

Implementing evidence-based clinical pathways for improved pressure injury (PI) population intervention outcomes.

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Fundamental gap in understanding PI etiology and pathophysiology

The effect of Incipient invisible microscopic damage, i.e., Sub-epidermal Moisture (SEM), or localized oedema^{1,2}, is not being addressed in pressure injury (PI) prevention standard of care practices.

- ✗ Risk assessment tools are subjective and not anatomy specific³;
- ✗ Anatomy-specific prevention interventions occur after Visual skin assessments (VSA) confirm skin redness = damage already occurred;

Current SoC ≠ Prevention

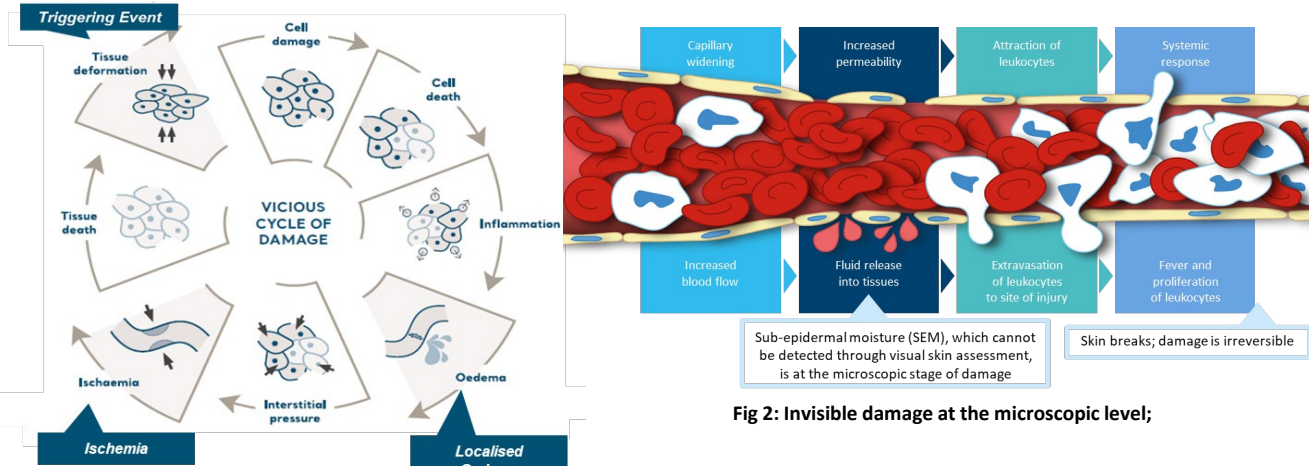


Fig 2: Invisible damage at the microscopic level;

SEM, or localized oedema is an early biomarker of pressure-induced damage

SEM assessment Technology*

- ✓ Objective, anatomy specific risk assessment
- ✓ Skin tone agnostic
- ✓ Early indication of risk (Median 5 days before VSA)⁴
- ✓ Enables keeping the skin intact even before skin redness

Uses biocapacitance sensors to compute a SEM delta value; SEM $\Delta \geq 0.6$ indicates increased risk of developing PIs at specific anatomies.

Fig 3: SEM Assessment Technology

Study Design

An evidence-based review approach was used to develop SEM assessment-based PI prevention pathways to implement in real-world care settings for treating SEM, also known as persistent focal oedema⁵, and achieving PI prevention.

Primary End Point

- Develop clinical pathways
 - Comprehensive literature review
 - “(sub-epidermal moisture) OR (sub epidermal moisture) OR (SEM Scanner)”
 - International Clinical Practice Guidelines²
- Real-world implementation of technology
 - Modernized PI reduction program
 - Treating SEM/localized oedema as a stage 1 PI
 - SEM assessment as an adjunct to SoC
 - 28 acute care settings
 - Pre and Post implementation data analysis

