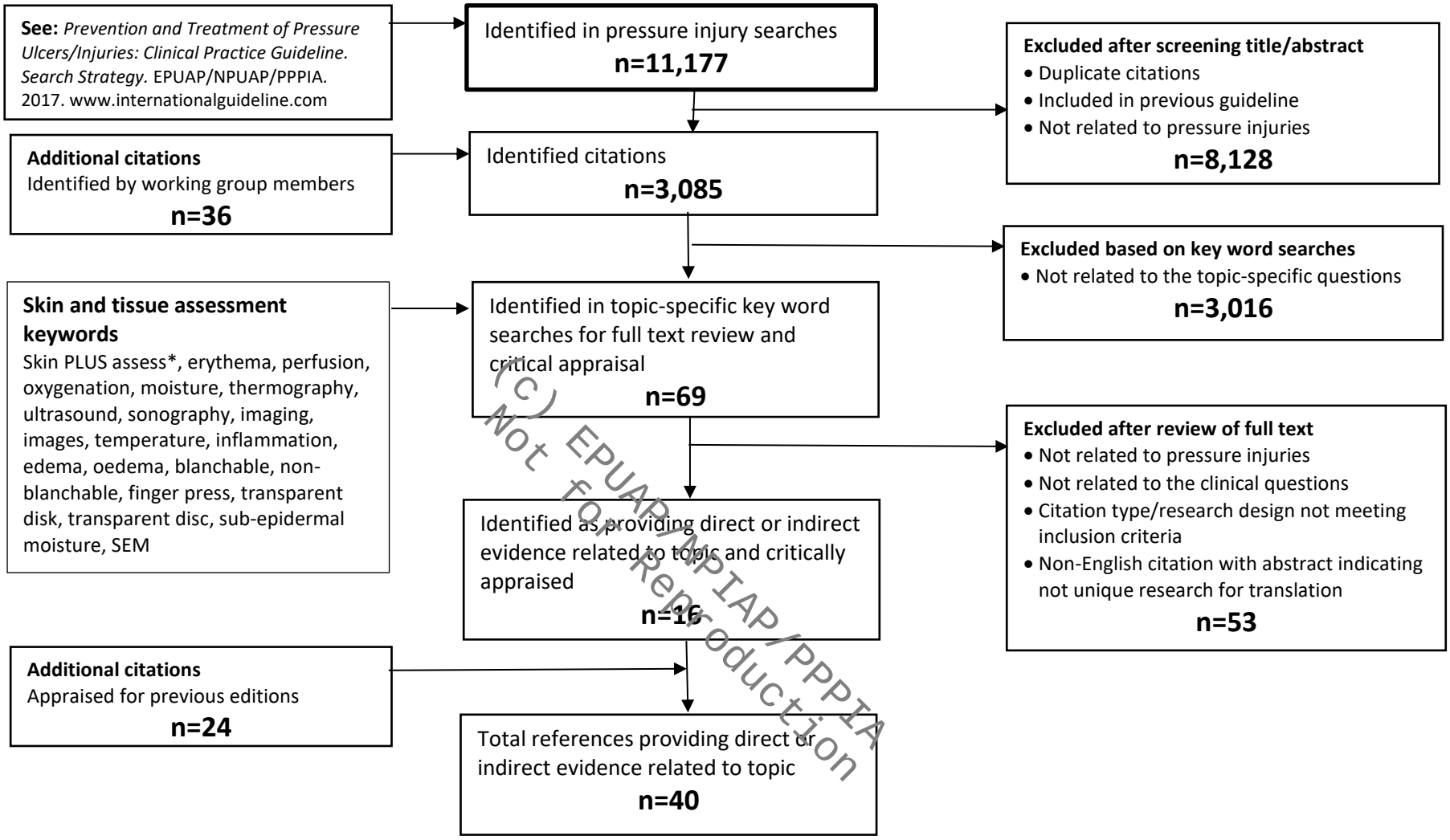
Search results for 2019 International Pressure Injury Guideline: Skin and Tissue Assessment



European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Articles Reviewed for International Pressure Injury Guideline

The research has been reviewed across three editions of the guideline. The terms pressure ulcer and pressure injury are used interchangeably in this document and abbreviated to PU/PI. Tables have not been professionally edited. Tables include papers with relevant direct and indirect evidence that were considered for inclusion in the guideline. The tables are provided as a background resources and are not for reproduction.

European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. The International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA; 2019

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Clinical question 1: What scale/ tools are effective methods to assess the skin and soft tissue?							
Honaker, Brockop p, & Moe, 2014	Psychometric study to describe the development of the Honaker Suspected deep tissue injury scale (HSDTISS)	• Study was conducted at one clinical site in the US with 10 clinical experts (medical/surgical nurses and critical care nurses) in phase one and focus group of 21 clinicians (6 physical therapists and 15 nurses) in phase 2 • No inclusion and exclusion criteria described	The HSDTISS is a 3-item scale that include; total surface area (1-7p), skin integrity (1-3p) and wound color/tissue assessment (1-7p). A cumulative score is calculated that ranges from 3 to 18 where three indicates normal skin and 18 indicates a stage IV pressure ulcer	The scale was validated by using photographs. The photos was of the 3 patients with suspect deep tissue injuries (SDTI) at admission and at discharge.	**Reliability measures** • Interclass correlation coefficient showed an excellent correlation among the 21 participants (r = 0.997; P <0.001). • There was 100 percent agreement among the staff nurses that the instrument was clear, concise, easy to use and reflected the various clinical presentations of STDI that they had encountered previously. **Feasibility** • The time to assess and score the six photographs took 8.2 minutes (± 2.3 minutes).	• Findings reflects only initial validation of the instrument and needs additional testing. • Data was collected at a single site • The use of photographs does not represent real life wounds and six photographs may be too few.	**Indirect evidence (PU not an outcome measure)**
Sving, Idvall, Högberg, & Gunning berg, 2014	Cross-sectional study exploring **likelihood of skin and risk assessment being conducted and whether pressure**	Study conducted in one general hospital and one university hospital in Sweden (n=1450 beds in total, n=825 patients included) Inclusion criteria: • Adult patients >17 years admitted prior to midnight on the day of the study	Audit of documentation of: • risk assessment • Skin assessment • Use of pressure redistribution mattress • Use of planned repositioning	• Two trained RNs collected all the data	**PU prevalence** • Prevalence HAPU Category/Stage I to IV was 12.6% • Prevalence HAPU Category/Stage II to IV was 4.7% **Likelihood of skin assessment** • Pressure injury prevention was conducted for 44.1% to 58.7% of patients rated as at risk of pressure injury	• Limited to two hospitals that excluded area of high PU risk	**Indirect evidence (PU not an outcome)**

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	injury prevention plan is implemented	Exclusion criteria: • ICU Characteristics: • The general hospital had more registered nurses in direct patient care (62.8% vs 52.8%) • The general hospital had more RNs with greater experience (14.8% vs 10.9%) • Mean stay 6 days (IQR 2 to 16) • 18% participants had Braden score < 17	• Demographics on the individual and the hospital		• Patients at risk of pressure injury had higher odds of having a skin assessment documented (OR 1.916, 95% CI 1.216 to 3.019, p<0.005) • Patients who were older were more likely to have skin assessment (OR 1.02, 95% CI 1.009 to 1.031, p<0.001) • Hospital and unit were also significantly related to OR of getting a skin assessment • Nursing staff hours, workload and qualifications was not associated with OR of having a skin assessment • Patient age and hospital were significantly related to likelihood of having a risk assessment performed **Author conclusions: Patients at risk of developing pressure injuries had higher chance of having risk and skin assessment documented , and when documented individuals were more likely to have a care plan developed**		
Clinical question 2: What are effective methods of assessing erythema?							
Sterner, Fossum, Berg, Lindholm, & Stark, 2014	Diagnostic study to evaluate if a reflectance spectrophotometer is of clinical value in differentiating blanching and non-blanching erythema in sacral region	Participants recruited in a hospital in Sweden (n=97 patients fulfilled inclusion criteria, n=19 withdrew; n=78 completed) Inclusion Criteria: • Age 65 years of older • hip fracture Exclusion Criteria: • pre existing skin dermatosis	• After visual inspection, sacral area was evaluated using a narrow-band spectrophotometer Skin color is determined by measuring the intensity of reflected or absorbed light of	• Finger press tests were performed by 2 assessors • Patients were followed from admission through post operative day #5 • Increased flow of red blood cells to the skin area causes less light to be reflected back to the spectrophotometer, and the erythema Index (E index) increases	Using the spectrophotometer, results showed significant change over time for the mean value of the e Index across 8 points of the sacral area (p<0.001) Post hoc contrasts showed significantly higher E index valued from day 2 to day 5 compared with day 1 (p=0.015, p=0.002, p 0.001 and p<0.001 respectively) Reference point on hip showed no significant changes during measurement period (no pressure was on hip area) (P=0.32)	• sample size limited • Instrument was only tested in the sacral area • Instrument had a small optical measuring head;; as a result: • red areas near this may have influenced the results	**Level of evidence: 1 (diagnostic)** **Quality: High**

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	of people having hip fracture surgery	• pressure ulcers stage 2 or greater in the sacral area • major trauma Participant characteristics: • all caucasian • 14 men, mean age 74 • 64 women, mean age 82 • 41 patients = pertrochanteric or subtrochanteric fractures • Approx 30% had a pressure injury at admission	a particular wavelength • recordings taken from admission to 5 days after surgery • patients were placed in a side lying position, & skin cleansed with a standardized method • pressure was removed from the sacral area 5 minutes before assessment done • finger-press test was conducted prior to the spectophotometr y test		Good ability to differentiate between blanching and nonblanching erythema **Conclusion:** • **reflectance spectophotometry is a useful tool in detecting skin areas at risk for development of pressure ulcers** • **device is easy to use** • **device can register minor changes in skin color** • **high precision in classifying blanching & nonblanching erythema was reached**	• large skin areas require several measuring points • author comment: further development of the equipment would be beneficial	
Scheel-Sailer et al., 2015	To measure the biophysical skin properties in the unloaded sacral region in healthy persons after supine position and to assess the absolute and relative reliability of	Participants were healthy volunteers recruited in Switzerland (n=10) Inclusion and exclusion criteria: • Not defined Participant characteristics: • healthy Caucasian volunteers	• Four x 15 minute bedrest on their back in a hospital bed with a standard mattress with an unload period of 30 minutes between • For the measurements, participants turned from supine position to lateral position	• Two researcher did the measurements alternately (A-B-A-B) • Skin hydration measured with a capacitance based measurement device (Corneometer CM 825) • Skin redness measured with an optical method (Mexameter MX 18) • Skin elasticity measured with a 4-mmdiameter-opening suction probe (Cutometer MPA 580)	• **Reliability** • The intra-rater correlation (ICC) was below the recommended quality level of 0.7 for skin hydration for both raters and for perfusion for one rater • The inter-rater correlation (ICC) was below 0.7 for skin hydration, elasticity and perfusion • The measurement of redness showed the best correlations for intra-rater and inter-rater while correlations of the other parameters varied widely between moderate to high (perfusion: 0.367 - elasticity: 0.911).	• Movements or activities and eventually influences by emotional stress or mental processes has not been observed during the study – aspects that can affect potential dynamic changes in the skin. • It is not guaranteed that researchers has located exact	**Indirect evidence: PU not an outcome measure/ healthy volunteers**

