[40] – SEM Scanner scores can differentiate between erythema and Category I PIs/PUs in nursing home residents**
- **Bates-Jensen et al (2009)[2] – higher SEM scores are associated with early PI/PU damage in nursing home residents with dark skin tone**
- **Guihan et al (2012)[41] – SEM scoring could be used for early detection of PIs/PUs in patients with spinal cord injury**
- **Harrow et al (2014)[42] – SEM differentiates PIs/PUs from intact skin**
- **Swisher et al (2015)[43] – impedance is robustly correlated with tissue health across multiple animals and wound types (tested in vivo).**

As an adjunct to existing methods, the SEM Scanner overcomes the problems of subjectivity, caregiver skill and patient characteristics, giving an objective view of underlying tissue

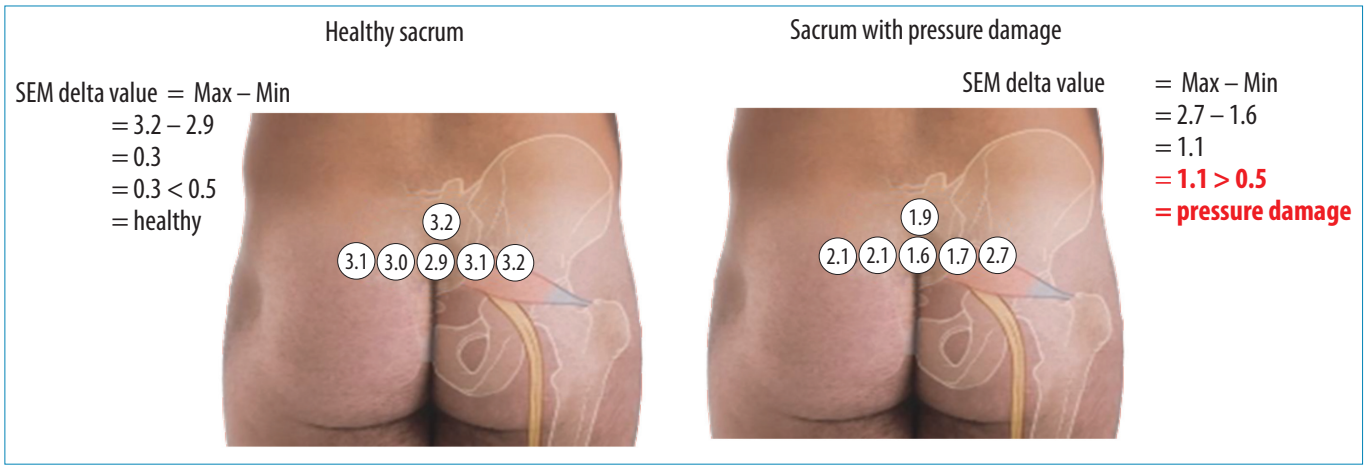

Figure 3: Comparative SEM delta values for healthy and damaged tissue

damage that leads to pressure damage development, reducing the risk of associated problems, including poor patient quality of life and increased levels of economic burden, morbidity and mortality related to PIs/PUs.

How to use the SEM Scanner?

The SEM Scanner detects SEM fluctuations using an integrated electrode sensor placed on the patient's skin:

- **Place the SEM Scanner sensor directly in contact with the skin for ~1 second**
- **The unit processes the signal and displays a reading**
- **Continue scanning until you have completed at least three readings at each anatomical site**
- **When completed for each site, the SEM Scanner will display the SEM delta value (Δ), which can be calculated as the difference between the highest and lowest readings**
- **A SEM delta value of >0.5 (0.6 and above) denotes possible underlying tissue damage and suggests the presence of early pressure damage.**

Figure 3 depicts comparative SEM delta values for healthy and damaged tissue. The SEM Scanner can be entirely individualised, with measurements taken for deviation in SEM delta values against the patient's own baseline, which could be affected by medicines, comorbidities (e.g. diabetes), or lifestyle choices (e.g. smoking).

What evidence is available for the SEM Scanner?

An overview of evidence for the SEM Scanner is provided in Table 2.

