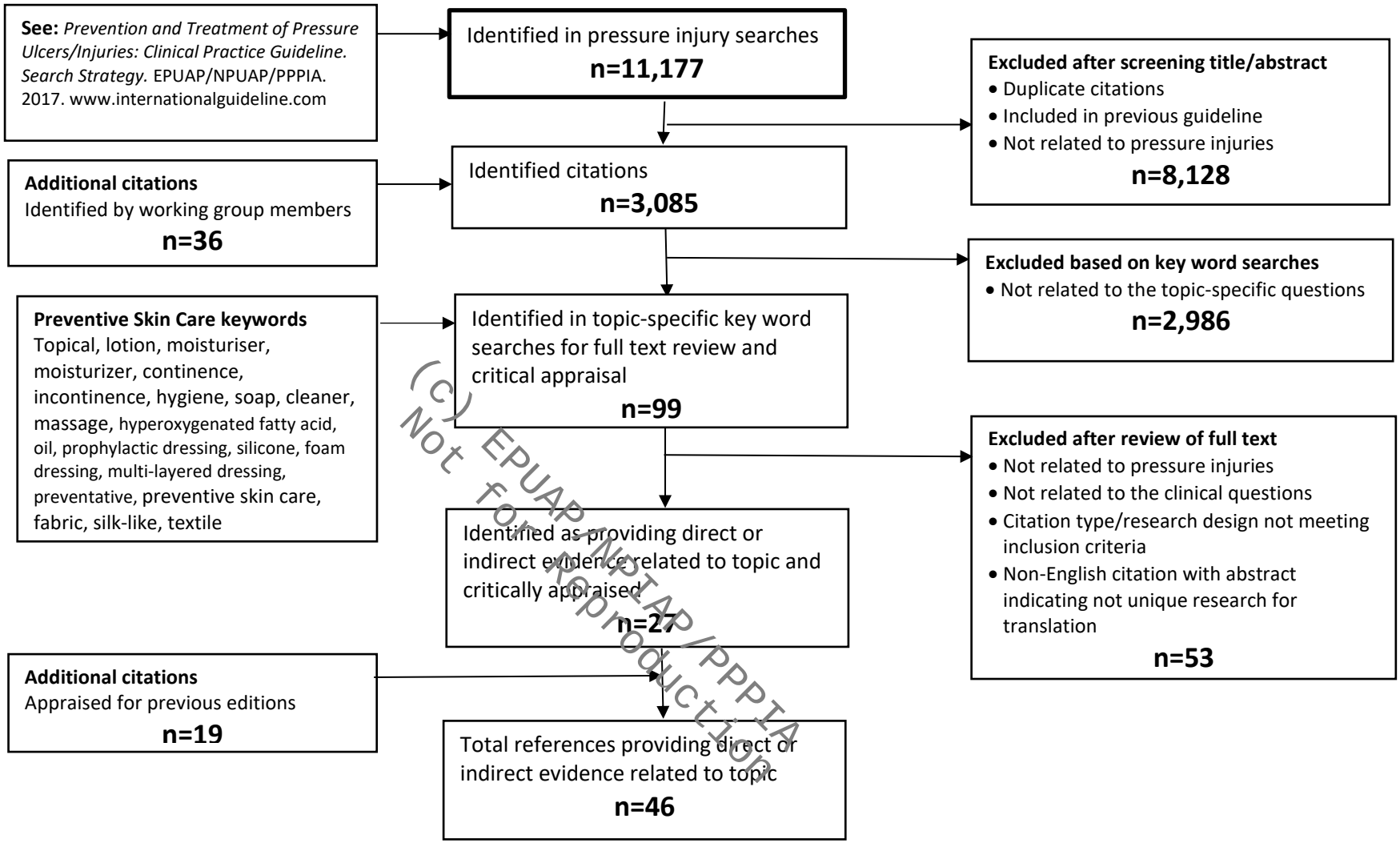
Search results for 2019 International Pressure Injury Guideline: Preventive Skin Care



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: Is massage effective in promoting healing of pressure injuries?							
Houwing, van der Zwet, van Asbeck, Halfens, & Arends, 2008	Double blind, randomized multicenter, placebo-controlled study **exploring DSMO and massage**	Participants were recruited from 8 nursing homes in the Netherlands (n=79) Inclusion: • pressure reliving support surface available • At risk of PU using Braden score of 20 as cut-off point Exclusion: • being treated with another topical cream • surgery within the previous 2 weeks of about to undergo surgery • existing PU • dark skin Characteristics: • Mean age 80 and 85 years for the three groups • >50% participants were always incontinent of urine	Participants were randomly assigned to: • control group with no topical application receiving regular repositioning (n=18) • placebo Vaseline cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=32) • 5% DMSO cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=29)	Incidence of PU evaluated by 2 external observers every 2 days and categorized using EPUAP staging	• No difference between the control group and the placebo treatment group therefore massage had no influence on PU incidence • Massage with a 5% DMSO cream demonstrated a higher incidence of PU development compared to the control and to the placebo groups (OR of PU at heal or ankle 8.80 95% CI 2.61 to 29.6)	• Methods of randomization and allocation concealment not reported	**Level of evidence: 1** **Quality: moderate**
Clinical question 2: Are topical products (e.g. moisturizers, emollients, hyperoxgenated fatty acids) effective in preventing pressure injuries?							
Lupianez-Perez et al., 2015	Non-inferiority RCT **determining if olive oil (non oxygenated**	Participants immobilized patients receiving home nursing services in Spain (n=831 recruited, n=574 completed trial) **Inclusion criteria:**	• All participants received regular preventive care including cushions, pressure relieving mattress, mobilization	• Category/Stage 2 PU or greater during 16 week follow up period confirmed via inspection	**Per protocol analysis** *(best analysis to report for non-inferiority trial)* ○ Sacrum PU rate: 3.08% vs 2.55%, Absolute risk	• Superiority of HOFA in Category/Stage 2 has not been established. Previous studies are in Category/Stage I PU, and	**Level of evidence: 1** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	fatty acid) is as effective as hyperoxygenated fatty acid (HOFA) for preventing Category/Stage 2 and greater PU	• ≥18 years • Family member or paid caregiver able to apply treatment • Braden Scale ≤16 • ≤ 10 on Mini Nutritional Assessment (MNA) **Exclusion criteria:** • Existing PU • Refusal, lived outside zone, follow-up an another center • Hospitalization during sampling • Terminally ill **Characteristics:** • No significant differences at baseline in comorbidities, Braden scale score, MNA score or mobility levels • Approximately 45% chair bound, approximately 40% bed bound approx. 15% walk occasionally • High levels of Category/Stage I PU at baseline (e.g. approx. 94%) of patients at sacrum and heels) but not significantly different between groups	equipment (use not significantly different between groups) • High use of incontinence pads in both group • Application of spray twice daily to sacrum, hips and heels. Randomized to receive either: ○ Hyperoxygenated fatty acid (HOFA) product that included Equisetum Arvense, Hypericum Perforatum and perfume (n=437 ITT, n=314 per protocol) ○ Liquid spray of 97% virgin olive oil with 3% Hypericum Perforatum and perfume (n=394 ITT, n=260 per protocol)	• Assessment performed at baseline, weekly and at conclusion or until PU identified	reduction (ARR) 0.53 (95% CI -2.2 to 3.6) ○ Right heel: 1.92% vs 1.27%, ARR 0.65 (95% CI -1.43 to 2.73) ○ Left heel: 1.15% vs 0.96%, ARR 0.2 (95% CI -1.49 to 1.88) ○ Right trochanter: 1.54% vs 0% ARR 1.54 (95% CI 0.04 to 3.03) ○ Left trochanter: 0.38% vs 0.32%, ARR 0.07 (95% CI -0.91 to 1.04) **Intention to treat analysis** ○ Sacrum PU rate: 2.28% vs 2.52%, ARR -0.23 (95% CI -2.31 to 1.85) ○ Right heel: 34.77% vs 28.6%, ARR 6.17 (95% CI -0.16 to 12.5) ○ Left heel: 34.26% vs 28.38%, ARR 5.89 (95% CI -0.42 to 12.2) ○ Right trochanter: 24.52% vs 27.69%, ARR 6.83 (95% CI 0.53 to 13.12) ○ Left trochanter: 13.96% vs 10.76%, ARR 3.2 (95% CI -1.28 to 7.69) **Author conclusion: Olive oil is as effective as HOFA in preventing Category/Stage 2 PU in patients at high risk.**	the most accessible English-language publication Bou 2005 does not specify Category/Stage. In that trial, the ARR was approximately 10%, which is the margin of difference defined in this current trial. • Power calculation was conducted and conditions were met • Did not present overall between group analysis, only analysis by anatomical site • 30% drop out including those getting a PU, those inadequately administering product, hospital admissions, lost to follow up, withdrawal and refusals • Unclear how stage 2 PU was defined as some participants had "partial skin loss" at baseline (but PU at baseline was an exclusion criteria) • Potentially insufficient follow up period	
Aloweni et al., 2017	RCT to determine effectiveness of prophylactic	• Participants were recruited from medical-surgical wards from acute tertiary care hospital in Singapore during the period of January 2014 to February 2016	Participants were randomized to receive: • The control group (n = 202) received standard care (repositioning every	• A RN assessed the participants' sacrum area at least once a day. • Study investigator assessed participants'	• There were no significant difference between the groups when incidence rates were compared: 5.4%	• The study was not blinded and was slightly underpowered. • The study was conducted in a single-site setting.	**Level of evidence: 1** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	silicone foam dressing and tropical application of fatty acids oil in reducing the incidence of sacral pressure injury among high-risk hospitalised patients	(n=416 recruited, n= 397 completed) Inclusion criteria: • ≥21 years of age • No pre-existing pressure injuries • high risk of developing pressure injuries (≤14 on Braden Scale) Exclusion criteria: • existing sacral pressure injury • allergy to fatty acids oil or silicone dressing • Fecal incontinence Characteristics: • The three groups were comparable on the major characteristics • Approximately 70% of participants > 71 years • Approximately 40% had diabetes	two or three hours when in bed, use of positioning devices, use of an alternating air mattress, use of slide sheet, frequent elimination rounds and diaper change and applying barrier creams or emollient cream if patients had dry skin • The silicon foam dressing group (n= 129) received standard care plusMepilex® Border Sacrum (Molnlycke Health Care), dressing changed every seven days or when soiled • The fatty acids oil group (n= 130) received standard care + Linovera oil ® three times daily.	sacrum every three days until discharge or (maximum two weeks of the hospitalization) • Pressure ulcer category defined as by NPUAP, EPUAP & PPPIA guideline	(n=7) in the fatty acid oil group and 5% (n=10) in the standard care group. • Analysis of patients with Braden score of ≤ 12 showed a significant difference between the fatty acid oil and standard care group (0% versus 4.8%, p = 0.048). **The authors conclude that additional preventive measures, such as silicon foam dressing or fatty acid oil, seem to be clinically beneficial in reducing sacral pressure injuries among very high-risk patients**	• The significance reached in the sub-group comparison was not very strong. • Results for prophylactic dressing group presented below	