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	the measurement methods.			• Skin perfusion was measured using a laser Doppler flowmeter (PeriFlux System 5000)	**Author conclusions: The results add to the understanding of skin physiology but raise questions about reliability of measurement methods and complexity of skin physiology**	the same spots of the skin each measurement	
Vanderwee, Grypdonck, Bacquer, & Defloor, 2006	Cross sectional study to **compare different methods of evaluating erythema**	Participants were recruited in one hospital in Belgium (n=265) Inclusion criteria: • Erythema at the heels, hips, and sacrum as assessed by the research daily in the morning Participant characteristics: Mean age 88 years 57.8% female	• Finger press method: pressure exerted by finger on the erythema for 3 seconds and classified as blanchable erythema if the erythema blanched when finger removed • Transparent disk method: disc taken by borders between fingers and pressed on skin, if skin beneath disk blanched, classified as blanchable erythema	• 20 day study • All participants observed by researcher to have erythema were evaluated by a trained nurse within 30 minutes • Researcher and nurse both used finger press method and transparent disc method to assess erythema (randomized order)	**Finger press method at all anatomical locations** • Agreement between researchers and nurses: 92.1%, κ = 0.69 • Sensitivity 73.1% • Specificity 95.5% • Positive predictive value 75% • Negative predictive value 95.1% • Interrater agreement ranged from κ = 0.62 to κ = 0.72 depending on experience of nurses **Transparent disc method at all anatomical locations** • Agreement between researchers and nurses: 91.7%, κ = 0.72 • Sensitivity 74.5% • Specificity 95.6% • Positive predictive value 79.5% • Negative predictive value 94.2% • Interrater agreement ranged from κ = 0.68 to κ = 0.76 depending on experience of nurses **Agreement between methods** • All anatomical locations: agreement 96.7% (95% CI 95.3 to 97.6), κ = 0.88 (95% CI 0.84 to 0.92) • Sacrum: agreement 93.4% (95% CI 89.4 to 96), κ = 0.83 (95% CI 0.75 to 0.92) • Heels: agreement 97.7% (95% CI 96.2 to 98.6), κ = 0.90 (95% CI 0.86 to 0.95)	• No blinding • Finger press method is variable, not consistently applied reference standard	**Level of evidence: 2 (diagnostic)** **Quality: high**

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					Conclusions: transparent disk method has advantages over finger press as pressure applied to the skin is less variable between assessors and blanching is observable immediately, which increases ease of assessment in individuals with rapid vascular refill.		
Sterner, Lindholm, Berg, Stark, & Fossum, 2011	To establish the interrater reliability between blanching and nonblanching erythema assessments	Participants with hip fractures recruited consecutively in an emergency department in Sweden (n=97 recruited, n=78 participated) Inclusion criteria: • Hip fracture • Aged above 65 years • Admitted to orthopaedic ward Exclusion criteria: Admitted to geriatric ward Pre-existing skin disorder Category/Stage II or greater pressure injury at sacrum Participant characteristics: • Primarily females • Age range 65 to 100 years	• Visual assessment: conducted using a standardized protocol and sacral skin condition documented as normal skin or visible erythema • Finger press method: light finger press and documented as blanching or nonblanching erythema	• two independent assessors performed both tests on a daily basis • Independent assessments made at the same time	**Interrater reliability visual inspection** Day one κ = 0.67 (95% CI 0.5 to 0.82) Day five κ = 0.76, 95% CI 0.61 to 0.91) **Interrater reliability finger press method** Day one κ = 0.44 (95% CI 0.21 to 0.67) Day five κ = 0.20 (95% CI –0.06 to 0.46) **Conclusions: visual inspection and finger-press are both unreliable methods of differentiating between reactive hyperemia and Category I pressure injuries**	• Unclear how visual inspection was performed, and how blanching vs non-blanching was established on visual inspection • Assessors had no training • No comparison between tests or to a reference standard	**Level of evidence: 3** **Quality: low**
Vanderwee, Grypdonck, Bacquer, & Defloor, 2009	To identify prognostic factors associated with the development of	Participants were recruited over 18 months in 16 nursing homes in Belgium (n=235) Inclusion criteria: • Category/Stage I pressure injury • Able to be repositioned	Standard preventive care	• Daily skin assessment • NPUAP/EPUAP staging system • To differentiate between blanchable and non-blanchable erythema, a transparent plastic pressure disk (4 x 4 cm) was used • Inter-rater reliability of skin	**Cumulative pressure injury incidence** 18.7% **Reliability of erythema assessment using plastic disc** Interrater reliability between researcher and nursing staff (K=0.89, 95% CI = 0.87 to 0.92) Interrater reliability between study nurse	• Unclear methods for evaluating interrater reliability (e.g. time between assessments)	**Level of evidence: 1 (prognostic)** **Quality: high**

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	Category/Stage II and greater pressure injuries	• Stay > 3 days Exclusion criteria: Category/Stage II to IV pressure injury Participant characteristics: • 100% Caucasian • Primarily females • Mean age 87 years •		• assessment monitored by the researchers on a weekly basis • Follow up until developed Category/Stage II or greater pressure injury, discharged or death	and nursing staff (K =0.88, 95% CI = 0.85–0.91)		
Nixon, Cranny, & Bond, 2007	Prospective cohort study to assess the validity of signs of erythema as a predictor of pressure injuries	Participants were recruited in an acute-care hospital in the UK(n=109) Inclusion criteria: Aged > 55 years Length of stay above 5 days Having elective survgery Exclusion criteria: Dark skin tones Liver, urology or breast surgery Existing skin conditions at sacrum, buttocks, heels Participant characteristics: At baseline n=97 had no pressure injury Median age 75 years	• N/A	• Classification of skin was made using a scale by Nixon et al 1999 • Grade 0 no changes; Grade 1a blanching redness; Grade 1b non-blanching redness; Grade 1b + non-blanching redness plus one or more of heat, induration, pain, edema or discoloration; Grade 3 full thickness wound with subcutaneous tissue involved; Grade 4 full thickness wound with subcutaneous tissue and muscle or bone involved; Grade 5 eschar	**Pressure injury prevalence** 15 individuals had 26 pressure injuries in the trial, 23 were Category/Stage II pressure injuries **Multifactor analysis of factors associated with pressure injury** • Significantly increased odds of pressure injury when assessed as having non-blanching erythema (OR 7.98, 95% CI 2.36 to 39.97, p=0.002) • Significantly increased odds of assessed as having non-blanching erythema when assessed as having other skin changes (OR 9.17, 95% VI 1.17 to 71.71, p=0.035) **Conclusion: Non-blanching erythema is a predictive indicator of pressure injuries**	• Did not reach required sample size • Difference between Grade 0 and Grade 1a could not be established	**Level of evidence: 1 (prognostic)** **Quality: high**
Kottner, Dassen, & Lahmann, 2009	Quasi experimental comparing a **transparent disc to a finger method**	The study was conducted as part of an annual prevalence survey in 39 hospitals and 29 nursing homes in Germany (n=9752) (intervention = 4657; control = 5095)	• Facilities were randomly assigned to either: o Application of a transparent disc to	• Skin assessment conducted by two nurses simultaneously • grade I PU point prevalence • Braden score • prior to data collection all participating nurses were trained	**Correlation between finger method and disc method** • Category/Stage I pressure injury prevalence was significantly higher in the control group versus the intervention group (7.1% versus 3.9%, p<0.001)	• Study design was inappropriate for exploring the reasons why prevalence was much higher when	**Level of evidence: 4 (diagnostic)** **Quality: low**

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	for assessing erythema	Characteristics: • 76.6% were hospital patients (p<0.001 between groups, significantly more in control group) • Mean age approx. 68 years • Mean BMI approx. 25	reddened skin so assessment of blanching could be made at the same time as pressure was applied (n=4657) or ○ Skin inspection using the finger method of depressing skin to assess blanching (n=5095)	• For all facilities, skin examinations were conducted by a team of 2 nurses – both nurses had to agree on the presence or absence of a pressure injury	• OR of having a pressure injury identified via the disc method versus finger method was 1.80 (95% CI 1.49 to 2.18, p<0.001) i.e. chance of identifying a Category/Stage I pressure injury increased by 80% when the finger method was used. **Study conclusion: more Category/Stage I pressure injury are identified using the finger method; however, it is unclear why this is the case or if this accurately reflects pressure injury prevalence.**	the finger method was applied • Assumed the two comparison groups were identical • potential selection bias • no intention to treat analysis • potential for attrition no interrater reliability	
Vander wee et al., 2006	Observational study investigating **interrater reliability in assessing blanching and non-blanching erythema**	Participants were recruited consecutively in an acute geriatric ward over 20 days (n=265) Inclusion criteria: • erythema observed by researcher Characteristics of patient participants: • 57.8% participants were female • mean age 88 years • median Braden score 17 • No participants had dark skin Characteristics of nurses (n=16): • Average age 32 years • 37.5% Level 1 nurses, 43.7% level 2 nurses	• All assessors received pre-trial training • researcher assessed all patients on ward during morning shift • Any patients with erythema were entered into study and both researcher and nurse used finger method and transparent disk to assess erythema (order of assessment methods was randomized) • Assessors conducted assessments	• Skin assessments using finger press and transparent disk • Assessments made within 30 minutes of each other • Assessments conducted at sacrum, heels, hips •	**Finger method** • κ = 0.69 between nurses and researchers for all body locations, 73.1% sensitivity, 95.5% specificity • κ = 0.78 between nurses and researchers for sacrum, 86.3% sensitivity, 93.9% specificity • κ = 0.63between nurses and researchers for heels, 65.3% sensitivity, 95.8% specificity **Transparent disk method** • κ = 0.72 between nurses and researchers for all body locations, 74.5% sensitivity, 95.6% specificity • κ = 0.79 between nurses and researchers for sacrum, 86.1% sensitivity, 93.4% specificity • κ = 0.67 between nurses and researchers for heels, 67.2% sensitivity, 96.1% specificity **Agreement between two methods** • κ = 0.88 all locations, all assessors	• Assessors were aware of their assessment results using different methods so possible contamination of assessments • Only conducted in one ward	**Level of evidence: 1 (diagnostic)** **Quality: high**

