TOPIC 6: ELECTRICAL BIOCAPACITANCE FOR ASSESSMENT OF PRESSURE INJURIES

PROVIZIO® SEM SCANNER

ICD-10 PCS Coordination and Maintenance Committee Meeting

12th September 2023

Speakers:

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*The views and ideas presented here by Dr. Padula are his opinions and do not reflect the opinions of the University of Southern California

A PERNICIOUS CLINICAL BURDEN

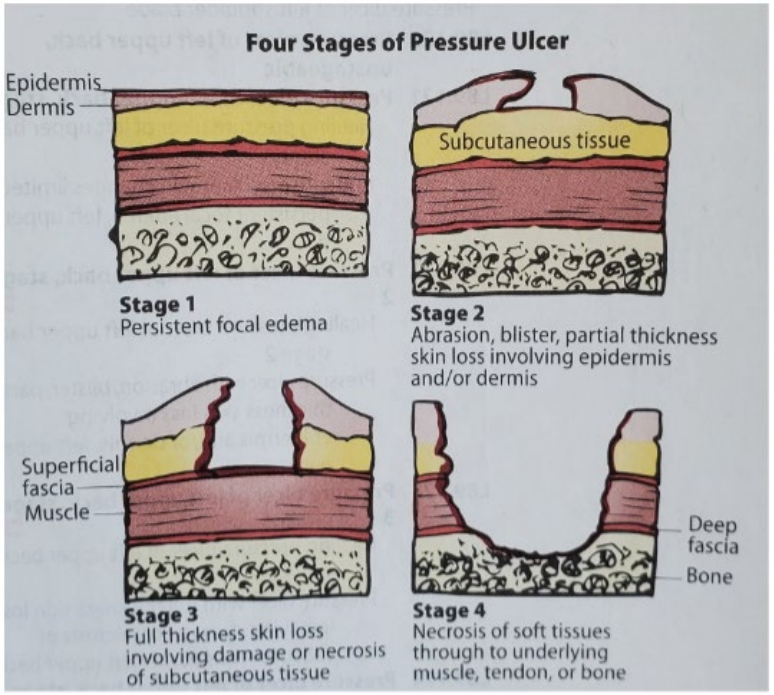
PRESSURE INJURIES/ULCERS (PI) ARE FREQUENT, SERIOUS, AND EXPENSIVE WOUNDS

- PIs occur in patients with restricted mobility in inpatient hospital and other settings[1]
- Not treating PIs leads to severe complications including infection, tissue necrosis and sepsis
- $27 billion is spent every year on PIs[2]

** Pressure Injuries (PI) will be used as the term to denote Pressure Ulcers, Bed Sores, Pressure Sores*

ASSESSING PIs IS A CLINICAL CHALLENGE

- Pre-ulcer skin changes limited to persistent focal edema, a condition requiring treatment
- This localized edema is invisible and precedes visible skin damage by 3-10 days[3]
- Current visual and tactile assessments do not detect pre-ulcer skin changes
  - Risk assessment tools are subjective and not anatomy specific
  - Skin assessments trigger anatomically specific interventions BUT only when redness is visible
- Visual diagnosis via skin redness fails dark skin tone patients[4]



Persistent Focal Edema – Stage 1 PI/PU (ICD-10-CM Rubric)