Duimel-Peeters et al. (2007)	Cross over RCT comparing anti-inflammatory DSMO cream with placebo cream	Participants were recruited from 8 nursing homes in the Netherlands (n=79) Inclusion: • pressure reliving support surface available • At risk of PU using Braden score of 20 as cut-off point Exclusion: • being treated with another topical cream • surgery within the previous 2 weeks of about to undergo surgery • existing PU • dark skin	Participants were randomly assigned to: • control group with no topical application receiving regular repositioning (n=18) • placebo Vaseline cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=32) • 5% DMSO cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=29)	Pressure injury incidence	• no significant difference in pressure ulcer rates between individuals massaged with DMSO cream and those massaged with a placebo cream • OR of developing a pressure ulcer when a placebo cream was applied in first half of trial was 1.135 (p = 0.441); in second half of trial was 2.526 (p = 0.516) • OR for developing a pressure ulcer when DMSO cream was	• Methods of randomization and allocation concealment not reported • Note this is the same study as Houwing et al. 2008 but reports different outcomes	**Level of evidence: 1** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Characteristics: • Mean age 80 and 85 years for the three groups • >50% participants were always incontinent of urine			applied was 2.571 (p = 0.126) in the first period of the trial and 2.182 (p = 0.516) in the second period		
Houwing et al., 2008	Double blind, randomized multicenter, placebo-controlled study **exploring DSMO and massage**	Participants were recruited from 8 nursing homes in the Netherlands (n=79) Inclusion: • pressure reliving support surface available • At risk of PU using Braden score of 20 as cut-off point Exclusion: • being treated with another topical cream • surgery within the previous 2 weeks of about to undergo surgery • existing PU • dark skin Characteristics: • Mean age 80 and 85 years for the three groups • >50% participants were always incontinent of urine	Participants were randomly assigned to: • control group with no topical application receiving regular repositioning (n=18) • placebo Vaseline cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=32) • 5% DMSO cream massaged into buttocks and heels/ankles every 6 hours for 4 weeks (n=29)	Incidence of PU evaluated by 2 external observers every 2 days and categorized using EPUAP staging	• No difference between the control group and the placebo treatment group therefore massage had no influence on PU incidence • Massage with a 5% DMSO cream demonstrated a higher incidence of PU development compared to the control and to the placebo groups (OR of PU at heel or ankle 8.80 95% CI 2.61 to 29.6)	• Methods of randomization and allocation concealment not reported • This is the same study as Dumel-Peeters et al 2007 but reports different outcomes	**Level of evidence: 1** **Quality: moderate**
Verdú & Soldevilla, 2012	Prospective, multi-centre, double-blind, placebo-controlled, RCT investigating **the effect of IPARZINE-4A-SKR topical preparation**	Participants recruited from hospitals and social health care centres in Spain (n=194) Inclusion: • Aged over 18 years • Braden score ≤ 15 indicating medium, high or very high risk of PU • No current PU	All participants had standard PU prevention programs and 12 hourly skin checks. Participants received either: • The product (IPARZINE-4A-SKR) applied topically 12 hourly to the sacrum, trochanters and heels with gentle massage until absorbed (n=99)	Primary Endpoint • PU incidence Secondary Outcome • tolerance	• PU incidence was 6.1% in intervention group and 7.4% in the control group (z=0.08,p=0.94) • Relative risk was 0.82 (95% CI 0.29 to 2.36, p=not significant) **Study conclusions: The topical hyperoxygenated fatty acids preparation**	• Sample did not meet apriori size calculation • The study was only 14 days in length, which may not be sufficient for a prevention trial in which comprehensive PU preventative strategies were also used.	**Level of evidence: 1** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	in preventing PU	Exclusion: • Terminal illness • Active PU • Peripheral vasculopathy • Allergies to ingredients in study products • Vasopressor or chemotherapy treatment • Been in a clinical trial in previous month Characteristics: • No significant difference at baseline for age, gender or Braden score. • Mean age approx. 78 years (range 29 to 101) • Mean Braden score approx. 12 (range 8 to 15)	• A placebo topical product applied as hourly to the sacrum, trochanters and heels (n=95) The intervention product is referred to as a galenic formula (i.e. compounded medicine) and contains hyperoxygenated fatty acids (actual ingredients not listed in English).		**IPARZINE-4A-SKR is no more effective than a placebo topical preparation at reducing the risk of PU over 14 days.**		
Shannon, Coombs, & Chakravarthy, 2009	Quality improvement cohort study investigating a silicon based emollient cream for preventing pressure injuries in incontinent patients	The study was conducted in a medical care ward in a US hospital	Hospital ran a refresher training course on patient care. WOC nurses analyzed the product use in the ward and developed a protocol for product use, including introduction of a silicon based dermal nourishing emollient. Full description of the product use was not reported.	Braden scale Financial cost considered costs of products, nursing time and hospital stay for pressure injury	• Risk of a PU was significantly reduced in the period following introduction of the emollient cream (χ^2 =7.09, p= 0.008) • PUs in the pre-intervention period peaked at 31% dropping to an average of 7% in the post-intervention period • There was a reduction in financial cost of USD $6,677.11 per patient associated with emollient cream ($2341 vs $9018)	• Full use of product not reported • No raw pressure injury data reported • Confounding issues not addressed • Cost analysis is based on a standardized cost for a pressure injury with no consideration not severity	**Level of evidence: 3** **Quality: low**
Bou et al., 2005	Double blind RCT comparing a product containing fatty acids	N=331	Participants were randomized to receive either: • Moisturizing hyperoxygenated fatty acids (Mepentol®) (n=164) or	pressure ulcer incidence	• There was a significant reduction in pressure ulcer incidence associated with use of the product containing fatty acids (17.3% versus	• did not include the methods of randomization and the analysis • The study report was not intention-to-treat (results for only 87% of the	**Level of evidence: 3** **Quality: moderate**

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	with a product containing trisostearin and perfume		• an emollient/moisturizer product containing trisostearin and perfume (n = 167) Products were applied twice daily to the sacrum, trochanter and heels.		7.32%, p = 0.006) at 30 day follow up.	recruited population were reported)	
Clinical question 3: Is a prophylactic dressing effective for preventing pressure injuries?							