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			within 30 minutes		• κ = 0.83 sacrum, all assessors • κ = 0.90 heels, all assessors • Agreement increased with increase in nurses experience and education levels •		
Sterner et al., 2011	Prospective cohort study **interrater reliability in assessing blanching and non-blanching erythema**	Participants were consecutively recruited in an emergency room in a hospital in Sweden (n =78) Inclusion criteria: • aged over 65 years • admitted to orthopedic ward with hip fracture • Exclusion criteria: • Pre-existing skin disease • Sacral PU Category/Stage II or greater Characteristics: • Mean age 82 years for women (n=64) and 74 years for men (n=14) • 58.7% (n=34) had no PU at discharge from orthopedic ward, 45.2% (n=34) had a Category /Stage I PU and 13.3% (n=10) had a Category /Stage II PU	• The sacral area of each participant was visually assessed by 2 blinded assessors • Skin assessment included a visual inspection and a finger press test •	• Blanching/non-blanching erythema • Pressure injury prevalence • Risk assessment • Assessments were made daily for up to 5 days or until discharge/death • Kappa statistics were used for analysis	**Finger press test** • κ = 0.44 (95% CI 0.21 to 0.67) on day 1, decreasing to κ=0.20 on day 5 (95% IC – 0.06 to 0.46) **Visual inspection** • κ = 0.67 (95% CI 0.53 to 0.82) on day 1, increasing to κ=0.76 on day 5 (95% IC 0.61 to 0.91) **Study conclusion: Finger-press tests and visual observation alone were not reliable methods to discriminate between blanching and non-blanching erythema**	• High rate of pressure injuries, potentially due to selection bias • Several different assessors were used, specific levels of experience not reported • Experience and education of assessors not reported • Blinded assessors had access to previous assessment results • Missing data	**Level of evidence: 4 (diagnostic)** **Quality: moderate**
Clinical question 3: Is ultrasound an effective method for assessing the skin and soft tissue?							
Scheiner, Farid, Raden, & Demisse, 2017	Prospective study to determine if ultrasound can detect DTI	Participants were recruited over one month in an emergency department in US (n=23)	• Educated on Identification of • Abrasions, rash, bruises and DTIs was given to	• Ultrasound by technician on 13 sites • CWON performed daily skin assessments up to 7 days • Braden risk assessment	**Ultrasound scan of deep tissue over bone and corresponding pressure injury (n=**299 scans) • 79 positives for DTI in subcutaneous tissue	• Very small study at one site • Consideration of ultrasound scans on admission in	**Level of evidence: 1 (diagnostic)**

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	not visible in the soft tissue	Inclusion criteria: • Minimum age 21 • One of 13 screening sites free of pressure injury • Ability to be moved for ultrasound screening • Braden scale ≤18 Exclusion criteria: • soft tissue trauma • Existing DTI or full-thickness pressure injury involving all 13 anatomical sites • Patients whose illness prevented moving	ultrasound technicians	• NPUAP Staging system used • Follow up period of 7 days • Ultrasound on admission at: Sacral, Upper buttocks, lower buttocks, hips, lateral malleoli, lateral foot, heels • 2.5 MHz transducer frequency for large patients (BMI >30) to 12 MHz transducer frequency for smaller patients • Skin failure risk factors: fever, hypotension, weight loss, coagulopathy, and acidosis/respiratory failure	• 74 positives for subcutaneous tissue did not deteriorate/open • 5 subcutaneous tissue led to necrosis (within 2 days of scan) • sensitivity 100.0% (47.8%, 100%) • specificity 74.8% (69.5%, 79.7%), • accuracy 75.3% (225/299). **Author conclusions: Ultrasound can predict deep tissue injury, however repeated, larger study size is required to confirm study results. Consideration of skin failure risk factors need to be included.**	combination with skin failure risk factors can provide early identification and treatment of uncommon skin injuries.	**Quality: High**
Grap et al., 2017	To compare **high frequency ultrasound (HFUS) tissue characteristics (dermal thickness and dermal density) with visual image examination**	Participants were recruited from medical respiratory ICU (MRICU), surgical trauma ICU (STICU) or neuroscience ICU(NSICU) in USA (n=136, n=113 analyzed) Inclusion criteria: Not described in this article. Exclusion criteria: • Significant skin moisture risk as determined by the Braden scale of "constantly moist" Participant characteristics: • Mechanically ventilated adult patients	• No intervention • All sacral scans were obtained in a lateral position with the subject turned from 60 to 90◦. Palpation of the coccyx was used to determine location for the HFUS probe.	• HFUS images, measured with EPISCAN over sacrum, obtained daily by trained staff for up to seven days or until hospital discharge • Outcome: Individual changes in dermal thickness and dermal density (three measurements obtained for each image and average used) • Changes in image were evaluated based on change from previous image and then categorised by type of injury as normal (no injury), injury with no change, injury and improving, injury and worsening.	**Mean dermal thickness at one day** There were no significant differences in one-day comparisons among type of injury and mean dermal thickness (p=0.6645) **Mean dermal intensity at one day** There were no significant differences in one-day comparisons among type of injury mean dermal median intensity (adjusted p=0.06 to 0.17) **Outcomes for other day-to-day comparisons** All other day-to-day comparisons were non-significant. **Conclusions: The use of HFUS as a screening and monitoring tool for the development of tissue injury in new, and comparative studies and common measures and language must be developed.**	• Although the participant patients were at high pressure injury risk for pressure ulcer, the majority showed normal images or no change in the HFUS image over the study period. • No ocular examination was described in the study, which was a limitation	**Indirect evidence (PU not an outcome measure)**

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		• All patients were bedridden and rested with a backrest elevation					
Akins et al., 2016	Feasibility study exploring a **hand-held ultrasound imaging device for measuring anatomical features associated with DTI**	Participants were recruited by unknown methods (n=6) Inclusion criteria: • Aged > 18 years Exclusion criteria: • Current pressure ulcer on seated surface of pelvic region • Weight > 113kg • Contraindications to MRI (e.g. pacemaker, aneurysm clips, implants) Participant characteristics: • X2 control participants with no SCI • X2 self-reported long term (>5 years) SCI • X2 short-term (<2 years) SCI	• Magnetic resonance imaging examinations were conducted using a 0.6 T Upright MRI with 14 minute sequence durations • Ultrasound examination conducted with ultrasound machine with a 5-12 MHz 50 mm linear array transducer	Muscle and adipose tissue thicknesses radius of curvature of each ischial tuberosities Measurements were made by two independent researchers to establish repeatability	**Interrater reliability** • Tissue thickness measured by ultrasound IRR was excellent (ICC=0.948) • Tissue thickness measured by MRI IRR was excellent (ICC=0.941) • IT radius of curvature measured by ultrasound IRR was good (ICC=0.712) • IT radius of curvature measured by MRI IRR was poor (ICC=0.214) • A significant proportional bias was identified in muscle tissue (r=0.897, p<0.001) • No significant bias noted for adipose tissue thickness (r=0.455, p=0.187) or total thickness (r=0.481, p=0.160). • US and MRI tissue thickness measurements were highly correlated (muscle r=0.988, p≤0.001; adipose r=0.894, p≤0.001; total r=0.919; p≤0.001) **Author conclusion: ultrasound imaging is viable for measuring bone and tissue features that influence SDTI risk.**	• Small sample size • Positioning of individuals may influence measurements • Significant differences were established in measurements for curvature of ischial tuberosities	**Indirect evidence**
Schafer et al., 2015	Observational study investigating the effectiveness of **ultrasound elastography in measuring changes in dermal and subcutaneous tissue**	Healthy volunteers (n=9) Inclusion criteria: • Female • Aged 60 to 80 years • Ability to sit, lie and move independently for prolonged periods Participant characteristics: • Mean age 70.1 ± 4.8 years • Mean BMI 26.3 ± 4.0 kg/m^2	• Anatomical sites with higher risk of PU (between scapulae, sacrum, left lateral heel calcaneus) were marked with skin marker • Participants followed a standardized lying protocol on	• B-mode and elastographic measurements (shear-wave velocity) were taken with an ultrasound system. • Measurements of tissues stiffness taken superficial skin (3mm depth) and subcutaneous tissue (16mm sacrum, 7mm heels, 13mm upper back) • Measurements taken at baseline, 90mins and 150 mins	**Sacrum** No significant difference in shear-wave velocity at superficial tissue from baseline to 150 mins (p=0.178) but significant changes in deep tissue indicating tissue stiffness (p=0.076) **Heel** No significant difference in shear-wave velocity from baseline to 150 mins at superficial or deep tissue.	• Small uncontrolled study • Only healthy, female participants	**Indirect evidence: Healthy volunteers**