Identifying microscopic conditions using macroscopic methods does not work

THE VICIOUS CYCLE OF PIs

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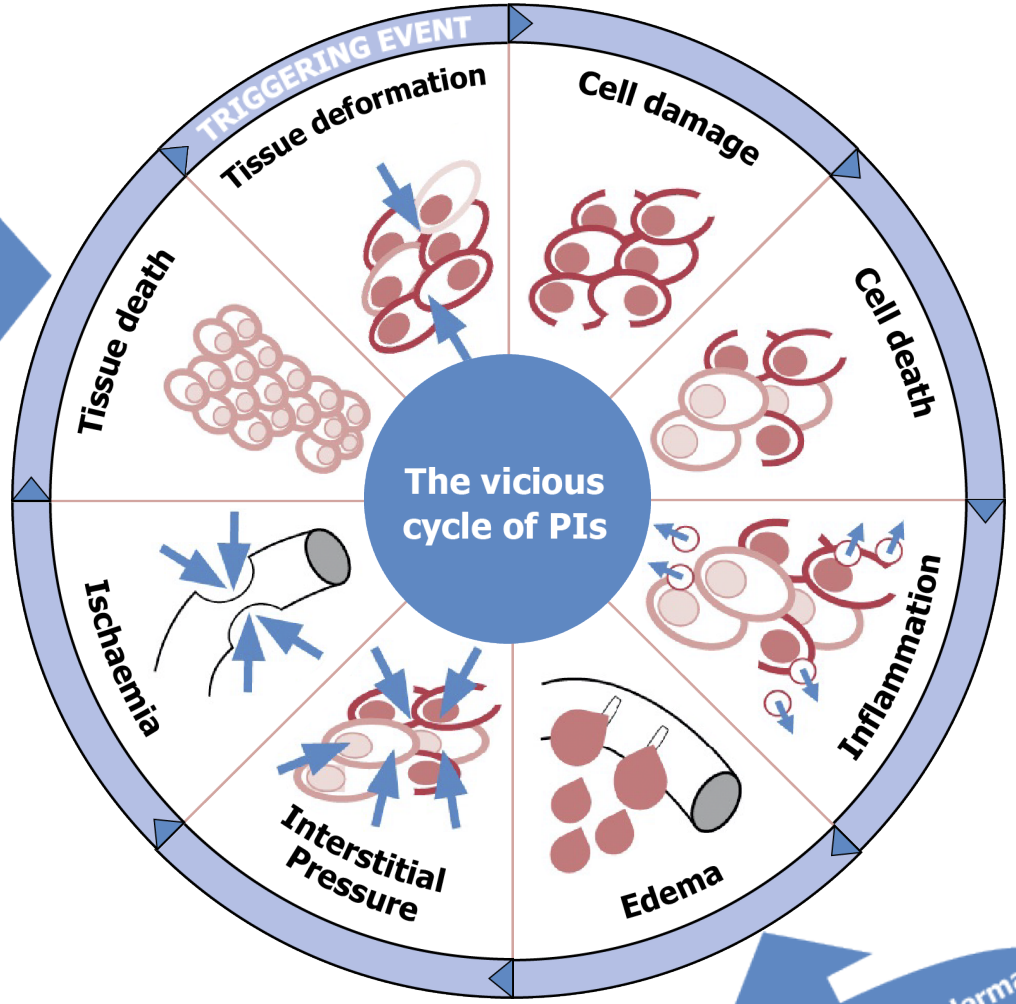
Skin Tissue Assessments detect tissue damage: latency in detection and intervention



Measurable by Sub-Epidermal Moisture (SEM) Assessments

Early detection 5 days before visual skin assessments

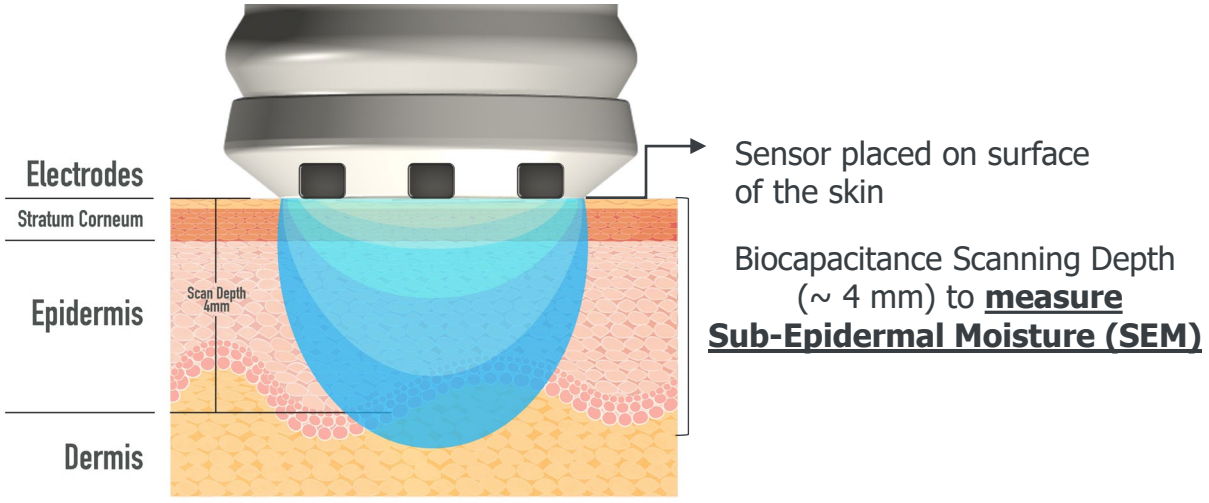
WHAT IS THE PROVIZIO® SEM SCANNER

1. Handheld, wireless, bedside technology
2. Single-Use Sensors
3. Charging and Data Transmission Hub
4. Digital Gateway Dashboard