Polyurethane film dressing							
T. S. Souza, M. T. Reichembach Danski, D. A. Johann, L. S. Marques De Lazzari, & P. Mingorance, 2013	Non-randomized study **investigating efficacy of polyurethane film for preventing heel PU in ICU patients**	Participants were recruited in a teaching hospital ICU in Brazil (n=100) Inclusion criteria: • Aged ≥ 18 years • No PU present at entry to study Exclusion criteria: • Pre-existing PU • Refusal • Discharge or death Participant characteristics • Mean age 53.3 years • 50% sample female • 85% sample Caucasian • 15% sample diabetic • 50% received vasoactive drugs • 72% received sedatives	• Assessed with Braden Scale within 48 hours of admission and classified as high, moderate or low risk • Participants acted as own control: • Left heels treated with transparent polyurethane film dressing replaced as needed plus standard care (defined as clinical guideline care, n=100) • Right heel receiving standard care only (n=100)	• Daily skin assessment • Maximum time in study (until death or discharge) was 24 days except two patients who were inpatients for > 40 days	**PU incidence** • Overall incidence 32% of heels • 8% participants had bilateral PU • Significantly fewer heels receiving a prophylactic dressing experienced a PU compared to control heels (6% versus 18%, p<0.001) **Mean time without a PU** Prophylactic dressing group 19.2 days (95% CI 17.3 to 21) **Author conclusion: Transparent polyurethane film was effective in the prevention of heel PU.**	• No blinding • Selection criteria not well defined • Participants acted as own controls • Control management was not defined (unclear if it included heel suspension) • Individuals who were discharged or died were excluded – unclear how many commenced trial	**Level of evidence: 2** **Quality: Low**
(Weng, 2008)	Quasi-experiment investigating **effect of acrylic film dressing and hydrocolloid dressing in preventing**	Participants recruited from a medical ICU and a cardiac ICU in Taiwan (n=90) Inclusion: • Diagnosed with respiratory failure • Using and tolerating with non- invasive face	Participants were assigned to one of three groups: • Control group with no dressing (n=30) • Tegasorb® hydrocolloid dressing (3M) group (n=30)	• Formation of PU assessed as being one of four grades (grading system not reported, Grade I defined as reddened area lasting more than 30 mins after change of position).	• Incidence of grade I PU was lower in the film dressing group compared with no dressing group (53.3% versus 96.7%, p<0.01) • Incidence of grade	• Small number of subjects • No blinding, no power calculations • Several factors may influence the findings (e.g. skin color precluding accurate assessment of PU	**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	device-related PU	mask • No facial skin breakdown Exclusion: • Not reported Characteristics: • No significant differences between groups at commencement for any demographics including BP and bloods • Primarily classified as having adequate nutrition and no sensory impairment • Majority had no sweating observed • Mean age approx. 75years	• Tegaderm® acrylic film dressing (3M) group (n=30) The materials were used to cover the nasal bridge and patients were observed for PU formation	• Time until PU formed in minutes	I PU was lower in the hydrocolloid dressing group compared with no dressing group (40% versus 96.7%, p<0.01) • Pressure injuries formed significantly faster in control group (1111±2169 mins) versus the film dressing (2628±1655mins) or hydrocolloid dressing groups (3272±2566 mins, p<0.01) • There were no statistical significant difference in occurrence duration and time between the hydrocolloid dressing and film dressing • Film adhered less effectively than hydrocolloid dressing and did not contain exudate **Study conclusions: A protective dressing was associated with decreased incidence of grade I PU in older adults wearing non-invasive face masks**	formation) • Facial formation may influence PU formation • No reporting of skin breaks/damage associated with dressing removal	
Hydrocolloid dressing							
Park, 2014a	Controlled trail to evaluate the	Participants recruited in an ICU in South Korea (n=32 screened, n=30 included) ICU	• All the patients were repositioned every 2 hours in a supine, and a 30°	• The dressing was removed on days 3 and 7, measurements	**Pressure injury incidence 3 day**	• One setting • Small sample	**Level of evidence: 2**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	effectiveness of a newly developed ceramide-containing hydrocolloid dressing for preventing pressure injuries by reducing pressure, friction, or shearing forces and improving skin hydration	Inclusion: • Braden Scale score ≤16 points or less • no skin problem on baseline skin evaluation • inability to position themselves to prevent friction and shearing due to own movement Exclusion: • rejected participation • Death or transfer or discharge • Participant characteristics: • 63% males • Mean age 60.7 years • Primarily diabetic • Most continent or catheterized	lateral position according to the standard study protocol at a regular interval • Participant hips were randomized to receive: ○ Intervention: Ceramide-containing hydrocolloid dressing ((Remois Pad® dressing, Japan) randomly applied to one of the participants trochanters ○ Other trochanter recovered standard care • Trial continued for seven days	performed after 20 minutes • Dressing replaced at the same site • Frequency of dressing application based on company's recommendation • Two primary wound care nurses performed assessment of erythema (IRR 0.979) • Moisture-retaining capacity measured using a moisture checker	No sign differences between the two groups , no nonblanching erythema in either groups **Pressure injury incidence 7 day** Experimental group 1 (3.3%) vs control group 4 (13.3%) had experienced non-blanching erythema (p = 0.353) **Water-retaining capacity** Water-retaining capacity was significantly higher in the exp group on both the 3. and 7. Day (p= 0.001, <0.001) **Author conclusion: Ceramide containing dressing did not reduce pressure injuries but did increase moisture retaining capacity of skin**	• Even though repositioning was planned every two hours, there was no data confirmation • Patients their own control • Lower number of non-blanchable erythema in both group than power calculation	**Quality: High**
Dutra et al., 2015	RCT **comparing hydrocolloid dressing to polyurethane film dressing for preventing sacral and trochanter PU**	Participants were recruited consecutively in three critical care units in a Brazil hospital (n=recruited 160) Inclusion criteria: • Aged ≥ 18 years • No PU on entry to study • Moderate to high risk of PU according to Braden scale assessed 48 hours after admission Exclusion criteria: • Pre-existing PU	After Braden assessment, individuals with moderate or high risk received a prophylactic dressing. Participants were randomized to receive either: ○ polyurethane film dressing applied to sacrum and trochanters (n=80), or ○ hydrocolloid dressing applied to sacrum and trochanters (n=80)	• Assessed by specialized nurses using Braden scale • Daily for 30 consecutive days or until discharge, transfer or death	• Incidence of pressure injuries was significantly lower in the polyurethane film dressing group compared with hydrocolloid group (8.7% versus 15%, p=0.038) **Dressing changes** • Overall there was significantly more dressing changes in hydrocolloid group	• The significant differences in characteristics between the two groups could have contributed to the outcome • Concurrent management strategies not reported • No blinding, dropouts excluded from analysis	**Level of evidence: 1** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Hospitaliszed <48 hours • Dropped out • Brain death Participant characteristics • Mean age 64-65yrs • Primarily Caucasion (significantly more Afro-Brazilians and mixed race in hydrocolloid dressing group, p=0.023) • Primarily mechanically ventilated, receiving vasoconstrictives, incontinent and fasting • Hydrocolloid dressing group had more agitation, p=0.024), higher level of sedation (p=0.06), poorer nutritional status (p=0.001) and more patients at higher PU risk (p=0.028)			(mean 6.09 versus 5.59, p=0.01) • There was significantly more dressing changes for the sacrum site in hydrocolloid group (mean 2.50 versus 2.05, p=0.001) • No significant differences in number of dressing changes at trochanters • There were no significant differences in reasons for dressing to be changed, except that hydrocolloid group were significantly more likely to have dressing changed due to shear (p=0.048) **Author conclusions: results may suggest that the film was more effective in preventing PUs compared with the hydrocolloid dressing**.		