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	stiffness during prolonged loading		a standard hospital mattress, lying in supine position		**Upper back** Shear-wave velocity in superficial tissue had significant differences from baseline to 15mins indicating tissue stiffness (p=0.046) but deep tissue readings were not statistically significant. **Study conclusion: Elastography quantifies skin and soft tissue stiffness and may be a new parameter for quantifying PU damage risk in deeper tissues or used as a new outcome in clinical PU prevention studies.**		
Yalcin, Akyuz, Onder, Unalan, & Degirmenci, 2013	Cohort study investigating **skin thickness measured with ultrasound in individuals with SCI at high risk of pressure injury**	Participants were recruited consecutively in Turkey (n=32) plus healthy volunteers who were hospital employees (n=34) Inclusion criteria (SCI): • Paraplegic with accident occurring > 6 months before study • > 3 month wheelchair use • Aged > 18 yrs • No previous PU • No non-blanching erythema Participant characteristics (SCI group): • Mean age 31 ± 11.1 years • Mean weight 67.9 ± 12.9 kgs • Mean time since injury 17.6± 17.8 months (range 6 to 72 months)	• N/A	• Albumin and hemoglobin • Ultrasound using linear array probe (7 to 12 MHz) – field depth 4.5cm and focus zone 1 cm • Same physiatrist collected the data for all participants • All images repeated three times at each body site • Measures taken at trochanter, ischial tuberosity and sacrum in transverse plane • Reference measure taken from waist	**Mean skin thickness** • Trochanter: patient group 1.8±0.4 mm versus control 1.9±0.5 mm (p=ns) • Sacrum: patient group 2.1±0.9 mm versus control group 3.2±0.5 mm (p<0.01) • Ischium: patient group 2.2±0.6 mm versus control group 2.6±0.5 mm (p<0.01) • Waist: patient group 2.3±0.5 mm versus control group 2.5±0.6 mm (p=ns) **Skin thickness versus blood tests** No significant correlation between albumin and hemoglobin and skin thickness **Author conclusions: skin thickness was significantly lower at anatomical sites under pressure in individuals with SCI** **Ultrasound may be a useful predictive tool for PU**	• Small study • One evaluator took all measures • Physician was not blinded to status of individuals • Did not compare assessments with pressure injury incidence	**Indirect evidence: PU not an outcome measure/ healthy volunteers**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics (control group): • Mean age 33.7 ± 11 years • Mean weight 69.7 ± 10.5 kgs (p=ns compared to patients)					
Porter-Armstrong et al., 2013	To explore whether **ultrasound images supported clinical skin assessment in a cohort of vascular surgery hospital inpatients**	Participants were volunteers admitted for elective vascular surgery in Ireland (n=50) Inclusion criteria: • Admitted for elective vascular surgery • Intact skin on one or more areas to be scanned (sacral coccygealarea and either/or both heels). Exclusion criteria: • Existing pressure damage of greater than, or equal to Category/Stage II pressure injuries of either heels or sacral coccygeal area Participant characteristics: • Mean age 65 years • mean weight of 82.57kg • Only three participants was considered to be at risk for pressure injuries	No intervention study	• A clinical skin assessment was conducted at baseline, postoperatively and at least every other day by a clinical research nurse • Modified EPUAP Pressure injury classification scale • High frequency ultrasound scanning was conducted by two trained researcher and the images were recorded at the same time as the clinical skin assessment. • The 1492 ultrasound images were assess by the two raters Images were classified into four distinct subgroups.	**Comparison between clinical assessment and ultrasound** • Clinical skin assessment non-blanching erythema on coccyx in two participants and on sacrum of one, all ultrasound images of the coccyx and sacrum for all participants were assessed as "normal" by both raters. • Clinical skin assessment assessed no participant with skin damage greater than blanching erythema of intact skin on the heels, but high frequency ultrasound showed 16 participants (32%) had at least one image indicating Category/Stage II pressure injury over heel **Author conclusions: Ultrasound imaging is potentially useful adjunct to clinical skin assessment to provide information on underlying tissue damage, but further work is required to determine what ultrasound results correlate to various stages of skin breakdown**	It is unknown whether or not the suspected subcutaneous damages on the heels, recognized by images, progressed into clinical signs of pressure ulceration. It is unknown if the16 participants who according to images had signs of category II ulcers were the same participants who had clinically signs of blanching erythema	**Indirect evidence: PU not an outcome measure/ volunteers**
Swaine et al., 2017	Cross sectional study evaluating the use of an ultrasound	Participants were a convenience sample of healthy volunteers (n=14) and people with SCI (n=8) recruited	• Measurements were taken for healthy volunteers and for SCI participants	• Ultrasound measurements of had soft tissue (tendon/muscle, skin/fat and total soft tissue layers	**Reliability** • For healthy volunteers, intra-rater reliability was high (ICC =0.81 to 0.90) for all three soft tissues layers in unloaded and loaded sitting	• Small sample of raters and participants • Study does not discuss clinical	**Indirect evidence (PU not an outcome)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	protocol adapted from MRI protocol to measure extent of tissue deformation of tissues over ischial areas	Exclusion criteria (SCI participants): • History of fractured pelvis • Having abnormal ultrasound signs with normal skin Participant characteristics: • Volunteers mean age 36.7±12.09 years • SCI participants mean age 31.6±13.6 years • Primarily males in both groups	• Measurements taken in seated position, loaded and unloaded	• Measures conducted independently by 2 sonographers • diameter short and long axis • Measures taken 10 times for healthy participants and 3 times for SCI participants (skin, fat, tendon, muscle and total and tendon/muscle, skin/fat)	• For healthy volunteers, interrater reliability was low for measuring ischial tuberosities on both axes (ICC = –0.028 and –0.01) • For people with SCI, interrater reliability was high (ICC =0.75 to 0.97) for unloaded and loaded sitting for measures of muscle, total, tendon/muscle and skin/fat • For people with SCI, interrater reliability was low for unloaded and loaded sitting for measures of fat and skin. • Interrater reliability was high for all measures in people with XCI (range ICC 0.38 to 0.96) **Author conclusions: Real-time ultrasound measurement of soft tissue layers with ultrasound shows good reliability for identifying tissue deformation.**	application/indications	
Quintavalle, Lyder, Mertz, & et al., 2006	Prospective study to compare **ultrasound to Braden risk scale for predicting pressure injuries**	Participants were healthy medical students and doctors (n=15) and older adults (n=119) Older adult characteristics: Braden score < 17 indicating risk	N/A	• Longport Digital Scanner (EPISCAN), a 20-MHz frequency system, was used • Images with high resolution to a depth of 2 cm • Ultrasound performed at 3 sites on heel, 2 sites on sacrum and 2 on ischial tuberosity • images obtained were classified as not readable, normal, or abnormal (4 categories) • Interrater reliability was 97%	• Most of images (55.3%) had ultrasound patterns consistent with abnormal skin and soft tissue • 11.7% of ultrasound images with abnormal findings had documented visual clinical signs for erythema **Conclusions: Pressure injuries form before there is observable erythema**	No correlation statistics Poorly described methods for assessing erythema	**Level of evidence: 3 (prognostic)** **Quality: Low**
Helvig & Nichols, 2012	Prospective cohort study to identify heel pressure injuries using ultrasound	Participants recruited by volunteering in a hospital in US (n=520 met inclusion criteria, n=100 received at least 2 scans)	N/A	• Pressure injury risk factors collected via exam and chart history • Heels assessed visually and with high frequency ultrasound	**Heel pressure injury prevalence** • 7.3% in population meeting inclusion criteria • 2% of people with abnormal first scan developed heel pressure injury	• Ultrasound reading is influenced by callous and peeling skin	**Level of evidence: 3 (prognostic)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Inclusion criteria: Aged 65 or older Braden scale score of 10 to 17 Hospitalized for <28 days At least one heel with no pressure injury present Participant characteristics: • Mean age 79.15 years, range 65-97 • Primarily white (82.8%)		• Braden Risk scale • Visual assessment included heel color, edema, sensation using monofilament, presence of wounds and scars, condition of skin (e.g. fungal, cracking), pain	**Ultrasound findings** • 10.1% of people without a heel pressure injury had 2 normal heel scans • High frequency ultrasound had low correlation with Braden scale sub-scores for friction/shear (r ranged from 0.22 to 0.337 across time and left/right heel locations. with some measurement points showing significance) • Scan was not significantly related to age, days since admission, heel elevation prior to scanning, heel turgor, BMI, foot temperature, albumin/prealbumin or glucose levels, or Braden scale score **Author conclusions: high frequency ultrasound detected injury more than a visual assessment of heels but interpretation of this finding is unclear**	• Did not explore correlation between pressure injury • No power calculation • Different nurses did assessments and interrater reliability not established • Validity of visual assessment not established • Only 11 participants developed pressure injuries	**Quality: Low**
Clinical question 4: Is evaluation of skin and tissue moisture an effective method of assessing the skin and soft tissue?							
Fletcher, Moore, & Smit, 2017	Study comparing Sub Epidermal Moisture (SEM) scanner to Waterlow scale for assessing risk	• Participants were recruited by unreported methods in medical and surgical wards in NHS facilities in UK (n=35) Inclusion criteria: • High risk as per assessed on Waterlow (score of ≥10) Participant characteristics: • 82% aged over 65 years • 74% aged over 75 years	• SEM scanner was taken on all patients identified as high risk on the Waterlow Scale • Nurses adjusted pressure injury interventions based on daily SEM readings	• 2 month period • Nursing staff were trained to take SEM measurements • Scanning took place on admission and daily • 3 measures were taken on high risk areas including sacrum and heals • Monitoring took place on discharge for the same time the patient was an inpatient. • Nurses interpreted results	**Pressure injuries** None experienced in the study period **SEM readings** 1 participant had deteriorated SEM readings that developed a PI within hours of transfer to the ward Majority of SEM values between 0.6 to 1.5 Some participants rated as high risk with Waterlow were not high risk on SEM **Cost effectiveness** • Annual savings £29,000 based on savings from not using unnecessary support	• Small sample • Short study length • Only included people considered at risk on Waterlow so correlations may be biased • No statistical analysis • Poor explanation of cut-off scores	**Level of evidence: 4 (diagnostic)** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 49% males			surfaces, reduction in antibiotics and reduction in dressing costs • Nursing productivity estimated at 1,420 nursing hours saved • Revenue was increased by £563,000 based on bed admissions saved **Author conclusion scanners are a newly diagnostic tool for PI identification that may be a cost effective interventions to put in place for the high risk patient.**	for at risk, risk and high risk • No information on participant backgrounds • Information for cost effectiveness analysis is not well reported	
Harrow & Mayrovitz, 2014	Cohort study reporting findings on use of SEM in a veterans with SCI and Category/Stage III and IV pressure injuries	Participants were a convenience sample of from a Veterans' spinal cord injury/disorders center in USA (N=16) Inclusion criteria: • Spinal cord injury (SCI) • Category/Stage III or IV pressure injury over sacrum or ischium Exclusion criteria: • Acute medical illness other than a PU • Participant characteristics: • Mean age 60.6±14.6 years (range 38 to 79) •	As per outcome measures	Single-rater Measurements were taken using a MoistureMeter-D (300MHz electromagnetic waves, Delfin Technologies) 4 point spaced angularly around the site on intact skin 4 measurements repeated two more times for a total of 12 measurements around the wound and control site, each subject had 24 measurements	**Short term reliability** • Single rater relative error was 2.5% (2.0 to 2.9% CI) **Repeated trials** • First readings were higher than second readings in 55 of 64 measurement sets suggesting repeated measures are not independent **Variations in readings** • SEM varied by angle at the PU site **Differentiation** • Differentiate pressure injuries from intact skin: SEM at PU sites was greater by 9% than control site ($p<0.05$) • Sacral locations had higher SEM than ischial at control sites by 20% ($p<.005$) **Author conclusions: Consideration needs to be given to factors that will influence readings when developing trials of diagnostic accuracy of SEM**	• Pilot cohort study • Single rater • Small sample • Future study designs must take into account order, angular and site effects • Lack control for many factors	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Borzdynski, McGuiness, & Miller, 2016	Comparative study assessing relationship **between skin hydration, color, and lipids to pressure injury risk scores on a validated risk assessment tool**	Participants were recruited in aged care facilities in Australia (n=38) Inclusion and exclusion criteria: None stated Participant characteristics: • Mean age 80.2 years • 63.1% females • Mean baseline Norton score 3.9 • 50% incontinence • 55% were ambulant or semi-ambulant	Not relevant	• Pressure injury risk based on scores of the Norton Scale • Skin Diagnostic measures (skin hydration, color, and lipids) using Sebumeter conducted once in the evening, for 7 days over nine pressure-prone areas: sacrum, right and left ischium, right and left trochanter, right and left calcaneus and right and left lateral malleolus • Skin hydration (skin dryness and skin wetness and/or maceration), pigmentation and presence of erythema at were also visually assessed • Visual assessments performed by research student immediately before diagnostics	**Correlations between visual assessment and skin diagnostics** • No significant correlation between visual assessment of skin dryness and Skin Diagnostic measures of epidermal hydration • Strong positive correlations between visual assessment of skin wetness and Skin Diagnostic measures of epidermal hydration at the sacrum, ischia and trochanters (r=0.589 to 0827, p<0.01) • Strong positive correlations between visual assessment of and measure of skin pigment at all anatomical sites (r= 0.354 to 0.616, p<0.01) • Strong positive correlations between visual assessment and measure of skin pigment at all anatomical sites (r= 0.354 to 0.616, p<0.01) • Strong positive correlations between visual assessment and measure of skin erythema at all anatomical sites (r= 0.435 to 0.808, p<0.01) **Correlations between Norton Scale score and visual assessment and skin diagnostics** • Objective assessment of epidermal hydration (skin wetness) was significantly associated with Norton Scale score at sacrum (r = –0.528, p< 0.01), ischia (r = –0.407 to –0.410, p<0.05) but not trochanters, calcaneus or malleoli • Erythema was significantly correlated with Norton scale score for sacrum (r = –0.322, p<0·05) **Author conclusions: clinical assessment by a registered nurse is strongly associated with objective measures of skin condition**	• Small sample size • One facility • Single assessor • Blinding of assessor in unclear • Recruitment is poorly reported	**Level of evidence: 4** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
