SEM Scanner – Further Evidence Summary

RSCI Academic in Confidence Project summaries

[redacted] ***(O Brien G, Moore Z, Patton D, O Connor T, 2015)***

This study was included in the assessment report.

[redacted] ***. (Molloy S, Moore Z, O Connor T, Patton D, 2015)***

[redacted]

May be included but very little methodological information available and low-impact results.

[redacted] ***(O Connor R, O Connor T, Moore Z, Patton D, 2015)***

[redacted]

No methodological information available.

[redacted] ***. (Budri A, Moore Z, Patton D, O Connor T, 2018)***

This study was previously published as a poster with limited information and was not included in the assessment report.

The RSCI document provides more information.
[redacted]

There is limited methodological evidence available.
[redacted] Diagnostic accuracy measures are

comparable; they presumably still suffer from the same methodological difficulties as Okonkwo 2017 and 2018.

It should be noted that this study has been published under another title (please see below in the Newly Published Studies section).

[redacted] ***(De Martinez A, Moore Z, O Connor T, Patton D, 2018)***

This is a PhD thesis and was not included in the assessment report.

[redacted] The outcomes and setting of the study are outside of the original scope of the assessment report.

[redacted]
(Shanley E, Moore Z, Patton D, O Connor T, 2017)

The primary outcome of this study was [redacted] (outside of scope). [redacted]

[redacted] ***(McEvoy N, Moore Z, Patton D, O Connor T, Ongoing)***

This study is ongoing and has been marked as Academic in Confidence.

[redacted]

No conclusions can be made at this stage.

[redacted]
(Bennett S, Moore Z, Patton D, O'Connor T 2020)

This study is academic in confidence. A manuscript has not currently been made available to KiTEC.

[redacted]

[redacted] This finding begins to answer research recommendation “how changes in clinical decision making from using the scanner lead to reductions in the incidence of pressure ulcers”, although more information about the study methodology is needed.

Other Unpublished Studies

[redacted] ***. (Calvo Aguirre et al. Unpublished)***

[redacted]

This is a limited study due to its small sample size and failure to investigate why the correlation varied greatly between the heels and sacrum.

[redacted] ***(Steve Gershon, Henry Okonkwo, Martin Burns. Unpublished)***

This unpublished study [redacted] which appears to be further analysis of the patients included in Okonkwo 2018 – included in the assessment report.

[redacted]

The AUC values are new but the paper appears to add little to the already reported results.

[redacted] ***(Louisa Musa, Nicky Ore, Gillian Raine, Glenn Smith. Unpublished)***

This is a very large study (n=1478 patients) recruited through the PURPs established in 2014 in the UK. Therefore, it is very likely that there will be significant overlap (likely 100% although this is not clear) in this population and the population included in Hancock & Lawrence 2019 (also n=1478), included in the assessment report.

There was an overall reduction in PU incidence of 87.2% in acute care; 46.7% in palliative care, and 26.7% in community care. Ten (66.7%) sites reported a 100% reduction. These results are not reported in Hancock and Lawrence, which compared the study cohort to a historical cohort. It should be noted that (discuss the stuff in the executive summary).

Newly Published Studies

Impaired mobility and pressure ulcer development in older adults: Excess movement and too little movement—Two sides of the one coin? (Budri A, Moore Z, Patton D et al. 2020)

This study included the same population (n=150) as discussed in the Budri et al. 2018, above. The study focuses on the movement score of the patients. It also reports the time of detection prior to a PU forming as 8.2 days. The paper does not offer any further outcomes but does give some more detail on the methodology (a sample size calculation was included based on mobility, all patients were over 65 years of age in 2 long-term care facilities in Ireland).

Bedside Technologies to Enhance the Early Detection of Pressure Injuries: A Systematic Review (Scafide K, Curry Narayan M, Arundel L. 2020)

This systematic review assessed Ultrasound, Thermography, Reflectance Spectrometry and Laser Doppler and Subepidermal Moisture measurements as methods for detecting pressure ulcers. The papers included in the review were excluded from the EAC's assessment report, as they used other technologies to measure SEM, such as the NOVA petite dermal phase meter (*Bates-Jensen BM , McCreath HE , Kono A , Apeles NCR , Alessi C . Subepidermal moisture predicts erythema and stage 1 pressure ulcers in nursing home residents: a pilot study. J Am Geriatr Soc. 2007 ; 55 (8): 1199 – 1205*) **and were therefore considered outside of the scope**.

It should be noted here that one of these studies (Bates-Jensen et al. 2009) is cited by the EPUAP 2019 guidelines and by the company as a reference for clinical benefits in **different skin tones**. While this study does conclude that sup-epidermal moisture is associated with PU development in people with dark skin tones, the device used in this study is again the NOVA petite dermal phase meter, **not SEM Scanner.**

A further note is that Barbara Bates-Jensen is a co-inventor of the SEM Scanner.

Sensitivity and laboratory performances of a second generation sub-epidermal moisture measurement device (Peko and Cohen, 2020)

This letter to the editor describes the new version of the SEM Scanner (the Provizio SEM Scanner, referred to as SEM-2 in the paper) in a laboratory based study. It is reported that the SEM readings taken from tissue phantoms with the newer device are consistent with the previous iteration. **This is useful to know but as it is not a human trial it is out of the scope of the decision problem.**

The subepidermal moisture scanner: the technology explained (Gefen and Ross, 2020)

This paper explains much of the basic science behind the SEM Scanner's mechanism of action but is not a clinical trial itself. It includes much of the same information as the Aetiology Chapter of the 2019 EPUAP guidelines but as it does not include any relevant clinical outcomes **it cannot be considered within the scope of the decision problem.**

Using Subepidermal Moisture Level as an Indicator of Early Pressure Damage to Local Skin and Tissue (Gershon, 2020)

This study includes 50 healthy patients from the US (it is very likely that these are the same 50 health patients recruited in the study "Differentiating between Healthy Tissue and Early Stage Pressure Injuries: A Pilot Study of Effectiveness of the SEM Scanner Authors" mentioned above and Okonkwo 2018 assessed in the EAC report.)

This paper reported that there were no associations between the sex of the participants and SEM readings at the heel. There were no statistically significant variations based on sex, age, race, ethnicity, body mass index, smoking status, diuretics, surgery, or osteoarthritis among participant measurements at the sacrum, and of those factors**, only race indicated a variation between groups for heel measurements. As before, callouses of the heel were mentioned to be a potential confounding factor as well. Nine of the 50 patients were black; the authors note that this a low proportion.**