Foam prophylactic dressings							
Aloweni et al., 2017	RCT to determine effectiveness of prophylactic silicone foam dressing and tropical application of fatty acids oil in reducing the incidence	• Participants were recruited from medical-surgical wards from acute tertiary care hospital in Singapore during the period of January 2014 to February 2016 (n=416 recruited, n= 397 completed) Inclusion criteria: • ≥21 years of age • No pre-existing pressure injuries	Participants were randomized to receive: • The control group (n = 202) received standard care (repositioning 2-3 hourly when in bed, use of positioning devices, alternating air mattress, slide sheet, frequent continence rounds, barrier creams or	• A RN assessed the participants' sacrum area at least once a day. • Study investigator assessed participants' sacrum every three days until discharge or (maximum two weeks of the hospitalization) • Pressure ulcer category defined as by NPUAP, EPUAP & PPPIA guideline	• There was no significant difference between the groups when incidence rates were compared; 3.9% (n=5) pressure injuries in the silicon dressing group and 5% (n=10) in the standard care group. • Analysis of patients with Braden score of ≤ 12 showed a significant	• The study was not blinded and was slightly underpowered. • The study was conducted in a single-site setting. • The significance reached in the sub-group comparison was not very strong. • Results for fatty acid group presented above	**Level of evidence: 1** **Quality: Moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	of sacral pressure injury among high-risk hospitalised patients	• high risk of developing pressure injuries (≤14 on Braden Scale) Exclusion criteria: • existing sacral pressure injury • allergy to fatty acids oil or silicone dressing • Fecal incontinence Characteristics: • The three groups were comparable on the major characteristics • Approximately 70% of participants > 71 years • Approximately 40% had diabetes	emollient cream if patients had dry skin • The silicone foam dressing group (n= 129) received standard care plusMepilex® Border Sacrum (Molnlycke Health Care), dressing changed every seven days or when soiled • The fatty acids oil group (n = 130) received standard care + Linovera oil ® three times daily.		difference between the silicon foam group and standard care group (0% versus 4.8% p = 0.04) and standard care group (0% versus 4.8%, p = 0.048). **The authors conclude that additional preventive measures, such as silicon foam dressing or fatty acid oil, seem to be clinically beneficial in reducing sacral pressure injuries among very high-risk patients**		
Yoshimura et al., 2016	Controlled trial **to determine effectiveness of soft silicone foam dressings compared to film dressings for preventing intraoperative pressure injury in people undergoing surgery in prone position**	Participants were recruited in one operating room in Japan (n=113 assessed for eligibility, n=100 enrolled) Inclusion criteria: Undergoing surgery in prone position using the Relton-Hall frame Exclusion criteria: • Emergency surgery • Skin disorders or scars in the area to be observed • Spondylosis deformation Age < 20 years Characteristics: • mean age 64.6 • 67% male • average BMI 23.7 • co-morbidities included HTN DM, CHF • surgical procedures included posterior lumbar interbody	• Participants examined 1-2 days prior to surgery for pressure injuries, scars or thoracic deformity • Dressings were applied after induction of anesthesia: ○ Left body side: multi-layer silicone foam (Mepilex® border, Molnlycke Health Ca) to the chest and iliac crest ○ Right body side: polyurethane film dressings (Opsite* Flexifix*, Smith & Nephew) applied chest and iliac crest	• NPUAP-EPUAP pressure ulcer classifications system was used • condition of the skin that was in contact with the Relton-Hall frame was evaluated by 2 OR nurses using the finger pressure method at 30 minutes after patient returned to the supine position from the prone position to distinguish non blanchable from blanchable erythema • all patients followed up by medical records review	**Operating room pressure injuries incidence** • 11% developed pressure injury within 30 minutes of returning to supine position (10 Category/Stage I and 1 Category/Stage 2) • 100% pressure injuries occurred on chest • 100% pressure injuries healed without deterioration before discharge • Significantly more pressure injuries occurred on polyurethane film side vs soft silicone side (11% versus 3%, p=0.027) **Author conclusion: Study showed that soft silicone foam dressings were more**	• Participants acted as own control • Only one operating room • Length of surgery and diastolic BP below 50 were es risk factors for operating room pressure injuries • Preventive effect of the dressing was small, this was considered to be a limitation of the dressing • Relied on medical records for follow up data • No blinding	**Level of evidence: 2** **Quality: High**

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		fusion, laminectomy, discectomy • mean procedure duration was 2.6 hours			**effective than polyurethane film dressings for preventing pressure injuries in patients undergoing spinal surgery in prone position using a Relton-Hall frame**		
Padula, 2017	Retrospective cohort study to examine the effectiveness & value of prophylactic 5-layer foam sacral dressings to prevent hospital acquired pressure injury rates in acute care setting.	Records of hospitalised adults from 38 acute care hospitals in US (n=618 with pressure injuries) Inclusion criteria: • Pressure injury as identified by Patient Safety Indicator (PSI-03) from 2010-2015 • Hospitalized at least 5 days Exclusion criteria: None stated Participant characteristics not reported . Among all types of dressings, 5-layer sacral dressings	Records were analyzed according to if prophylactic prophylactic 5-layer sacral dressing (Mölnlycke Health Care) was in use in the facility versus when dressing not in use	• Longitudinal data (hospital-level patient outcomes such as admissions, PSI-03 and pressure injury rate) pertaining to prophylactic 5-layer foam sacral dressing purchased by hospital for quarters between 2010-2015 from 38 hospitals • Merged data on volumes of dressings purchased by each hospital as per dressing manufacture • Mixed -effects negative binomial regression was used to test the longitudinal association of prophylactic foam sacral dressings on pressure injury rates, adjusted for hospital case-mix and Medicare payment rules	**Pressure injury incidence** • Average hospital-level HAPI per quarter for Category/Stage III, IV or unstageable: with prophylactic dressing 1.2± 0.045 vs no dressing 1.5±0.125 (p=0.0063) • Average facility experienced a 1.0 case reduction in Category/Stage III, IV or unstageable/quarter following introduction of dressing • 1.72/1,000 patients Category/Stage III, IV or unstageable in 2010 (no standard use of dressing) versus 0.62 cases in 2015 **Cost analysis** • Estimated cost of $70,000 per case • average hospital purchase of prophylactic foam dressings in 2010 was 355/1000 prophylactic foam sacral dressings versus	• Hospital level data providing aggregate hospital patient outcomes data quarterly • Patient level data was not available, similarity of cohorts uncertain • Some data provided directly from product manufacturer • No information on how dressing was used, other interventions that might be different between cohorts • Can't rule out facilities using other types of prophylactic dressings • Only considers costs of dressings • Pressure injuries may have occurred at other places than the sacrum	**Effectiveness Level of evidence: 3 Quality: Low** **Economic analysis Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					2662/1000 in 2015, cost of $7.50/dressing • Spending on pressure injuries decreased from $120/ patient to $43/patient • Spending on prophylactic foam sacral dressings increased from $2.60/patient to $20/patient **Author conclusion: Prophylactic 5-layer foam sacral dressings could save hospitals $200,000 to $600,000 per year in expenses associated with pressure injuries**		
Walker et al., 2017	RCT to determine effectiveness of prophylactic dressings to prevent pressure injuries	Participants were recruited in surgical and emergency departments in unknown location (n=125 screened, 80 recruited, 77 analyzed) Inclusion criteria: • Aged ≥ 18 years • High risk or greater for pressure injuries as per Waterlow scale • Expected ≥3 day stay Exclusion criteria: • Suspected or actual spinal injury • Low back surgery • Existing sacral pressure injury • Fecal incontinence Characteristics:	• Participants were randomized (stratified by medical vs surgical) to: ○ Standard care only (n=38) ○ Intervention: standard care plus silicon foam border dressing (manufactured by Molnlycke Health Care) applied to the sacrum, replaced every 3 day or if it became loose or soiled (n=39)	• Sacral photography at baseline and at the 3. day and • Photo evaluated by blind assessor • IRR 95% • Dressing removed 10-15 min prior to photos but blinded assessor	**Pressure injury rate** • 3 patients (2 in dressing group, 1 in routine care group)were assessed to have a Category/Stage I sacral pressure injury, however one case disputed by inter-rater assessor **Feasibility of sacral dressing** • Dressing remained in situ for median 2 days or 49 hours (24-69) • Main reasons for dislodgement were non-adherence when wet from hygiene, rolling edges, fecal incontinence, discomfort	• Main goals were testing feasibility of methods • reported observing dressing markings reducing blinding to the intervention. • Pilot study, small sample size, single health care setting • No info if the patients with sacral PU were among the 7 patients have • Nurses were not blinded ITT analysis	**Level of evidence: 1** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean age 75 years • 70% females • 7 patients had PU on other sites prior to study					
Park, 2014b	Controlled trial to evaluate effect of a silicone border foam dressing to the sacral and coccygeal areas on pressure injury incidence occurrence	Participants recruited in ICU in Korea (n=102 patients were recruited) Inclusion criteria: • aged ≥ 40 years • No IAD or pressure injury • Braden score of ≥16 Exclusion criteria: • contraindication to changing positions • Participant characteristics : • 64% male • Mean age 62 years • 90% continent of urine and 77% normal stools	• Both intervention and control group patients received standard PU preventive care regimen • Participants were assigned to receive: ○ intervention group: Silicone border foam dressing (Mepilex® Border, Molnlycke Health Care) applied for 9 days Dressings were changed every 3 days or more if soiled or detached. Surrounding skin was cleaned and dried at each dressing change. ○ Control/comparison group if relevant: No use of silicone border foam.	• 2 primary wound care nurses made rounds every 3 days during the 9 days the patient was in the study. Skin assessments and presence of PU and IAD were evaluated. • The worst scores for the PU and IAD status during data collection period were used • Braden Scale for pressure sore risk was used to evaluate the patient's risk of developing PU. • NPUAP classification • system • Study period only for 9 days.	**Pressure injury incidence** • The intervention group showed lower occurrence of pressure injury compared to control group (6% vs 46%, x^2= 21.722, p<0.001). • Category/Stage I pressure injuries (46% control vs 6% intervention group) • Category/Stage II pressure injuries (34% control vs186% intervention group) **Author Conclusions: The use of silicone border foam dressing lowered the occurrence of hospital-acquired PU development.**	• Study also reported IAD incidence • More additional research is required to clarify the nature of the relationship between PU occurrence and IAD, as both conditions etiologies differ. This study looks only at critically ill patients • Achieved recruitment required by power calculation • Group allocation methods not reported • No blinding	**Level of evidence: 2** **Quality: High**
Cubit, McNally, & Lopez, 2013	Historical control cohort study effectiveness of using a low-**shear, silicon-coated, sacral dressing to reduce the prevalence of sacral PI**	Participants recruited in a hospital in Australia (n=109) Inclusion: • admitted to medical ward via the ED • aged 65 years or over • medical condition • high or very high risk of PU development (Waterlow score) • no existing PI at the sacrum	• Intervention cohort: Prevention plan documented and sacral dressing Mepilex® Border - polyurethane foam (Molnlycke Health Care) applied (n=51) • Control (n=58): regular care, matched sample	• Nursing staff undertook sacral skin checks three times every 24 hour • Four stage system approved by the Australian Wound Management Association • LOS/follow up ranged from 1 to 68 days, mean of 15.2 (SD 16.1)	**Pressure injury incidence** Intervention group 1/51 (1.96%) vs 6/58, 10.3%) developed a sacral PI, control group had more than 5 times incidence of a PI. This was not a significant difference (p<0.08)	• Pilot study with small sample • one setting • Known group: retrospective data collection, bias possible	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Exclusion: • sacral PI Characteristics: • Age range 65 to 96 years					

Byrne et al., 2016	Non randomized quasi experiment **exploring prophylactic dressing for reducing incidence of sacral PU in individuals at high risk**	Participants were recruited in three ICUs in an academic hospital in US (n=584 met inclusion, n=243 received dressing, n=200 had complete data)
		
		Inclusion criteria:
		• Aged ≥ 18 years
		• At least of following criteria:
		  ○ Surgery ≥ 4 hours or cumulative surgeries ≥ 6 hours
		  ○ Cardiac arrest on admission
		  ○ Vasopressors for ≥ 48 hours
		  ○ Shock, sepsis or multiorgan failure
		• If not meeting above, having at least 5 common risk factors for PU including older age, weight, disease factors, inactivity, malnutrition etc
		
		Exclusion criteria:
		• Incontinence not managed by IDC or fecal management system
		• Weeping edema or sacral diaphoresis
		• Pre-existing sacral PU
		
		Participant characteristics
		• 32.5% had long surgeries
			• Baseline period: daily collection of incidence of sacral, buttocks, coccyx PU over a 7 month period
			• Study period: nurses received education and practice in risk assessment and application of prophylactic dressings. In this period all admissions meeting inclusion criteria received a prophylactic silicone adhesive hydrocellular foam dressing (Allevyn®, Smith & Nephew) . Sacral dressings changed every 3rd day
				• Risk factor tool was validated by 3 WOCNs
				• Nurse evaluation of dressing qualities (ease of application, removal, wear time etc)
				• Skin assessments conducted every shift (minimum 12 hours) including a skin inspection under the dressing
					Use of dressings
					• Mean duration of sacral dressing 3.26 days (SD 3.17, range 0 to 24)
					• 71.5% had dressing in-situ for ≤ 3 days
					
					PU incidence (per 1,000 patient days)
					• Surgical coronary IC: no significant difference in PU incidence, pre 13 vs post 5.38, mean decrease 7.62, incidence rate ratio 0.41 (95% CI 0.16 to 1.09) p=0.08
					• Medical coronary ICU: no significant difference in PU incidence, pre 7.40 vs post 3.96, mean decrease 3.44, incidence rate ratio 0.54 (95% CI 0.16 to 1.78) p=0.31
					• Medical ICU: no significant difference in PU incidence, pre 6.98 vs post 3.40, mean decrease 3.58, incidence rate ratio 0.49 (95% CI 0.14 to 1.73) p=0.27
					
					Author conclusions: prophylactic dressings may decrease incidence of PU for some patients.