O'Brien, Moore, Patton, & O'Connor, 2018	Observational study to investigate relationship between SEM measurement and visual skin assessment	Participants were recruited using purposive sampling in an acute care facility in Ireland (n=47) Inclusion criteria: At risk of pressure injuries based on Norton Score No existing pressure injury Characteristics: Mean age 74.7 years 61.5% females 8.5% had history of pressure injuries 36% immobile, 39% slightly limited	Not relevant	• Daily SEM scanning at heels and sacrum for 4 weeks • Visual skin assessment daily for 4 weeks	**Pressure injuries** 40% participants developed 21 Stage 1 pressure injuries/abnormal skin **SEM measurements** • 100% sensitivity (95% CI 83.89% to 100%) of SEM readings in predicting pressure injuries • Specificity was 83% (majority of false positives has insufficient follow-up) (95% CI 75.44% to 89.51%) • Correlation with visual skin assessment r=.47 (p=0.001) was identified. • Mean days for detection of pressure damage with visual assessment was 5.5 (±2,5; max 11, min 2), • Mean days for detection of pressure damage with SEM measurement was 1.5 (±1.4; max 7, min 1) **SEM measurement detected damage, on average, 4 days sooner than Stage 1 PUs were visually detected**	• No blinding	**Level of evidence: 3 (prognostic)** **Quality: Low**
Clendenin, Jaradeh, Shamirian, & Rhodes, 2015	Observational study to evaluate the **interrater and interdevice agreement and reliability of the SEM scanner in the prediction of the presence of pressure injuries**	Healthy volunteer participants were recruited in the US (n=31) Inclusion Criteria: • 18 years or older • No pressure injuries or skin breakdown	Not relevant	• More than 3000 SEM Scanner readings collected by 3 trained operators using 3 independent devices • Tested at 4 different anatomical sites • NPUAP staging system used	There was good interoperator and interdevice reliability with all intraclass correlations coefficients (ICC's) exceeding 0.80. **Author conclusions: Promise shown as an objective reliable tool for assessing presence of pressure injuries**	• Study population not representative of the population in which the device will ultimately be utilized • Mean age of study subjects was 29.8 and not at risk for pressure injuries	**Indirect evidence: PU not an outcome measure/ healthy volunteers**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
C. G. Kim, Park, Ko, & Jo, 2018	Observational study to investigate relationship between SEM measurement and visual skin assessment	Participants were recruited by unreported methods in an aged care facility (n=29, n=2612 SEM measurements) Inclusion criteria: Not stated Characteristics: 69% aged over 80 years 86.2% females 65.6% had dementia 34.8% high risk on Braden scale	N/A	• Braden Scale score • Visual identification of erythema • SEM measurements using a dermal phase meter to detect skin hydration • All values taken at 8 anatomical locations once weekly for 12 weeks	**Mean concurrent SEM values**: • normal skin =216.3 • blanching erythema 232.3 • stage 1 PI 387.6 (p=0.013 between the three values • blanching erythema compared to normal skin: OR = 1.003, p=0.047 by 1-point increase of 1 week prior SEM value • erythema compared to normal skin: OR = 1.004, p=0.011 by 1-point increase of concurrent SEM value **SEM value increased with the higher stage of skin damage**	Limited information about selection of participants No blinding	**Level of evidence: 3 (prognostic)** **Quality: Low**
Park, Kim, & Ko, 2018	Observational study to investigate relationship between SEM measurement and visual skin assessment	Participants were recruited in an acute facility (n=22) Inclusion criteria: Jaundice Characteristics: Mean age 70.5 years 45% females 22.7% had history of pressure injury	N/A	• Braden Scale score • Visual identification of erythema • SEM measurements using a dermal phase meter to detect skin hydration • All values taken at 8 anatomical locations once weekly for 6 weeks	196 cases of blanching erythema, 19 cases of pressure injuries **Mean concurrent SEM values**: • normal skin =115.9±32.6 • blanching erythema 164.8±107.5 • stage 1 PI 208.7±76.5 (p<0.001 between the three values • blanching erythema compared to normal skin: OR = 1.016, p<0.01 by 1-point increase of 1 week prior SEM value **SEM value increased with the higher stage of skin damage**	Limited information about selection of participants No blinding •	**Level of evidence: 3 (prognostic)** **Quality: Low**
Bates-Jensen, McCreath, Pongquan, & Apeles, 2008	Descriptive cohort study	Participants were recruited in 2 U.S. nursing homes (n = 31) Inclusion: • Long stay resident • participating in a concurrent trial and consented for this additional study	• Braden scale assessments conducted monthly • Skin assessment conducted by trained staff weekly for 20 weeks	• SEM moisture was measured with a surface electrical capacitance dermal phase meter and reported as dermal phase units (DPU) (NOVA Petite,® NOVA Technology Corporation)	• SEM was 104 DPU for normal skin, 185 DPU for erythema, 264 DPU for stage I PU, 727DPU for stage II PU • SEM was predictive of Category/Stage I or greater pressure injuries identified by visual skin assessment: odds ration [OR] 1.99 per 100DPU • SEM predicted the incidence of erythema and/or stage I PU damage identified 1	• Recruitment is not clearly reported • Study was not designed or powered to measure the objectives reported • Interrater agreement was	**Level of evidence: 3 (prognostic)** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Characteristics: • 72% light skin tone • Mean age 84.14 years • n=28 completed the study, n=2 deceased, n=1 discharged	• Erythema and stage I PU categories • subepidermal moisture (SEM) obtained at the right and left buttocks and sacrum weekly for 20 weeks	• Visual assessment was rated as normal, erythema/stage I PU or stage II + PU • Discoloration was graded as: minimal, moderate or severe	week later adjusting for concurrent SEM and Braden Scale PU risk status (OR 1.003, 99% CI 1.000 to 1.006, OR 1.32/100 DPU) **Conclusions: A handheld dermal phase meter to measure subepidermal moisture may have clinical value to differentiate between erythema and Category/Stage I pressure injury**	established prior to study	
Bates-Jensen, McCreath, & Pongquan, 2009	Descriptive cohort study reporting use **of SEM to predict skin breakdown in individuals with light and dark skin tones**	Participants were recruited in 4 US nursing homes (n = 66) Inclusion: • Long stay resident • participating in a concurrent nutrition trial and consented for this additional study Characteristics: • light skin tone (n=55) and dark skin tone (n=11) • n=56 completed the study, n=6 deceased, n=2 discharged, n=3 withdrew	• Braden scale assessments conducted monthly • Skin assessment conducted by trained staff weekly for 20 weeks • Erythema and Category/Stage I pressure injury categories • subepidermal moisture (SEM) obtained at the right and left buttocks and sacrum weekly for 20 weeks	• SEM moisture was measured with a surface electrical capacitance dermal phase meter and reported as dermal phase units (NOVA Petite,® NOVA Technology Corporation) • Visual assessment was rated as normal, erythema/ Category/Stage I pressure injury or as a Category/Stage II or greater pressure injury • Discoloration was graded as: minimal, moderate or severe	**Correlation between SEM and visual assessment** • There were significant differences in SEM values according to level of skin damage detected by visual assessment • SEM identified local tissue edema related to inflammatory changes that occur from 3 to 10 days prior to visual skin breakdown **Comparison of SEM results in light and dark skin tones** • SEM values for persons with dark skin tones compared to persons with light skin tones were: ○ lower for sacral sites ○ lower for normal skin assessment conditions ○ SEM pattern of scores was similar in both groups • Among persons with dark skin tones, SEM values detected the incidence of stage II or greater PU I week later (OR 1.02 per 1 dermal phase units, 95% CI 1.001 to 1.01; OR = 1.15 per 100 DPU) **Study conclusion: Visual assessment to detect early pressure injury breakdown is difficult in darker skin tones. A handheld dermal phase meter to measure**	• Recruitment is not clearly reported • Study was not designed or powered to measure the objectives reported • Interrater agreement was established prior to study	**Level of evidence: 3 (prognostic)** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					subepidermal moisture may have clinical value, particularly in darker skins.		
Guihan et al., 2012	Observational study assessing feasibility of attaining SEM scanner measurements	Participants were people with SCI recruited in two SCI centers in the US (n=32) Inclusion criteria: SCI Exclusion criteria: None reported Participant characteristics: • 56.25% white, 34.38% African American, 3% Hispanic • 53% had no pressure injury • 12.5% Category/Stage II, 3.13% Stage III, 28.13% Stage III, 28.18% Stage IV	• Daily (n=10) or weekly (n=22) SEM measurements at nine anatomical locations (sacrum, heels, trochanter, ischium, buttocks)	• Study continued for 16 weeks • MoiustureMeter®, Delfin Technologies) • Measures take approximately 8 second to attain using a light touch on the skin • Visual skin assessment using NPUAP 1998 classification • Munsell colour value	**Interrater reliability (n=13 health volunteers)** Two pair of observers (r=0.92 and r=0.86) **SEM measurements** • Mean for those with no pressure injury by visual skin assessment 41 dermal phase units [DPU] (SD 10) • Mean for those with Category/Stage I by visual skin assessment (42 DPU, SD 11) • Mean for those with Category/Stage II or greater by visual skin assessment • Mean SEM at heels was lower than other anatomical sites (normal skin 30 DPU; erythema/Category/Stage I pressure injuries 33 DPU). **Conclusions: SEM was feasible to use and had good interrater reliability. More research on sensitivity and specificity of SEM scanner, differing readings at different anatomical sites.**	• Recruitment not seel described • Small sample size • Researchers suggest diuretic use, comorbidity conditions such as cardiac failure may influence edema.	**Level of evidence: 4** **Quality: moderate**
Clinical question 5: Is evaluation of skin and tissue temperature an effective method of assessing the skin and soft tissue?							
Higashino et al., 2014	Retrospective review observing **accuracy of early detection of DTPIs with a combined use of**	Participants were recruited at a hospital in Japan (n=21 patients with 28 pressure injuries) Inclusion criteria: Early stage pressure injury Exclusion criteria not listed	• Thermographic images with an infrared Thermotracer • Ultrasonographic images with a portable ultrasound system	• DESIGN-R to assess pressure injuries • measurements of wound temperature compared to temperature of ajdacent tissue with Thermography • Assessment of unclear layered structure, hypoechoic lesions, discontinuous fascia and	**Thermographic assessment** • 13/28 pressure injuries with low temperature had a good outcome (healed or no progress) • 2/12 high temperature ulcers were DTIs • 2 ulcers with poor outcomes (deteriorated to DTI) had even temps **Ultrasound results**	• Only 2 subjects showed an outcome indicating that methods may be effective in early detection • study states that a disadvantage of	**Level of evidence: 3 (prognostic)** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	thermographic and ultrasound assessment	Participant characteristics: • 52.4% males • Average age 66.4 years • 14.3% were stage d1 on DESIGN-R and 85.7% were stage d2 • 50% sacral pressure injuries		heterogenous hypoechoic areas • Initial readings and readings after 1 week taken • all patients were followed for at least 2 weeks	• Two pressure injuries had heterogenous hypoechoic areas, both also had high thermographic temperatures and were DTI	ultrasound is that it requires a level of skill for it be be accurate, however, there was no discussion of who the investigators were or their skill level/training • no discussion of inter-rater reliability or validity	
Cox, Kaes, Martinez, & Moles, 2016	Determine if skin temperature measured using **infrared thermography could predict the progression of discolored intact skin to necrosis**	Participants were recruited in 7 skilled nursing facilities in USA (n=73 entered, n=6 eliminated, n= 67 analyzed) Inclusion criteria: • Observed pressure related area of discolored intact skin (blanchable erythema, Category/Stage I pressure injury, SDTI) • Length of stay >6 days Exclusion criteria: • Intact blisters • Ulceration other than pressure • Dying • History of pressure injury or tissue damage at the site of current discolored skin	Usual standard care	• 7-14 day follow-up • Trained nurses at each facility collected data using infrared thermography • Variables for prognostic model for skin necrosis included age, gender, race, comorbidity, admitting diagnosis, type of admission, Braden scale score, body temperature, room temperature, skin temperature, capillary refill, discolored area temperature, skin color, presence of demarcation, anatomical location	**Discolored skin progress** • 45% completely resolved • At day 7, 16% had skin necrosis, at day 14, 32% had s kin necrosis • Mean temperature at discolored skin was 33.6°C (SD 3) • Mean temperature at the adjacent skin 33.5°C (SD 2.5) **Predictors of skin necrosis at day 7 (multivariate using 8 variables)** • Cooler rather than warmer skin temperatures at the center of the discolored area as compared to the adjacent skin were more likely to develop necrosis by day 7 (odds ratio [OR] 18.8, 95% confidence interval [CI] 1.04 to 342.44) • Admitting diagnoses, gender, age, room temperature had no significant prognostic value **Nurse survey on utility and feasibility**	• Small sample • Possibly too many variables into the model in this study? (Large Confidence interval) • Primarily white skinned participants	**Level of evidence: 1 (prognostic)** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics: • Mean age 85 years • Primarily female Caucasians • Most common diagnoses were neurologic, cardiac and orthopedic • Participants were short and long stay patients • Mean area 11cm^2 (SD 21) • Most frequent anatomical location was heels (40%) • Capillary refill was absent for 72% of discolored areas			• Average time to measure temperature of discolored skin was 3 to 5 mins • 70% did not believe the thermography could be implemented in practice **Author conclusions: Thermography is new and use as a screening too for necrosis needs more exploration**		
Farid, Winkelman, Rizkala, & Jones, 2012	Observational retrospective study **investigating relationship between temperature at a pressure-impacted skin site versus intact skin site**	Records were reviewed from eligible participants admitted in an 18 month period to one university hospital (n= 85) Inclusion: • admitted to med/surg, ventilator, critical care units • record of directly observable pressure-impacted skin at least 4cm^2 • hospitalized at least 6 days Exclusion criteria: • lower extremity pressure-impacted skin area together with history of peripheral vascular disease • blistered or disrupted skin over pressure-impacted area potential diabetic foot ulcer as determined by history	• Data from all acute care hospital patients with an observed pressure-related intact discolored areas of skin (PRIDAS) who received a skin integrity consult, including a skin temperature measurement with a handheld thermographic device	• Skin temperature • Presence or absence of capillary refill • Initial assessment and follow-up 7 to 14 days later • Correlated temperatures with the development of skin necrosis at 7 to 14 days • Examined the effect of additional patient variables on the progression or resolution of a PRIDAS	**Relationship between skin temperature and visual observations** • 55 participants (65%) had a lower temperature at baseline in the pressure-impacted region compared with than adjacent skin. Of these, 29 participants progressed to necrosis compared to one of 30 with a higher temperature in pressure impacted region than adjacent skin. • At 7 day follow up, having a cooler PRIDAS was 31.8 times more likely to progress to necrosis than the warm PRIDAS (OR 31.8, 95% CI 3.8 to 263.1, p=0.001) • Skin tone (white, dark) showed a trend towards significant relationship with skin necrosis (OR 7.7, 95% CI 0.8 to 70.8, p=0.07) • 0% of 26 patients who had blanching and a warm PRIDAS developed skin necrosis Study conclusions: skin temperature measures and comparison to intact normal skin may provide an indicator for likelihood	• Use of a single device to measure temperature • Very wide confidence intervals, suggesting uncertainty with findings	**Level of evidence: 3 (prognostic)** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					of skin necrosis and possible indication of STI rather than Category/Stage I pressure injury		