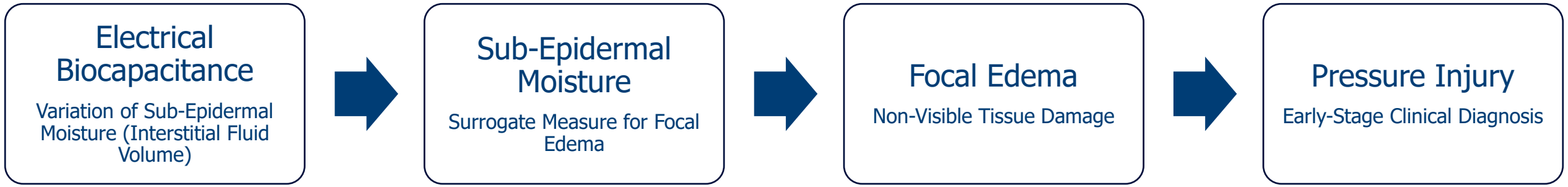
The SEM Scanner's anatomy-specific measures of SEM/localized edema/persistent focal edema, when treated, break this vicious cycle, changing the clinical course of PI progression

WHAT THE DEVICE DOES - BIOCAPACITANCE TECHNOLOGY

- Biocapacitance is an electrical property of tissue
- "Tissue **biocapacitance rises** when the extracellular water content (SEM) increases, because a localized **inflammatory response** is triggered"[6]
- Biocapacitance sensor measures and monitors changes in SEM or localized edema (~ 4mm beneath the skin surface)



CLINICAL APPLICATION OF THE TECHNOLOGY



SCANNING PROCEDURE

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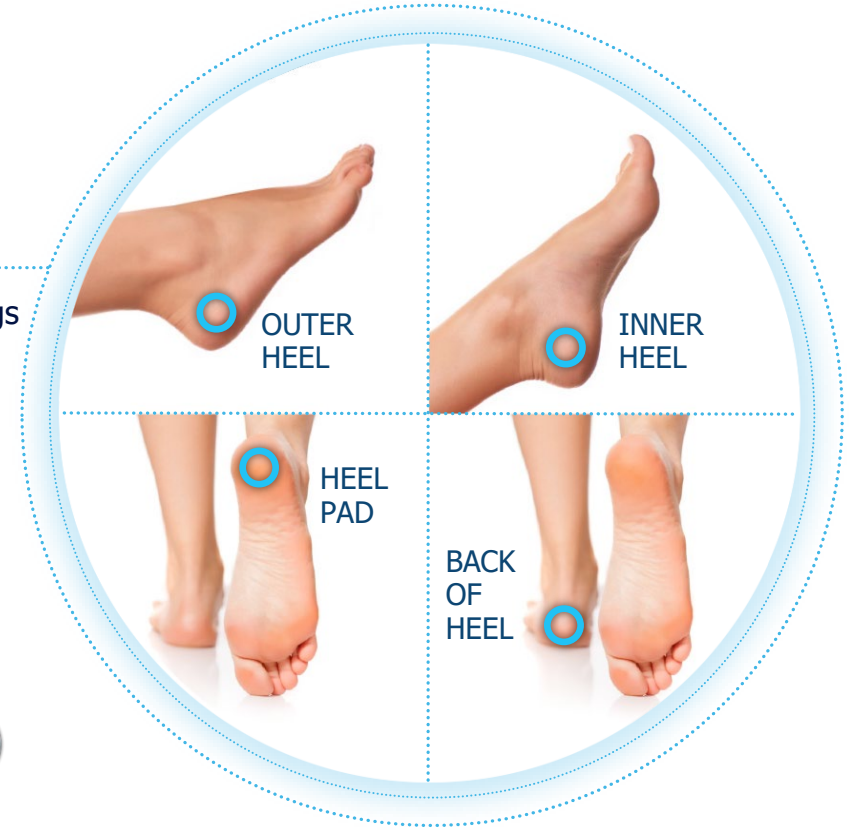
PRESSURE INJURIES ARE MOST COMMON AT THE SACRUM AND HEELS

SACRUM

6 Six Readings around the sacral bony prominence

HEEL

4 Four Readings around the heel bony prominence



SEM Δ ≥ 0.6 indicates an increased risk of PI development

WHEN TO USE THE PROVIZIO® SEM SCANNER

Once placed in cradle, data automatically transfers to **Gateway Dashboard** for patient, ward and facility management purposes