						• No randomization
						• Conducting risk assessments may have changed nursing behaviors
						• Other CQI activities were being conducted concurrently including wound champions and education
						• Approx 20% participants no analyzed
						• Lack of pooling of results between units
						• Dressing manufacturer donated some materials for study
						• Comparable population not demonstrated
							Level of evidence: 2
							
							Quality: Low

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 23.5% had sepsis • 65.5% extended bed rest • 41.6% aged > 65 years					
Santamaria et al., 2015a	Historically controlled cohort study evaluating effectiveness of the multi-layer soft silicone foam dressing for heels	Participants were recruited in trauma and critical care setting in Australia (n=412 probable admissions, n=357 transferred to ICU and eligible, n=302 analyzed) Inclusion criteria • all major critically ill and trauma patients admitted to ED and transferred to the ICU Exclusion criteria • under 18 years of age • pre-existing heel pressure ulcer • spinal injuries preventing repositioning Participant characteristics: • Similar patient demographics in cohorts • Longer average length of stay in ICU for patients in study group (107 hours vs 86 hours, p=0.007)	• standard preventative care included risk assessment, routine re-positioning, nutrition support, incontinence management) • Regimen for intervention group (n=150): Mepilex® Border Heel dressing (Molnlycke) applied to both heels & retained with Tubifast tubular bandage on admission to the ED, dressings partially peeled back every 24 hours for skin inspection, • Regimen for control/comparison group: preventative care only	• Skin inspection performed by research team every 24 hours • Research team members underwent inter-rater reliability testing prior to study commencement • Pressure Ulcer staging identified using the AWMA (Australian Wound Management Association) system	**Pressure injury incidence** Control 9.2% versus intervention 0%, p<0.001 Most were Category/Stage I pressure injuries **Challenges** Adhesive border tabs and margins rolled easily and were difficult to unravel during skin inspections (especially when wearing gloves) Heel dressing was difficult to maintain in position in agitated people (needed to use tubular bandage) **Author conclusions: use of prophylactic multi-layer silicone foam dressings can prevent hospital acquired pressure injuries on the heels of critically ill patients**	• More participants were discharged before first assessment in control group • Control group had been a control group for another study	**Level of evidence: 3** **Quality: High**
Richard-Denis, Thompson, & Mac-Thiong, 2017	Prospective cohort study **comparing multi-layer foam dressing applied pre-operatively to viscose polymer gel mattress for**	Participants were recruited in a level I trauma center in France (n=315) Inclusion criteria: • Aged ≥ 18 years • SCI above L1-L2 and undergoing surgery Exclusion criteria: • Pre-existing PU	**All participants** received either: • Transfer on a foam stretcher pad with a viscoelastic polymer gel (Blue Cloud™; Batrik Medical Manufacturing) mattress from arrival in surgery • Log roll mobilization every 2 hours pre-operatively	• Participants were followed from admission to discharge • Primary outcome measure was occurrence of sacral PU during acute hospitalization	**Occurrence of sacral PU during acute hospitalization** No significant difference between prophylactic dressing group and gel mattress (17.7% dressing vs 19.1% gel, p=0.77) In complete tetraplegic participants, sacral PU occurred more often in	• Participants with prophylactic dressing sometimes received a gel pad, but did not receive the gel mattress pre-operatively • Author states that individuals with the dressing may not have been repositioned as often	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	individuals with SCI	• Refusal • Discharge or death Participant characteristics • Mean age 48.6±19.3yrs • Primarily males • Mean length of stay 26 to 30 days • Approx 15-18% obese • Mean surgical delay 80-98 hours • Mean transfer delay 60 – 70 hours	• Low air loss mattress post operatively with 2 hour positioning and skin care (n=226) **Experimental group** received all of the above except received no gel mattress and instead had a • prophylactic multi-layer foam dressing applied to the sacrum pre-operatively with repositioning of dressing every 8 hours if required (n=89)		individuals with dressing vs gel mattress (82% vs 64%, p=0.009) **Severity of sacral PUs** • No significant difference between prophylactic dressing group and gel mattress (p=0.71) • Gel mattress group was the only group to have any Category/Stage III (2.5% of PU) or IV (5% of PUs) Pus	• No randomization or blinding • Groups not equivalent in size	
Kalowes, Messina, & Li, 2016	To compare differences in incidence of HAPUs between preventive care compared to a preventive care **+ foam dressing**. in critically ill patients.	Participants recruited in coronary care ICU Magnet hospital in USA (n=366) Inclusion criteria: • 18 years or above • Braden 13 points or below • intact sacral skin • Exclusion criteria: • Braden score of 14 or more • existing sacral PU • moisture-related skin damage • end-of-life or undergoing withdrawal of life-sustaining treatments	Randomized to: intervention group • Usual care (SKIN bundle) plus 5 layer soft silicone foam dressing (Mepilex® Border, Molnlycke Health Care) to the sacrum within 24 hours of admission to the ICU (n=184), or • Control/comparison group: usual care (SKIN bundle) (n=182)	• Daily skin inspection by members of the study team • NPUAP staging system • Patients remained in the study while in the ICU	**PU incidence** • Significant difference between intervention (0.7%, 95% CI 0.1 to 2.5) and control (5.9%, 95% CI 2.8 to 12.4, p=0.01) • HAPU incidence was highest among patients receiving sedation and vasopressor medications • Time to injury: intervention group had a hazard ratio of 0.12 (95%CI 0.02 to 0.98, p=0.048), intervention had an 88% reduced risk of developing a HAPU	• Power estimate needed 185 in each group. Have 182 and 184 • One site • Not blinded	**Level of evidence: 1** **Quality: high**
Miller, Sharma, Aberegg, Blasiole, & Fulton, 2015	Observational study **effect of multilayer foam dressing on interface pressure**	Health volunteers recruited via verbal and email invitations (n=50) Inclusion criteria: • Aged ≥ 18 years	• All participants applied the multilayer polyurethane foam dressing (Mepilex® Border, Molnlycke Health Care) to one heel (side randomized by coin)	Interface pressure at the heel recorded 4 minutes after lying down	**Average interface pressure** • Silicone foam dressing significantly reduced interface pressure compared to no heel dressing (p<0.001)	• Healthy volunteers • Positioning may not have been identical • Relationship between high interface pressure and PU not demonstrated in this study	**Indirect evidence (healthy volunteers)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	compared to no dressing	Characteristics: • Mean age 39.6±15.2 years • Mean BMI 26.6±5.9	• Participants lay on a viscoelastic hospital bed mattress • Participants repeated the trial with no dressing		**Factors that influenced interface pressure** • Dressing vs no dressing (p<0.001) • Weight (p=0.02)		
Walsh, Blanck et al.,2012	Case series exploring the influence of a **silicone foam dressing in reducing incidence of sacral PU**	Sample of participants recruited in a US ICU (n=62) Selection criteria included: • Cardiac arrest or vasopressors for > 48 hours • Surgery for > 8 hours • Shock, SIR, MODS • > 5 PU risk factors Participant characteristics: • Mean age 66 years • Mean Braden score 12	For participants meeting the selection criteria, a silicone border foam dressing was applied to the sacrum every 3 days while in the ICU	• Skin/dressing assessed daily • NPUAP PU staging system • Follow up period is not reported	• 4.8% of patients with the silicone border foam dressing experienced a sacral PU	• Selection of participants into study is not reported • No control group • Combination of change in interventions, therefore cannot clearly indicate outcome is associated with a dressing	**Level of evidence: 4** **Quality: low**
Santamaria, Gerdtz et al.,2013	RCT investigating the influence of a **silicone foam dressing in reducing incidence of heel and sacral PU**	Participants were recruited in an acute hospital and admitted to ICU in Australia (n=440) Inclusion: • Emergency dept. and ICU admission • Aged ≥ 18 years Exclusion: • Suspected/actual spinal injury precluding repositioning • Pre-existing sacral or heel PU • Trauma to sacrum or heels Participant characteristics: • Mean age 54 to 56 years • Primarily admitted due to critical illness • Mean stay in ED was 6 hours, mean time in OR was 4 hours, mean time in ICU 86 to 91 hours	Participants were randomized to receive: • Control group: normal PU care • Intervention group: silicone border foam dressing applied to heels (retained with net stocking) and sacrum. Dressings were applied in ED and changed every 3 days unless soiled/dislodged	• Skin assessed every 2 to 4 hours by researcher • All researchers underwent inter-rater reliability in staging PU (AWMA staging system) prior to the study commencement	• There was significantly less PUs in the intervention group (4.3% versus 17.8%, p=0.002) • There was significantly less heel PUs in the intervention group (3.1% vs 12.5%, p=0.002) • There was significantly less sacral PUs in the intervention group (1.2% versus 5.2%, p=0.05) • Number need to treat = 10	• Patients who did not have first skin assessment after dressing applied were excluded • Non-blinded assessment and analysis • Inconsistency in reporting (Table 2 reports 2 different % of PU incidence) • No confidence intervals reported • Category/Stage not reported	**Level of evidence: 1** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Mean Braden score 12					