Judy, Brooks, Fennie, Lyder, & Burton, 2011	To evaluate infrared device that enables objective assessment of the skin and tissues	Participants were recruited in one medical center in US (n=399 screened, n=100 enrolled) Inclusion criteria: Adults Exclusion criteria: Pressure injury on admission	• Participants were in lateral decubitus position for imaging, resting in position for 3 minutes before images taken	• TMI ImageMed System with a camera that captures a thermal image was used to image the scarum and heels • Images were 8x8 matrix of risk area • 95% intrarater reliability achieved before commencing study • Daily skin temperature reading taken • Braden Scale Risk Assessment • Three methods of calculating risk based on 1.°5C temperature differential were used were tested: ○ difference between maximum and minimum temperature within 8x8 matrix ○ 75th percentile temperature minus minimum temperature ○ Mean temperature minus minimum temperature	**Pressure injury prevalence** 5% participants developed pressure injury (x2 Category/Stage II and x3 Category/Stage I) **Risk assessment by imaging** Based on imaging 22-39% participants were at high risk of pressure injury depending on the method to calculate temperature differential **Relationship between Braden Scale and imaging** Odds ratio (OR) of images classifying high risk of pressure injury ranged from 6.8 (95% CI 4.3 to 10.8, p<0.0001) to 2.2 (95% CI 1.5 to 3.1, p<0.0001) depending on whether clinical or research nurse evaluations on Braden scale were used, and depending on method of measuring risk on infrared image **Author conclusions: Infrared imaging identified more at-risk people than Braden Scale**	• High level of potential participants did not consent to the study due to being "too sick" • Limited information about participants and possible confounders • Small number participants • Did not compare infrared risk finding to pressure injury outcomes	**Level of evidence: 3** **Quality: low**
Clinical question 6: What additional technologies are accurate and effective methods of assessing skin and soft tissue?							
Hettrick, Hill, & Hardigan, 2017	Determine if an alternate light source can identify trauma before visible evidence of injury	Participants were recruited in a long term care setting in US (n=7) Inclusion criteria: • Medically stable • At least 1 intact lower extremity • cognitive able and agreeable	Subject placed side lying to obtain ambient light SLR photographs, Subsequent series of photos with ALS camera. 12 photos obtained	• Weekly exam for 6 weeks by the research team, • 12 photos per participant weekly. • The assistant verified if absorption present and documented • NPUAP Staging system used	**Relationship between wavelength and absorption** (detecting injury) 1st analysis: p=0.257 2nd analysis: p=0.002	• Size limitations • Alternate light source equipment large and bulky. • Environmental challenges to reduce natural light sources.	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion criteria: • Unstable • No intact lower extremity			**Author conclusions: Alternate light sources could prove valuable in early detection of tissue trauma**		
Borzdynski et al., 2016	Correlational study **exploring relationship between diagnostic equipment (Sebumeter and mexameter) and visual skin assessment techniques**	Participants were a convenience sample of adults in aged care (n=38) Inclusion and exclusion criteria: None stated Participant characteristics: • Mean age 80.2 years • 63% female • Mean Norton risk assessment score 13.9±4.2 • 50% incontinent	• Measurement taken with SD202 Skin Diagnostic that combines a Corneometer, Mexameter and Sebumeter allowing direct measurements of melanin, hydration • Immediately before use of the diagnostic equipment was used a visual assessment was conducted • A single researcher took all the measures (equipment and visual)	• Assessment of epidermal hydration, pigmentation and erythema • Measurements taken twice daily at nine pressure-prone areas for 7 consecutive days • For Visual assessment, skin was assessed in dichotomous categories of 'yes' or 'no' for skin dryness, skin wetness and/or maceration; erythema in two grades; melanin graded as light or moderate • Norton risk assessment for PI risk	**Correlation between visual and diagnostic equipment** • Visual and diagnostic assessments of skin dryness were not significantly correlated • Significant strong positive correlation between visual and diagnostic assessment of skin wetness at sacrum, ischia and trochanters (p<0·01) • Significant strong positive correlation between visual and diagnostic assessment of skin pigmentation (melanin) (p=0·01) and erythema (p=0·01) across all anatomical testing site **Correlation between assessment and PI risk** • Significant correlations between visual assessment of skin wetness at the sacrum (r=−0·441,p=0·01) • and ischia (r=−0·468, p=0·01) and the Norton scale, with risk increasing as wetness increased • Epidermal hydration on diagnostic equipment was associated with higher PI risk on Norton scale at the • sacrum (r=−0·528, p=0·01), right ischia (r=−0·410, p=0·05) and left ischia (r=−0·407, P=0·05) • Erythema on diagnostic equipment was significantly correlated with PI risk at the sacrum (r=−0·322, p=0·05) **Author conclusions: Clinical skills of a nurse in visual skin assessment of pressure-prone**	• A single researcher took all the measures (equipment and visual) • Small sample of participants • Short period of time (7 days) in which values did not change a great deal, thereby reducing assessment of change • Primarily Caucasian participants • Did not associate results with actual pressure injury incidence	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					areas are important. In the assessment of red colors displayed in erythema, diagnostic equipment may provide advantage over clinical assessment.		
Ceylan, Gunes, & Uyar, 2017	Observational study exploring effect of immobility on **sacral tissue oxygen saturation in patients lying on a supporting surface in supine position**	Participants from ICU in university hospital in Turkey (n=46) Inclusion criteria: • > 18 years old • Body Mass Index range of 18.50 to 29.99 • immobile (≤2 points on mobility subscale of Braden Scale) • peripheral oxygen saturation (SpO_2) ≥ 90% • blood pressure > 90/60 mmHg Exclusion criteria: • sacral inflammation, hyperemia or erythema • Lacking full tissue integrity • difficulty positioning (spinal-cervical fractures, lung diseases) • capillary damage in the sacral region • taking steroids, vasopressors or cytotoxic drugs • sacral edema • SpO_2 ≤ 90% and whose blood pressure remained below 90/60 mmHg	• The patients were their own control • Patient in lateral position for all measurements • Patients in supine position with head of the bed at 30° for 1 hour between measurements • Procedure repeated over 4 hours Other interventions: • At one ICU participants had alternating pressure air mattresses and at the other ICU vicsoelastic foam mattresses were used	• Sacral tissue oxygen (StO_2) was measured with an InSpectra Tissue Oxygenation Monitor providing a noninvasive method using near infra-red light • Mean $StO_2$was at baseline (30 mins), after 1h, 2h, 3h and 4h. • The sacral site was evaluated in terms of hyperemia during the measuring but no patient developed hyperemia before the fourth hour.	**Mean StO_2** • Over time, there was no significant change in StO_2 (p=0.094) • 73.36%±10.04 at baseline • 74.91%±11.52 at first hour • 72.32%±11.49 at second hour • 71.89%±12.97 at third hour • 71.89%±14.09 at fourth hour **Authors conclusions: Changing the position of a patient lying on a supporting surface every four hours is justified based on data for supine position**	• The use of different mattresses was not discussed and may have influenced findings • To be able to measure the sacral StO2 they needed to reposition the patient into a lateral position, this only took 20 sec but it may have affected the results. • The cumulative effect of pressure on tissue oxygen saturation could not be evaluated.	**Level of evidence: 4** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Participant characteristics: • Mean age 55.1±21.7 years • 22 were female • Mean BMI 25.2±4.1 • Mean SpO_2 95.2±2.6 • Mean systolic BP 131.6±21.6 • Mean Barden Score 13.4±1.7					
J. T. Kim, Wang, Ho, & Bogie, 2012	Observational laboratory study **investigating relationship between interface pressure and tissue blood oxygen**	Participants were healthy volunteers (n=20) Characteristics: • 50% sample female • Mean weight 69 kgs (SD 17) • Mean age 24 years	• Measurements were performed for every participant in supine on a standard hospital mattress and sitting positions • Measurement of tissue blood oxygen • Measurement of interface pressure	Tissue oxygen using a radiometer calibrated to room air temperature that (maintained at 25°C SD 2°C throughout study) and electrodes placed on bony prominences Interface pressure measured using a pressure mat Data was collected at 5-minute intervals over 20 minute period for each position •	**Supine position** • No significant difference in transcutaneous tissue oxygen or interface pressure for right ischial tuberosity • Significant increase in transcutaneous tissue oxygen at sacrum between baseline and 15 minutes ($p<0.05$) but no significant difference in interface pressure. • For left ischial tuberosity there was a statistically significant increase in interface pressure over time between baseline and 15 minutes ($p<0.01$) and 20 minutes ($p<0.001$) and a significant increase in interface pressure between 5 minutes and 20 minutes ($p<0.10$) **Sitting position** • No significant differences in transcutaneous tissue oxygen **Conclusions: Relationship between transcutaneous tissue oxygen and interface pressure showed no statistically significant correlation.**	• Small study with healthy volunteers – results may not be generalizable to populations at risk of pressure injuries • Potential morbidity was not identified e.g. unknown if any of these volunteers had underlying disease, but low mean age • No visual assessment of skin condition	**Indirect evidence: healthy volunteers**
Hagblad et al., 2010	Observational laboratory study to validate	Participants were healthy volunteers (n=11) No demographics provided.	Measurements were performed at room temperature firstly in a sitting	• Changes in blood flow measured using photoplethysmogram (PPG)	**Study conclusions: In clinical situations without pressure present, the probe appears to measure changes in blood flow related to exercise accurately.**	• Probe was used only in situations	**Indirect evidence: (healthy volunteers)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	measurement of blood flow using photoplethysmogram (PPG) and laser doppler flowmetry (LDF)		position, then in an exercise phase and in a post-exercise sitting position	and laser doppler flowmetry (LDF)		without applied pressure	
Hagblad, Folke, & Linden, 2012	Observational laboratory study investigating **changes in temperature and skin blood flow during supine lying**	Participants were healthy volunteers (n=20) No demographics provided.	• The measurement procedure was preceded by a 15 min resting period to control for any confounding factors Measurements for all participants were taken using a sensor on the participant's back and with the participant in supine position and on both the participant's sides.	• Changes in temperature measured using a temperature sensor • Changes in blood flow measured using photoplethysmogram (PPG) and laser doppler flowmetry (LDF) • Measures were taken continuously for half the participants and intermittently every 15 minutes for the other half of participants.	• There is a statistically significant ($p < 0.001$) rise in temperature in all subjects from baseline to one hour, from baseline to 20 minutes, from 20 minutes to 45 minutes and f rom 45 minutes to 60 minutes. • There were significant increases in blood flow measured via PPG and LDF from baseline to 60 minutes, from 20 minutes to 45 minutes and from 45 minutes to 60 minutes.	• Does not state the type of support surface • No demographics provided for the participants • Potential morbidity was not identified e.g. unknown if any of these volunteers had underlying disease, but low mean age • No visual assessment of skin	**Indirect evidence: (healthy volunteers)**
Clinical question 7: What methods are effective for assessing skin and soft tissue in individuals with darkly pigmented skin?							
McCreath et al., 2016	Psychometric and prognostic study to assess the validity, **reliability and feasibility of classifying**	• Participants were recruited in 19 nursing homes in US (n=490 enrolled, n=417 analyzed) Inclusion criteria: • residents whose ethnicity/racial categories as American Indian, Asian,	The Munsell System of Color Notation (Munsell chart) is designed to objectively assess skin tone (categorized skin as 'dark' or 'light' toned)	• Weekly skin assessments and had a handheld dermal phase meter to measure subepidermal moisture, edema or water • Residents were followed up for a total of 16 weeks, initial baseline at 8th week and completion at 16th week.	**Reliability of Munsell ratings for arm and buttock** • For all ethnic groups, inter-rater reliability for buttocks at baseline was high (ICC r=0.97, $P < 0.001$, Kappa coefficient = 0.84). • Intrarater reliability was consistent over time for arms (r=0.85 from baseline to 16	• Munsell values were not collected for the heels. • There were high levels of participation from ethnic minorities and were not included in this	**Level of evidence: 3 *(prognostic*)** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	skin tone using Munsell color chart values and to compare the tool to ethnicity/race to predict pressure injury risk in nursing home residents	African American, Hispanic and Caucasian were recruited Exclusion criteria: • Not stated Participant characteristics • Mean age 76.5 years • 29% African American,37% Caucasian, 21% Hispanic, 12% Asian American • Mean Braden scale 15.6		• Risk for pressure injuries assessed with Braden scale t at baseline and each month were assessed by research staff. • Visual assessment of the skin at the sacrum, buttocks, ischium and heels were checked weekly.	weeks), and buttocks (r=0.91 from baseline to 16 weeks) for all ethnic groups • ICCs were highest when rating African Americans (r=0.93, p<0.001) and lowest for Caucasians (r=0.91, p<0.001) **Consistency of Munsell ratings across anatomical sites** • Arm-buttock consistency was high overall (ICC r =0.88, p<0.001) • Arm-buttock consistency was high for African American people (ICC r =0.83, p<0.001) • Arm-buttock consistency was moderate for Asian people (ICC r =0.53, p<0.001), Caucasian people (ICC r =0.55, p<0.001) and for Hispanic people (ICC r =0.64, p<0.001) **Predictive accuracy** • Logistic regression models showed that skin tone categorization using Munsell ratings predicted the incidence of Category/Stage I pressure injuries (p=0.003) • Munsell ratings were not predictive of incidence of Category/Stage II or greater pressure injuries (p>0.05) • Ethnicity was not predictive of incidence of pressure injuries (p>0.05) **Author conclusion: Munsell color chart could provide objective method of pressure injury risk assessment with increased sensitivity**	study, by including them can enhance the generalizability of the findings. • No reliability and validity of the Munsell chart usage. • Validity measures not stated • Cut-off points/Specificity/Sensitivity not stated	