Results

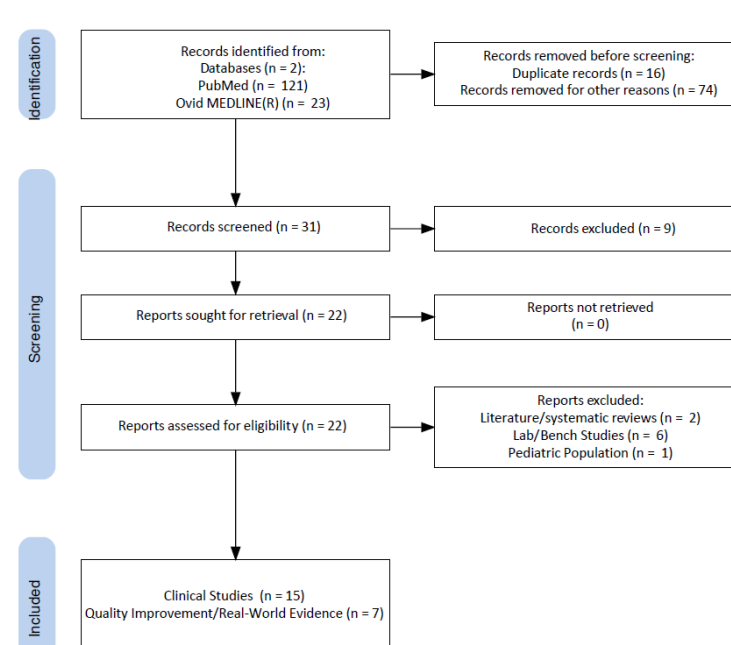


Fig 4: Literature Review Search Results

Clinical Pathway

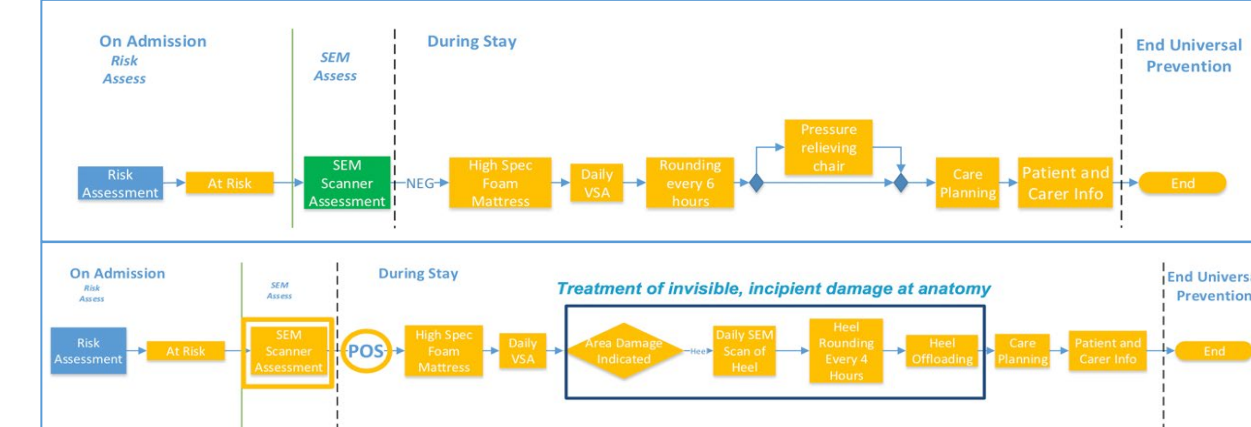
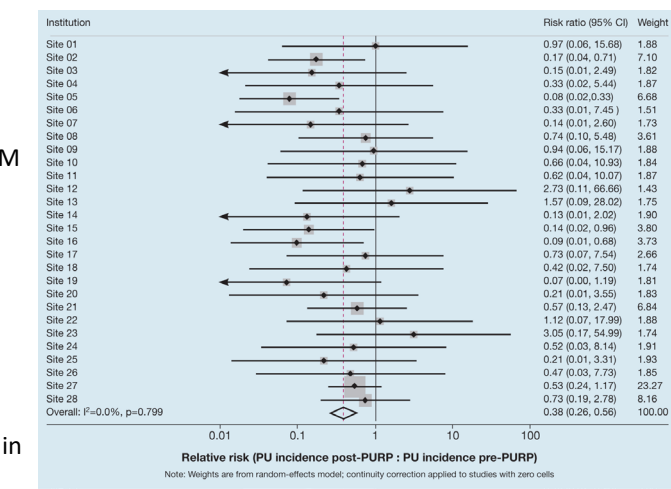


Fig 6: SEM assessments as an adjunct to existing standards of PI care

- ✓ No new staff
- ✓ No new interventions
- ✓ No new resources
- ✓ Acting on raised SEM delta (SEM $\Delta \geq 0.6$)
- ✓ Directing anatomy-specific
- ✓ Early interventions before skin redness

Real-World Impact

- 1995 Patients: Total at-risk patients scanned across 28 global facilities
- 83.9% SEM assessments: indicated a prompt for clinical action (SEM $\Delta \geq 0.6$)
- 100% PI incidence reduction achieved in 19/28 facilities during the program (Zero HAPIs)
- 6 Sites achieved statistically significant PI incidence reductions ($p < 0.05$)
- RR=0.38: Meta-analysis identified statistically significant reduction in relative PI incidence risk post implementation ($p < 0.05$)



Ousey, K, et al. Sub-epidermal moisture assessment as an adjunct to visual assessment in the reduction of pressure ulcer incidence. J Wound Care. 2022 Mar 2;31(3):208-216

- Step 1: On Admission**
 - Initial risk assessment, VSA and SEM assessment by health care practitioners (no additional resources)
- Step 2: During Stay**
 - Routine scanning coincides with risk and skin assessments (no change to current practice)
- Step 3: At Discharge**
 - Transfer a complete patient record with evidence of current tissue status
 - Facilitates integrated care

Fig 5: Implementing SEM assessment technology into clinical practice

Conclusion

Real-world implementation of SEM assessment technology into PI prevention pathways enables early, anatomy-specific interventions. Objective SEM assessment data enables clinicians to treat localized oedema, even before skin redness, enabling facilities to achieve consistent PI incidence reductions at scale.

References

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 4. Okonkwo et al, 2020. A blinded clinical study using a subepidermal moisture biocapacitance measurement device for early detection of pressure injuries. Wound Repair Regen.
 5. WHO 2020. ICD-10 : International Statistical Classification Of Diseases And Related Health Problems : Tenth Revision. 2nd ed. US Revision Geneva: World Health Organization.
- * Provizio® SEM Scanner