Table 2: Summary of published literature for the SEM Scanner

Reference	Name of paper	Summary of results
Clendenin et al, 2015[44]	Inter-operator and inter-device and reliability of the SEM Scanner	More than 3000 SEM Scanner readings were obtained during this study. Agreement between operators was good (mean differences ranged from 0.01 to 0.11). Inter-operator and inter-device reliability exceeded 0.80 at all anatomical sites. The results of this study demonstrate a high level of reliability and good agreement of the SEM Scanner across different operators and devices.
Gershon et al, 2014[45]	SEM Scanner readings to assess pressure-induced tissue damage	The SEM Scanner was used in two clinical studies to assess sacral and heel regions in persons affected and unaffected by PIs. SEM scores consistently showed a pattern of pressure-induced damage where it was present. Using the SEM Scanner Score (Δ) algorithm (the within-subject difference between the highest and lowest readings at an anatomical site), with a threshold of ≥0.6 as an indicator of the presence of a wound, the SEM Scanner achieved positive and negative predictive values over 91% and 86% for the sacrum. Additionally, it was found that the mean SEM Scanner reading at the periphery (e.g. Ring 3) of PIs was significantly higher than the mean reading from the same anatomical region unaffected by PIs/PUs.
O'Brien, 2015[46]	An investigation of the accuracy of early pressure ulcer damage assessment using subepidermal moisture measurement versus nurses' skin assessment	Cohort sampling of all at-risk patients took place over a 4-week timeframe (*n*=47). The SEM Scanner was more accurate in detecting skin changes versus nurses' assessment alone: 34% of patients (*n*=16) exhibited sustained elevated deviation in SEM and 100% of these patients went on to develop a PI/PU. The SEM Scanner also identified early damage on average 3.9 days ahead of the nurse specialist. These results demonstrate the SEM Scanner is an accurate and objective means of identifying early pressure damage.
de Oliviera, 2015[5]	The accuracy of ultrasound, thermography, photography and subepidermal moisture as a predictor of pressure ulcer presence – a systematic review	According to a systematic literature review assessing SEM, ultrasound and thermography, SEM and ultrasound showed the best outcomes in predicting PIs/PUs (although more studies are needed looking at the role of thermography), in particular, as it concerns accuracy of early detection. Visual skin assessments are important to daily practice, but cannot identify when PIs/PUs are developing, as this only becomes evident when visible changes at the skin occur.

FAQs for practice

Which patients should be scanned?
Any patients assessed as being at risk using the current risk assessment tool.

Who should be using the SEM Scanner?
The SEM Scanner can be used by any suitably trained operator; however, the results should be interpreted by trained healthcare practitioners.

How does the nurse identify the patients that should be scanned daily?
It should be based on the centre's protocol for identifying patients with high risk for PIs/PUs. For example, some centres may use certain values from risk assessment scales.

How do I integrate use of the SEM Scanner into my nurses' clinical workload?
Where the SEM Scanner is currently being used, it is being incorporated within admission assessment and inspection of the skin.

How long does the SEM Scanner take to get a reading?
Less than 1 second.

Does the patient feel pain or discomfort during the examination?
There is no pain or discomfort from the SEM Scanner assessment. However, the patient might feel discomfort from the position they are lying in to get the reading, but this would be the same position for the standard SSKIN (UK PI/PU prevention skin bundle) assessment and would also be for the same length of time.

How do I position the patient so that I can access the anatomical site where I will take the reading?
The skin needs to be dry and clean, preferably without moisturising cream applied. For a heel assessment, dorsiflex the forefoot by pointing the toes towards the shin. Place the electrode at the base of the heel and adjust for full skin contact. Four readings should be taken around the heel. For a sacrum assessment, position the patient at a 90° lateral position and take six readings over the sacral prominence and surrounding area. Make sure to reposition the patient comfortably when you have finished taking the readings.

How often do I need to examine the pressure areas with the SEM Scanner?
They should be examined once a day.

Does the SEM Scanner assessment take longer than standard skin assessment?
SEM Scanner examination usually takes the same length of time as standard SSKIN assessment.

Does the SEM Scanner have any wires that are attached to a power source or to the patient?
No, the SEM Scanner is a portable device with a built-in battery; there is no wire attached to the patient.

How long does the SEM Scanner battery last?
It lasts for around 4 hours of usage. Make sure to clean the device after each patient use.

What would I do differently as a result of using the SEM Scanner?
The SEM Scanner may lead you to target your preventative actions differently; for example, to use a different type of mattress or alter the frequency of repositioning.

This Made Easy has been supported by Bruin Biometrics. The views expressed in this Made Easy may not necessarily reflect those of the company.