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
Other evidence							
Bliss et al., 2014	Cohort study **exploring the racial disparity in PU time to development in aged care**	For-profit nursing homes (n=90,580 residents) Inclusion: • Aged > 65 years • Admitted without a PU stage 2-4 and developed same while in aged care Exclusion: • Category/Stage I pressure injuries not included in analysis Characteristics: • Mean age 78 to 82 years • Primarily female • High levels of immobility • Mean length stay (LOS) 12 days (SD6.9) • Mean BMI 22 to 25 • Mean co-morbidity index 1.8 to 2.3		• Collected individual and facility characteristics using Minimum Data Set information and Online Survey, Certification and Reporting and US Census	Overall pressure injury rate was 7.7% over three years Black residents in aged care where more likely to develop a PU than was expected when controlling for individual and facility factors – expected rate 20.35% over 12 months vs actual rate 28.66% over 12 months **Predictors of time to pressure injuries for White admissions to mixed race facilities:** • ADL deficit: hazard ratio (HR) 1.06 95% CI 1.05 to 1.06, p<0.001 • Immobility: HR 1.13, 95% CI 1.03 to 1.23, p<0.01 • Comorbidity index: HR 1.08, 95% CI 1.06 to 1.10, p<0.001 • Cognitive score: HR 0.95, 95% CI 0.93 to 0.97, p<0.01 • Fecal incontinence: HR 1.55, 95% CI 1.39 to 1.73, p<0.01 • Malnutrition: HR 1.16, 95% CI 1.11 to 1.22, p<0.01 • Care quality deficiency in facility: HR 1.01, 95% CI 1.002 to 1.01, p<0.05 • Geographic location in US: HR 1.26, 95% CI 1.08 to 1.47, p<0.01 **Author conclusions there were disparities in time to pressure injuries in older Black NH residents.**	• Stage 1 PUs not included in analysis • For profit nursing homes that may not represent all aged care (unsure how many facilities)	**Level of evidence: 1 (prognosis)** **Quality: Moderate**
Sullivan, 2013	Retrospective observational **study to**	Retrospective chart review over 2 years in an acute care hospital in US (n=77	All participants received care with the standard PU	• Wound, ostomy, continence nurses performed all assessments using wound	**Characteristics of DTIs** • 39.5% occurred on sacrum, 28.9% on heel/Achilles region	• One single unit with a small sample size	**Level of evidence: 3**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	evaluate patterns of evolution and prognosis for SDTIs	participants with n=128 DTIs)) Inclusion criteria: • Aged > 18 years Participant characteristics: • Mean age 67years (range 32 to 91) • 67% males • 88% Caucasian • 31% overweight or obese • 50% coronary artery disease, 43% diabetes, 84% incontinent	bundle including education, soft silicone foam dressing for prevention and (when required) treatment, off-loading, barrier cream Existing wounds treated with honey, hypochlorite solution (if infected)	measurements and characteristics as per the NPUAP staging description • Categorization using NPUAP staging guideline • Assessments 1-2 times weekly • Median follow up was 6 days (range 1 to 41) • Percent change in each pressure injury	• 89.9% of DTIs were described as maroon-purple • Mean length of DTI was 6 days (range 1 day to 14 weeks) **Prognosis** • 66.4% healed or were progressing to healed • 24.2% unchanged at final follow up • 9.3% progressed to full thickness pressure injury • 74% ulcers decreased in size with a median healing rate of 61% • Only 1 DTI developed into a Stage III pressure injury • 45% of individuals who developed a DTI died within 2 months of the DTI **Author conclusions: Early identification appears to limit the number of DTIs that progress to a full thickness ulcer, however there appears to be no standard development pattern**	• Assessment timeframes was not consistent, and there was no interrater or intrarater reliability established • Endpoint was variable as either long of stay or until WOC nurse stopped evaluations • Start point not always clear from documentation	**(prognostic)** **Quality: Low**
Scheel-Sailer et al., 2017	To measure baseline data of **biophysical skin properties in the sacral area in SCI patients over Category/Stage I pressure injuries and the healthy skin close to the pressure injury**	Participants were recruited in an acute care and rehabilitation clinic in Switzerland (n=36 participants) Inclusion criteria: • group 1: SCI and pressure injury Category/Stage I (n=6) • Group 2 SCI without pressure injury (n=20) • group 3 able bodied volunteers (n=10) Exclusion criteria:	Participants in supine position for 30 mins o a standard mattress with one sheet	• Hydration (capacitance-based measurement device • Redness (optical method) • Elasticity (4 mm diameter opening suction probe) • Perfusion (laser Doppler flowmetry) • Measures at unloaded skin in the sacral region	**Skin hydration** • No significant differences between pressure injury skin and skin without pressure injury (p=0.626) **Skin perfusion** • Significant differences between pressure injury skin and skin without pressure injury (p<0.001) • Perfusion value was higher in pressure injury skin vs healthy skin • Perfusion value was higher in SCI than healthy people **Redness**	• Small sample • Different sample of each group, baseline differences between groups (age, age at injury and ASIA impairment scale) • Measurement strategies were not reported in detail • One site	**Level of evidence: 3** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• skin lesions or scarring at the sacral region • severe comorbidities (diabetes, coronary heart disease, kidney failure) • tumors, progressive disease, severe brain injury or infections Participant characteristics: • Mean age 62 years (significantly different between groups) Weight, BMI, smoker status were not significantly different between groups			• Significant differences between pressure injury skin and skin without pressure injury (p<0.001) • Redness value was higher in pressure injury skin vs healthy skin • Redness was higher in SCI than healthy people **Elasticity** • No significant differences between pressure injury skin and skin without pressure injury (p=0.365) **Author conclusions: Differences in perfusion and redness in SCI may increase susceptibility to pressure injuries**	• Only Category/Stage I pressure injuries • Not adjusted for confounding variables because of small sample	