Torra I Bou, Rueda López et al., 2009	multi-center RCT **comparing a protective bandage to a hydrocellular dressing for preventing PU**	Participants recruited from 3 long term care facilities and 3 home care programs in Spain (n=130 recruited, 111 completed trial) Inclusion: • At risk of PU according to Braden score • Able to consent Exclusion: • Existing heel PU • Diabetes • Using a preventative support surface • Using local device for offloading heel pressure Characteristics: • Groups were comparable at baseline • Mean age approx. 85 years • Primarily female participants • Mean Braden score 13.4±3 • Mean time spent in bed each day was approx. 14.5 hours, with repositioning approx. every 3 to 4 hours.	All participants treated according to the standard PU prevention care in the facilities including skin inspections and regular repositioning. Participants were randomly allocated to either: • Bandage group: protective bandage of the heel (covering ankle articulation) • Dressing group: polyurethane foam hydrocellular dressing applied to heel and fixed with a net bandage Study duration was 8 weeks	• PU development at 8 weeks determined according to skin assessments • Relative risk of developing a PU	• The dressing group had a significantly lower incidence of heel PU at 8 weeks (3.3% versus 44%, p<0.001) • Bandage group required replacement of bandages significantly more often than dressings required replacement (2.04±1.1 times/week versus 0.58±0.48 times/ week, p<0.001) • Relative risk of developing a PU was 13.42 (95% CI: 3.31 to 54.3) for the bandage group compared to the dressing group • **Study conclusions: A preventative hydrocellular dressing is associated with a lower incidence of PU in older adults at high risk compared with a non-standard protective bandaging intervention.**	• Minimal reporting of methods • Co-morbidities and risk factors not reported (e.g. nutritional status) • Protective bandaging is not considered a standard preventative strategy for heel PU therefore was not a reasonable comparison	**Level of evidence: 1 Quality: low**
(Brindle & Wegelin, 2012	RCT investigating the **effectiven**	Participants were admitted to a cardiac ICU in USA. Beds in the unit were randomised as control or intervention beds,	• Staff members in ICU were provided with education on PU prevention for 3 weeks	• Incidence of PU	• 9 Category/Stage II or greater pressure injuries developed during the course of	• Overall incidence of PU was less than expected or reported in other studies	**Level of evidence: 1 Quality:**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	ess of a silicon border foam dressing in preventing sacral PU	participants entered the group assigned to their bed (n=100 included participants, n=85 participants completed study and analysed). Inclusion: Participant considered to have high risk of PU based on: • Surgery duration >6 hours • Cardiac arrest during admission • Vasopressors > 48 hours • Presence of shock, systemic inflammatory response	prior to the study. • All participants received low air loss mattress, repositioning, hydration, dietitian referral, regular skin checks. • All participants had prophylactic dressing in place during surgery. • Participants were assigned to either: • Control group received only standard • preventative care plus a prophylactic dressing applied to sacrum (Mepilex® Border, Molnlycke Health Care)		the study. • No patient developed a pressure injury until at least 6 days after the operative procedure. • 8 pressure injuries developed in 4 participants in the control group (11.7%) versus 1 PU (2.0%) in the intervention group (p=NS between groups). • The unadjusted hazard ratio obtained was 4.4 (95% CI 0.49 to 39.4, p=0.19). • After adjustment by propensity score the hazard ratio was 3.6 (95% CI 0.32 to 40.7, p=0.30) i.e. those in standard care group experience a risk 3.6 times greater than the dressing group, but this is not significantly different. • **Study conclusions: in patients in the ICU**	• Study was insufficiently powered to test for clinical significant results • Randomisation by bed instead of participant, no blinding, no intention to treat analysis.	**moderate**
Forni, Loro et al., 2011	Historical controlled clinical trial **investigating effectiveness of polyurethane foam applied**	Participants recruited from an orthopaedic ward in Italy (n=158, 156 completed study). Study used an historical control group. Inclusion: • Orthopaedic disease requiring plaster cast on lower limb and foot, including heel	• Study group: received sterile polyurethane foam pad measuring 10 x 10 cm in contact with the skin of the heel before applying the cast (n=71). Treated 2007 to 2009. • Control group: retrospective participants with the	• Presence/absence of PU in the treated limb using NPUAP staging	**Participants with stage I PU (sore skin) as a risk** (n=56 in study group, n=49 in control group) • Significantly less participants in the experimental dressing group who presented with stage I PU	• Historical control • Length of plaster cast insitu is not reported and may be significantly different • Other management strategies (e.g. patient education) were not reported and may vary between groups	**Level of evidence: 3** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	inside a foot plaster cast for reducing device-related heel PU	• Sore skin (stage I PU) on presentation OR undergoing chemotherapy Exclusion: • Cast not including foot • PU > stage I • Not having a risk factor of sore skin or chemotherapy	same risk factors but not administered the foam prior to cast application (n=85). Treated 2005 to 2006.		experienced PU of the heel on cast removal (3.6% versus 42.9%, p < 0.0005 • The relative risk of heel PU on cast removal was 0.08 (95% CI 0.02 to 0.33) equating to a 92% (95% CI 58% to 97%) reduction in risk of a heel PU associated with the foam heel dressing. • Number needed to treat (NNT) was 3 (95% CI 2 to 4). **Participants with chemotherapy as a risk**		
Cost-effectiveness of prophylactic dressings							
Santamaria et al., 2014; Santamaria & Santamaria, 2014	Evaluate the cost-benefit of using soft silicone multilayered foam dressings in PU prevention	Sub-study of a RCT where participants were recruited in an ICU in Australia (n=440) 440 participants Inclusion: older than 18 years admitted to the ED and transferred to ICU Exclusion: pre-existing sacral or heel PUs trauma to sacral or heel areas	Participants were randomized to receive: • Standard pressure injury prevention care plus Mepilex® Border Sacrum or Mepilex® Heel was applied (,Molnlycke Health Care). Daily skin inspection by partially peeling off the dressing to visualize the skin, reapplying the bandage. Change of bandage every third day or if soiled or dislodged (n=219), or • Control: standard pressure injury prevention care, daily skin inspection	• Incidence of PU in ICU • Daily skin inspection • 4-point staging system by the Australian Wound Management Association • Cost analysis included dressing (prophylactic dressing plus tubular bandage (for heels) • Compares to costs for dressings and preventive support surfaces and nutrition management •	**Incidence** • intervention: 3.1% (n=5 of 161), control group 13.1% (n=20 of 152) **Cost of PU treatment within the trial** • Marginal cost of PU prevention was $8017.2, average cost of $36.61 per person • Total treatment cost in control group ($25173.2), intervention ($6920.2) • Average cost lower in the intervention group than in control group ($70.82 vs $144.56)	• Cost-benefit study • No societal cost of PUs • Only data from ICU stay, not from the whole trajectory • Assumes preventive care cohort has no specialized mattress or nutrition for prevention of pressure injuries	**Level of evidence: N/A economic analysis** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					Cost savings of preventing pressure injury • Annual national saving of 34 million AUD associated with using heel and sacral pressure injuries in ICU		
Inoue & Matsuda, 2015, 2016	Secondary analysis comparing **cost-effectiveness of hydrocolloid versus film dressing for preventing sacral PUs**	Non-random sample of participants in an ICU in Brazil (n=25) Inclusion criteria: • Aged ≥ 18 years • Motor or neurological limitation that reduced mobilization in bed • Admitted to ICU • Received a sacral prophylactic dressing Exclusion criteria: ICU admission ≤ 24 hour duration Participant characteristics: (did not differ significantly between groups) Mean age 67-77 years Mean APACHE II score 22.5 to 27 Mean BMI 21.48 to 25.39 Mean duration in ICU 3-5 days Mean follow up 2-3 days	• All prophylactic dressings applied by nursing team after cleaning of skin with chlorhexidine • Preventive PU care instigated for all participants • Participants received either: ○ Hydrocolloid dressing to sacral region (n=10) ○ Polyurethane transparent film prophylactic dressing to sacral region (n=15)	• Follow-up occurred at discharge from ICU or death or when PU or skin changes occurred • Efficacy calculated as number days without a PU and proportion of patients without a PU • Cost calculated as amount of product used and cost to purchase: (Brazil currency) R$15.80 for film dressing and R$68.00 for hydrocolloid dressing	**Cost effectiveness in all participants** Film dressing: cost R$347.60 (mean cost per patient of $23.17) median days without PU 7.6, cost effectiveness: R$45.74 per day without PU Hydrocolloid dressing: cost R$1,904, (mean cost per patient $190.40) median days without PU 10.9, cost effectiveness: R$174.68per day without PU **Cost effectiveness in participants who did not have a PU** Film dressing: cost R$347.60, median days without PU 80, cost effectiveness: R$28.97 per day without PU Hydrocolloid dressing: cost R$1,904, median days without PU 70, cost effectiveness: R$272.00 per day without PU **Author conclusions: Film dressing is 3.8 times (all participants) or 9.4 times (participants who did not experience PU) more cost**	• Does not state how participants were selected and included in the study • Unclear how many participants experienced a PU – mean days to PU is longer than the mean study follow-up time • Did not consider longer term PU prevention • Costs of experiencing a PU were not included • Unclear how participants were selected for each dressing – nurses may have selected dressing type based on risk assessment • Did not include foam dressing with silicone border in comparison, despite stating it was the recommended practice	**Quality: low quality analysis**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					effective than hydrocolloid dressing		