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Author details

Moore Z[1], Gershon S[2], Fletcher J[3]

[1] Professor and Head of the School of Nursing and Midwifery, Royal College of Surgeons in Ireland; [2] President of Gershon Pain Specialists; Assistant Professor at Eastern Virginia Medical School, Department of Physical Medicine and Rehabilitation; [3] Independent Nurse Consultant

Case Study:

Aglécia Moda Vitoriano Budri, PhD Scholar, Science without Borders Programme, School of Nursing and Midwifery, Royal College of Surgeons in Ireland

USE OF THE SEM SCANNER: CASE STUDY

Background: An 80-year-old Caucasian patient with a history of thrombotic stroke, acutely treated followed by a stay of 2 months in a stroke rehabilitation unit, was admitted to a long-term care setting. At first examination, she had no cognitive impairment, was bedridden and presented with right side hemiplegia and right side hemiparesis. She was doubly incontinent with occasionally moist skin on the buttocks, but no signs of surrounding erythema, maceration or incontinence-associated dermatitis. In the visual skin assessment (VSA), no wounds and no signs of erythema over pressure areas were found. She had a Braden score of 12 and a PI prevention protocol was in place.

Results: An innovative approach was used to objectively assess pressure areas measuring SEM delta values using the SEM Scanner. Although the VSA showed no abnormalities, the SEM Scanner presented abnormal scores (greater than 0.5) for the sacrum area, indicating damage in the underlying tissue. Other pressure areas presented normal readings. During the following days, the VSA and SEM Scanner scores were performed once a day. VSAs were normal between day 1 and day 12; however, by day 13, a redness area was visually detected and on day 14 a non-blanchable erythema appeared on the right hand side of the sacrum (Grade I PI). SEM Scanner scores had shown mostly abnormal values since admission. In addition, before the visual confirmation on day 14, the SEM Scanner showed 5 days of consistent abnormal scores, indicating the presence of tissue damage (Figure 4).

Discussion: Although the VSA is still the gold standard and most common method of skin inspection, this case study demonstrates the value of SEM technology in early PI detection. PIs may start in the deeper tissues in patients with impaired mobility and may not be detected visually before tissue damage has occurred. Therefore, by measuring SEM, early tissue damage could be detected and the SSKIN bundle was employed in order to prevent tissue damage. These prevention strategies can be re-evaluated over time, as the scores show improvement or deterioration in tissue damage, thus providing clinicians with an objective guide to whether the elected prevention strategy has been successful.

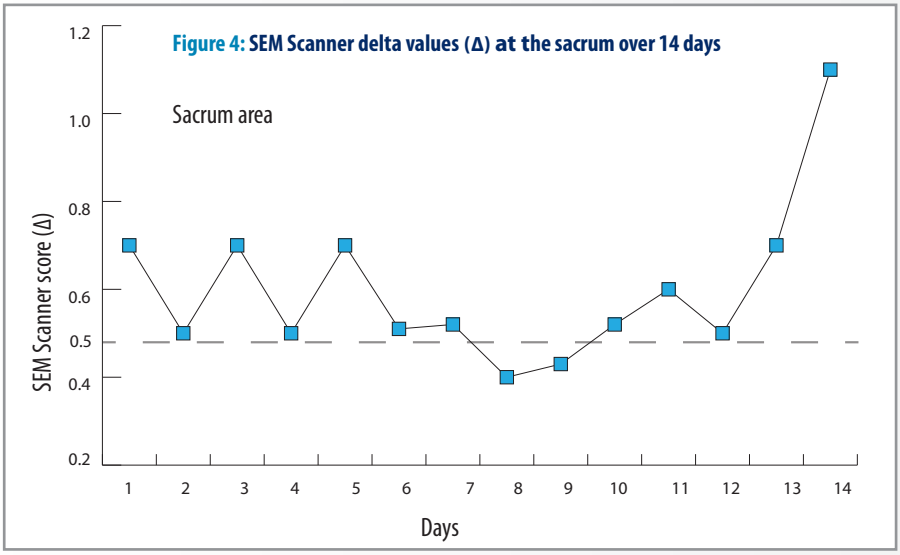

Figure 4: SEM Scanner delta values (Δ) at the sacrum over 14 days

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Summary

The SEM Scanner is a simple, reliable and effective means of identifying early pressure damage, allowing preventative strategies to be implemented, thus avoiding extension of the pressure injury and associated problems. SEM scores should be taken routinely when patients are admitted, in much the same manner as vital signs, whether to an acute hospital or a skilled nursing facility.