Table 1: Level of Evidence for Intervention Studies

Level 1	**Experimental Designs** • Randomized trial
Level 2	**Quasi-experimental design** • Prospectively controlled study design • Pre-test post-test or historic/retrospective control group study
Level 3	**Observational-analytical designs** • Cohort study with or without control group • Case-controlled study
Level 4	**Observational-descriptive studies (no control)** • Observational study with no control group • Cross-sectional study • Case series (n=10+)
Level 5	**Indirect evidence**: studies in normal human subjects, human subjects with other types of chronic wounds, laboratory studies using animals, or computational models

Table 2: Levels of evidence for diagnostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	Individual high quality (cross sectional) studies according to the quality assessment tools with consistently applied reference standard and blinding among consecutive persons.
Level 2	Non-consecutive studies or studies without consistently applied reference standards.
Level 3	Case-control studies or poor or non-independent reference standard.
Level 4	Mechanism-based reasoning, study of diagnostic yield (no reference standard). Low and moderate quality cross sectional studies.

Table 3: Levels of evidence for prognostic studies in the EPUAP-NPUAP-PPPIA guideline update

Level 1	A prospective cohort study.
Level 2	Analysis of prognostic factors amongst persons in a single arm of a randomized controlled trial.
Level 3	Case-series or case-control studies, or low quality prognostic cohort study, or retrospective cohort study.

APPRAISAL FOR STUDIES PROVIDING DIRECT EVIDENCE (i.e. ELIGIBLE FOR SUPPORTING AN EVIDENCE-BASED RECOMMENDATIONS

Each criteria on the critical appraisal forms was assessed as being fully met (Y), partially met or uncertain (U), not met/not reported/unclear (N), or not applicable (NA). Studies were generally described as high, moderate, or low quality using the following criteria:

- High quality studies: fully met at least 80% of applicable criteria
- Moderate quality studies: fully met at least 70% of applicable criteria
- Low quality studies: did not fully meet at least 70% of applicable criteria

CROSS SECTIONAL/SURVEY/PREVALENCE STUDIES/OBSERVATIONAL

ID	Author/year	Focussed question	Sampling method	Representative sample	States number invited participants	Clear outcome measures	Valid reliable outcome measurement	Comparable results for multiple sites	Confounders identified and accounted for	Minimal bias	Reliable conclusions	Level of evidence	Quality
14858	Swaine et al., 2017	Y	N	Y	Y	Y	Y	NA	U	Y	Y	4	Moderate
15055	Ceylan et al., 2017	Y	N	Y	Y	Y	Y	NA	U	Y	N	4	Moderate
17281	C. G. Kim et al., 2018	Y	N	U	N	Y	Y	NA	Y	Y	U	4	Low

COHORT STUDIES

ID	Author/year	Focussed question	Comparable source populations	States number invited	Likelihood of outcome at enrolment considered	Per cent drop out in study arms is reported	Comparison btw drop outs and participants	Clear outcome measures	Assessment blinded, or discuss potential bias	Valid, reliable assessment with supporting reference	More than one measure of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
6347	Bliss et al., 2014	Y	Y	Y	Y	NA	NA	Y	N	U	U	Y	Y	Y	Y	1 (prognostic)	Moderate
3018	Harrow & Mayrovitz, 2014	Y	N	N	Y	N	N	Y	N	Y	Y	N	Y	N	N	3	Low
13791	McCreath et al., 2016	Y	N	Y	U	Y	N	Y	Y	Y	NA	Y	Y	Y	Y	3	Moderate

CASE CONTROL STUDIES

	Author/year	Focussed question	Comparable source populations	Same exclusion cases and controls	Per cent drop out in study arms is reported	Comparison btw participants and non-participants	Cases clearly defined	Established that controls are non-cases	Knowledge of primary exposure not influence case ascertainment	Valid, reliable assessment of exposure	Confounders identified and accounted for	Provides confidence intervals	Minimal bias	Reliable conclusions	Level of evidence	Quality
14133	Scheel-Sailer et al., 2017	Y	Y	Y	Y	Y	Y	Y	N	Y	N	Y	Y	U	3	Moderate

DIAGNOSTIC STUDIES

	Author/year	True diagnostic test – a test is compared to another test	Selection is either consecutive enrolment or random selection	No case-control methods	No inappropriate exclusion of participants	Independent interpretation of test and standard (i.e. without knowing results of other test)	Any threshold is pre-determined	Reference standard test is likely to correctly identify condition	Appropriate interval of time between index and standard tests	All participants receive same reference standard	All recruited participants are included in analysis	Minimal bias	Level of evidence	Quality
14092	Fletcher et al., 2017	Y	Y	Y	U	U	N	Y	U	Y	U	N	4	Low
14821	Scheiner et al., 2017	Y	Y	Y	Y	U	Y	Y	U	Y	Y	Y	1	High
3179	Sterner et al., 2014	Y	Y	Y	Y	U	Y	Y	U	Y	N	Y	1	High
13683	Borzdynski et al., 2016	Y	U	Y	U	N	Y	Y	Y	Y	U	Y	4	Low
17246	O'Brien et al., 2018	Y	N	Y	Y	Y	NA	Y	Y	Y	Y	Y	4	High

PROGNOSTIC STUDIES

	Author/year	Adequate description of baseline characteristics	Satisfactory study attrition	Clear definition of outcome measures/prognostic factors	Range of prognostic factors/confounders measured identified and	Method of measuring prognostic factor is reported, valid and reliable	Same method of measure of prognostic factor for all	Continuous variables or appropriate cut offs	Percent participants with complete data acceptable	Appropriate imputation method	Confounders/prognostic factors accounted for in analysis	Selective reporting avoided	Adequate sample size (10 PIs per factor)	Level of evidence	Quality
16257	Cox et al., 2016	Y	Y	Y	Y	U	Y	Y	Y	NA	Y	Y	N	1	high
1486	Sullivan, 2013	Y	U	Y	N	Y	Y	Y	Y	NA	N	U	NA	3	low
6677	Higashino et al., 2014	Y	Y	Y	N	Y	Y	U	Y	NA	N	Y	Y	3	High

SYSTEMATIC REVIEWS FOR DISCUSSION

RATING CRITERIA:
1 Partial yes: states review question, search strategy, in/exclusion criteria and risk of bias were a-priori; full yes: meta-analysis/synthesis plan, investigation of heterogeneity and justification for protocol deviation
2 Partial yes: At least 2 databases, provides keywords and search, justifies publication restrictions; full yes: searched reference lists of included studies, searched trial registries, consulted experts in field, searched grey literature, search within 24 months of review completion
3 At least two reviewers independently agreed on selection of studies to include or reviewers achieved 80% agreement on a sample of studies
4 Either two reviewers did data extraction and had >80% agreement, or two reviewers reached consensus on data to extract
5 Partial yes: list of all relevant studies that were read and excluded; full yes: every study that was excluded is independently justified
6 Partial yes: described populations, interventions, comparators, outcomes and research design; full yes: detailed descriptions of same plus study setting and timeframe for follow-up
7 FOR RCTS Partial yes: appraised risk of bias from unconcealed allocation and lack of blinding; full yes: appraised risk of bias on true randomisation, selection of reported result from multiple measurements/analyses
FOR non randomised studies: Partial yes: appraised confounding and selection bias; full yes: appraised methods to ascertain exposures and outcomes, selection of reported result from multiple measurements/analyses
8 Must include reporting of the source of funding of individual studies, or reports that the reviewers considered this even if individual funding sources aren't listed in review

Endnote ID	Author/year	PICO research question and inclusion criteria	Explicitly states a-priori protocol[1]	Rationale for selection of study designs	Comprehensive search[2]	Duplicate study selection[3]	Duplicate data extraction[4]	Excluded studies listed[5]	Adequate description of	Risk of bias assessed[7]	Source of funding reported[8]	Appropriate meta-analysis including weighting and	Meta-analysis considers risk of bias of studies	Discussion consider risk of bias of studies	Assessment of publication bias if quantitative analysis is done	Potential conflicts of interest of authors reported and managed	Review Quality	Type of evidence included in review
14335	Oliveira, Moore, T, & Patton, 2017				Y			N		Y		NA		Y	N		Exclude	Experimental studies with animals and humans

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