ON ADMISSION

Initial risk, skin and tissue assessment including SEM scanning

DURING STAY

Daily scanning integrates with risk and skin assessments

AT DISCHARGE

Transfer a complete patient record with evidence of current tissue status

Six (or more) scanning sessions may be used per patient depending on the length of stay (average of 5.5 days; 1 sensor per scanning session; 6-18 sensors used per patient)

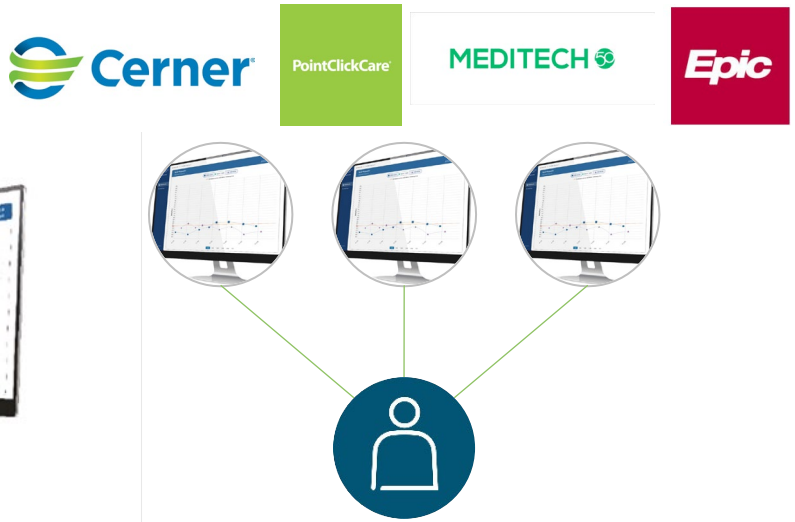
PROVIZIO® GENERATES ACTIONABLE DATA FOR BEDSIDE INTERVENTIONS

Healthcare Professional

- Early identification of localized PI risk
- Implement and measure intervention impact

Facility

System



- Digitized data and EMR integrations (e.g., Cerner, Epic, MEDITECH, PointClickCare)
- Monitor and manage enterprise-wide compliance
- Real-time deployment and redirection of care protocols
- End-to-end encrypted quality data
- Readily available for hospital reporting

REGULATORY AND CLINICAL STATUS

REGULATORY

- Authorized by FDA under De Novo, December 2018
- Worked with FDA to create a new category Pressure Ulcer Management tool; product code QEF
- Breakthrough Designation to be sought FY 2024
- New Technology Add-On Payment (NTAP) to be sought FY 2025

CLINICAL

- Used in all types of inpatient care settings across the USA
- No reported safety events
- Clinical workflows using Provizio® SEM Scanner are well-established, validated and deployed for different care settings

MEDICAL RECORD DOCUMENTATION & KEY TERMS

Standardized, electronically reportable:

- Patient admission records
- Daily progress notes
- Discharge records

Key terms:

- Electrical Biocapacitance
- Sub-Epidermal Moisture (SEM)
- Interstitial Tissue Fluid
- Focal Edema
- Early detection of pressure injuries and deep tissue injuries

THANK YOU

REFERENCES

1. Okonkwo H., et al. (2020). A blinded clinical study using subepidermal moisture biocapacitance measurement device for early detection of pressure injuries. Wound Repair and Reg; 1-11. https://doi.org/10.1111/wrr.12790
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3. Moore, Z., Mcevoy, N. L., Avsar, P., Byrne, S., Vitoriano Budri, A. M., Nugent, L., O'connor, T., Curley, G. & Patton, D. 2022. Measuring subepidermal moisture to detect early pressure ulcer development: a systematic review. Journal of Wound Care, 31, 634-647
4. Oozageer Gunowa, Neesha et al. "Pressure Injuries in People with Darker Skin Tones: A Literature Review." Journal of Clinical Nursing, vol. 27, no. 17-18, 2018, pp. 3266-75, doi:10.1111/jocn.14062.
5. Adapted from Gefen, A., et al. (2020). Update to device-related pressure ulcers: SECURE prevention. COVID-19, face masks and skin damage . Journal of Wound Care Vol 29, NO 5, May 2020. Figure reprinted by permission of MA Healthcare Ltd.
6. Gefen, A., (2020). The Subepidermal Moisture Scanner: the technology explained. Journal of Wound Care 1;29(Sup2c):S10-S16