Properties of prophylactic dressings							
de Wert et al., 2016	To explore the effect of a foam dressings (multi and single layered) on improving the effect of shear on skin viability	Participants were health volunteers (n=10) Inclusion criteria: • Healthy male volunteer • Aged 20 to 30 years • BMI range 20 to 30 kg/m^2 • No active skin disease Exclusion criteria: • Diabetes mellitus • Volar forearm trauma • Muscular dystrophy • Malignancy • Non-steroidal anti-inflammatory drugs in previous 7 days Participant characteristics: • Mean age 22.5 ±1.6 years • Mean BMI 22.3 ±2.4 kg/m^2	• Application of combined loading of 2.5kPa pressure and 14.5N shear force to the volar forearm for 30 mins • One forearm received loading on skin with a foam wound dressing applied and the alternate forearm received loading without a dressing. • Three different dressings trialed on different days: ○ Mepilex® Border (Molnlycke Health Care) polyurethane foam with non-woven spreading layer and polyacrylate fibres, 3 layers of foam ○ Allevyn Adhesive - hyrocellular foam, 1 layer of foam ○ Aquacel™ Foam polyurethane foam with hydrofiber, 2 layers of foam	• IL-1α/Total Protein-ratio measured using Sebutape (used as a • measure of skin damage) Cutaneous blood cell flux measured using laser Doppler (measure of reactive hyperaemia); • Lactate concentration measured using Sebutape (measure of tissue ischemia) • Measures were taken before and after loading	**IL-1α/TP-ratio** • Significantly lower with all prophylactic dressings in place compared to control skin (p<0.01) • Mepilex was superior to Allevyn (p<0.01) • No significant difference between Mepilex and Aquacel (p>0.05) or Allevyn and Aquacel (p>0.05**)** **Cutaneous blood cell flux** • Significantly lower compared to control for the Mepilex and Aquacel (p<00.001) but Allevyn was not significantly better than no dressing • Mepilex and Aquacel were not significantly different in effect from one another, but both were superior to Allevyn (p<0.01 for Mepilex and p<0.001 for Aquacel). **Lactate concentration** No significant difference between baseline and after pressure/shear applied (P=0.07) **Author conclusions: Foam dressings can improve effects of shear on skin in healthy humans, with multilayered dressings**	• Healthy volunteers • Effect over extended time was not measured so it is not known whether this is sustained over 3-5 days (length commonly used for dressing application) • Effect in preventing PU was not measured	**Indirect evidence (PU not an outcome meaure)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					having a superior performance to single layer foam dressings.		
Bernatchez, Mengistu, Ekholm, Sanghi, & Theiss, 2015	Laboratory study **comparing coefficient of frictions (CoF) of prophylactic dressings**	The hands of two experimenters was used for the trials.	Three measurements were made: • Bare skin • Skin with No Sting Barrier Film (applied to moist skin condition) • Skin with Border Foam Dressing (applied to dry skin condition) Fabric was laminated onto a flat sliding glass using a double adhesive that prevented wrinkling Experiment was repeated with two different experimenter hands with both dry hands and moist hand (hand soaked in room temperature water for 5 mins and lightly dotted)	• Measurement of friction between two surfaces made with ForceBoard™ to compare friction between fabric representing bed linen and the skin	Both test products significantly reduced the mean CoF of skin against fabric (0.65 versus 0.45 versus 0.6, p<0.001) No Sting Barrier film mean CoF was 32.8% lower than bare skin (0.65 versus 0.45, p<0.001) Border Foam Dressing mean CoF was 8.6% lower than bare skin (0.65 versus 0.6, p<0.001) No Sting Barrier film mean CoF was significantly lower than Border Foam Dressing mean CoF (0.45 versus 0.6, p<0.001) **Conclusions: Prophylactic dressings are associated with lower coefficient of frictions than bare skin when interacting with regular cotton linen.**	• Lab study • Only two different experimental hands • Study conditions were not representative of real-life because linen was forced into non-wrinkle state • Reliability and validity of measurement strategy not reported	**Indirect evidence: PU not an outcome measure**
Matsuzaki & Kishi, 2015	Laboratory study **investigating the effects of pressure reduction using dressing materials with various structural characteristics**	Ten dressings were trialed: • ALLEVYN Non-Adhesive polyurethane foam • ALLEVYN Adhesive • ALLEVYN Gentle Border • Mepilex Border • Biatain Silicone • TIELLE • Versiva XC • DuoDERM CGF • DuoDERM Extra Thin CGF	• Portable interface pressure sensor was placed in the center of a high-resilience urethane foam that simulated a mattress. • A dressing was placed central to sensor pad. • A cone-shaped container • was used to simulate the sacral bony prominence, placed so that its vertex	Pressure was expressed as mean ± standard deviation (mmHg)	• All dressings had significantly lower pressure measure than control state • mmHg readings for each dressing: ○ Control 74.667 ± 1.405 ○ ALLEVYN Non-Adhesive polyurethane foam 35.833 ± 1.155 ○ ALLEVYN Adhesive 44.233 ± 0.777	• All dressings were in a dry state and would not represent an exuding wound state • Reliability and validity of measurement strategy not reported • Measurement strategy does not account for different patient anatomical shapes and anthropometrics that may	**Indirect evidence: PU not an outcome measure**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Melolin	was in the center of the dressing. • A 2 kg weight was placed in centre of cone shaped container.		○ ALLEVYN Gentle Border 46.967 ± 1.537 ○ Mepilex Border 53.867 ± 0.231 ○ Biatain Silicone 56.000 ± 0.520 ○ TIELLE 57.267 ± 3.403 ○ Versiva XC 65.900 ± 0.800 ○ DuoDERM CGF 57.267 ± 1.007 ○ DuoDERM Extra Thin CGF 66.867 ± 1.060 • Melolin 53.433 ± 1.973 Pairwise comparisons were made between different dressings	influence pressure reducing effect	
Levy & Gefen, 2016	Computer simulations to explore shear stress with and without a multilayered foam dressing	Finite models (n=20) of heels 20 finite element models representing diabetic tissue and healthy tissue in different foot postures (neutral, 10° and 30°) were developed	• Support surface was modeled on flat elastic foam • Dressing was modelled as 3 layers (airlaid, nonwoven and polyurethane foam) • Models were exposed to loads designed to replicate the calcaneus bone against a flat support surface during supine position.		• Peak effective strains were found at the bone-fat interface in all the model variants and these were shifted distally with an increase in plantar flexion • Peak effective strains in the soft tissues of the heel decreased in presence of the dressing in healthy models (by 14.8%) and for diabetic models (by 13.5%) • Effect of prophylactic dressing is a cushioning effect that persists over time **Author conclusions: Prophylactic dressings provide a cushioning effect**	• Computational modeling • Accuracy of modeling is hard to evaluate; however authors have high standing in the field and the paper is peer reviewed	**Indirect evidence (computer modelling)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					to heel soft tissues heel, and also temper deformations from the tissues by deforming internally themselves in shear mode thereby lowering exposure to strains and stresses		
Levy, Schwartz, & Gefen, 2017	To explore modes of action and **biomechanical efficacy of prophylactic dressings in protecting the the sacrum** .	Six finite element (FE) model variants representing diabetic tissue conditions and an additional six model variants of comparable healthy tissue cases. • Multiple three-dimensional anatomically detailed finite element (FE) model variants representing diabetic tissue conditions were used, and tissue loading state data were compared with healthy tissue simulations.	• Comparison of soft tissue exposures to elevate internal shear stresses and strain energy densities (SED) near sacrum during supine weight bearing on a standard (foam) hospital mattress ○ without a dressing ○ with a prophylactic dressing lacking directional stiffness preferences and ○ with an anisotropic dressing	Body loads and shear and friction conditions in tissue was simulated of the weight-bearing sacrum during supine bed rest or in 45 degree Fowler's position, without a dressing, with a (hypothetical) isotropic, multilayer dressing or with the anisotropic Mepilex® Border Sacrum (MBS) dressing. A total reaction force of 40N (roughly 7% of the total bodyweight of the subject) was used.	• The peak stress in healthy and diabetic tissues was reduced by approximately 24% and 27·5%, respectively, when using the five layered foam border dressing • The percent of reduction in soft tissue exposures to strain energy density (SED), was larger with the multilayer dressing in comparison to the isotropic (theoretical) multilayer dressing and under pure compression loading and combined compression and shear loading, with diabetic tissue conditions. **The authors conclude that multilayered prophylactic sacral dressings are effective in reducing exposure to**	• Modeling built on assumptions based from one individual • The assumptions of diabetic stiffness does not reflect the heterogeneous variations in tissue stiffness existing in reality	**Indirect evidence (computer modelling)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					sustained soft tissue deformations and stresses near sacrum, particularly in diabetic tissues		
Clinical question 4: Are continence management strategies effective in preventing and treating pressure injuries?							
Structured skin care regimen							
Bateman & Roberts, 2013	Case series exploring **skin care regimens to promote healing of moisture lesions, including those combined with PUs**	A sample of participants was recruited by unreported methods in a UK Health Trust (n=20) Inclusion and exclusion criteria: Not stated Participant characteristics: • 85% medium risk of PU based on Braden scale • 15% high risk of PU based on Braden scale • 65% high risk of malnutrition • Age range 38 to 86	Interventions were selected based on assessment of the skin integrity and included: • Erythema (n=3): shower/wash, foam cleansing spray, barrier cream, incontinence pad, fecal incontinence system if more than three episodes of Bristol Stool Type 6 or 7 • Moisture lesion (n=10): shower/wash, foam cleansing spray, non-stick tacky barrier spray, polyurethane foam prophylactic dressing, fecal incontinence system if more than three episodes of Bristol Stool Type 6 or 7 • Combined erythema/moisture (n=7): shower/wash, foam cleansing spray, barrier spray, polyurethane foam prophylactic dressing, fecal incontinence system if more than three episodes of Bristol Stool Type 6 or 7	• An adapted version of the EPUAP classification tool using the classification healthy, erythema, moisture lesion or PU • Observed for 3 to 28 days	**Skin integrity** After between 3 to 28 days, 80% of individuals had skin classified as healed and 20% had skin classified as healing	• Poorly defined outcome measures, method of assessment and follow-up period • Non-blinded study with no direct comparator group • Combined interventions prevents meaningful evaluation of any single component of the management regimen • Unclear which individuals healed (i.e. may not have been those with PU) • Selection criteria for participants is not reported	**Level of evidence: 4** **Quality: Low**
Park & Kim, 2014	Quasi-experiment investigating	• Participants were recruited in 5 ICUs in Korea (n=76)	• Intervention cohort (n=38): Structured skin care protocol consisting of: skin	• Severity of IAD • PU development 7 days	**Pressure injury incidence** • There was a significantly lower incidence of	• Different type of ICU compared which may	**Level of evidence: 2** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
	effect of a **structured skin care regimen on pressure injury incidence**	Inclusion criteria: • Fecal incontinence with • Bristol • Exclusion criteria: • Non noted Participant characteristics: • Mean age 68 years • 67% over 65 years • Braden scores all below 13 • 60.5% had Bristol stool form 7	assessment on admission and on repositioning using Braden score, special skin assessment for people with deteriorating skin condition, frequent linen change, use of incontinence pads, no massage, no repositioning on erythema, mild washing with minimal friction using wet tissue cloth, perineal cleanse with foaming cleanser, moisturized applied 2-3 minutes after bathing, avoid high humectant moisturizer, moisture barrier, Anal Plug (Coloplast) for patients with Bristol stool type 5 and 6, FlexiSeal® (Convatec) for patients with Bristol stool type 7, skin protectant on mild skin erosion, fungal agent for skin candidiasis, avoid hydrocolloid paste with border foam dressing if erosion with exudate present • Control ICUs (n=38): standard care	• Nurses on wards conducted the assessment	pressure injury in skin protocol group vs standard care (13.2% vs 50%, X^2=11.936, p=0.001) • Multivariate analysis: patients with higher IAD score had a higher likelihood to develop pressure injuries (OR=1.168 (95% CI 1.074 to 1.271) **IAD** • Reduced severity of IAD in the structured skin care group compared to standard skin care (5.19±3.14 vs 14.13±11.7, p <.001) **Author conclusion: Structured skin care protocol decreased pressure injuries and IAD**	have an impact of comparability • No blinded outcome assessment • Unclear control protocol	
Cooper & Gray, 2001	RCT comparing soap and water to a foam cleanser for preventing PU	Participants were randomly selected at 5 nursing home and a hospital sites providing long term care. Inclusion criteria: • Some form of incontinence or catheterization • Consenting	Randomized to: • standard hospital soap and water: 1% aqueous solution with a pH of 9.5-10.5 (n=49) or • foam no-rinse cleanser: combination of emollient, water-repellant deodorant and water-	Skin assessed using Stirling Pressure Severity Scale and classified as: • broken skin (Category/Stage II pressure ulcer or above) • erythematous (Category/Stage I pressure ulcer) or	• Skin condition maintained or improved for more participants receiving the cleanser compared with the soap and water (66% versus 37%, p = 0.05) • Participants classified with healthy skin at	• No blinding • Mean LOS was significantly different between groups, but skin condition was similar between groups at commencement • No analysis per facility • Potential that participants did not receive care to	**Level of evidence: 1 Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		Characteristics: • Average age 79 to 85 tears • Mean length of stay between 0.38 yrs (soap group) and 1.72 years (foam cleanser group).	repellant barrier with a pH of 5.5 (n=44)	• healthy (no alterations to skin integrity) Follow up 14 days.	commencement experienced more erythema (30.3% versus 15.1%) and more broken skin (12.1% versus 0%) when using soap and water	which they were assigned at one facility • Unclear if participants were similar with respect to comorbidities and nutrition.	
Incontinence Pads							
Williamson, Lachenbruch, & VanGilder, 2013	Observational laboratory study to determine the effect of adding incontinence pads and sheet layers on a therapeutic low-air-loss (LAL) surface	One healthy 61-year-old woman	LAL suface performance was assessed in tow ways: A sweating guarded hot plate (SGHP) was used to quantitatively measure total heat withdrawl capacity and evaporative capacity of nine variety of linen and pad configurations in the sacral region of a LAL suface. A participant lay on her back for three hours on two different linen surfaces per time.	• Evaporation was measured with a SGHP method (ST-2 Comfort Test System). A fitted sheet only was used for comparison. • Skin temperature was measured using IR camera. A IR image was taken of the buttocks immediately after the woman was rolled to her side after 3 hour	**Outcome 1** All combinations that included plastic-containing underpads significantly reduced the surface's ability to dissipate heat and evaporate moisture ($p < 0.05$) **Outcome 2** Use of the maximum number of layers (nine) reduced heat withdrawal to the level of a static, non-LAL surface. **Author conclusion: Putting additional linens or under-pads on LAL surfaces may adversely affect skin temperature and moisture, and reduce the pressure injury prevention potential of surfaces.**	• Laboratory work • Only one participant • PU not an outcome measure	**Level of evidence: 5** **Quality: Low**
Teerawattananon et al., 2015	Cohort study **exploring effectiveness of diapers in reducing PUs and PU risk**	Convenience sample recruited at two rehabilitation centers in Thailand (n=90, n=71 assessed at week 10) Inclusion criteria: • Age ≥ 15 years	• Participants were provided with the highest quality (based on water absorption capacity) adult disposable diapers on individualized needs base	• Primary outcome measure was HRQOL • Secondary outcome measures were development of PU measured by clinical observation and change	**Development of PU** No significant difference in risk that PU present in week 2 Risk of having a PU was lower in week 6 (risk decreased 58%, 95% CI 8 to	• No control group or blinding • Not reported if PUs were present at baseline, and it was not an exclusion criteria	**Level of evidence: 3** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Incontinence for ≥1 month or urine leakage despite indwelling catheter (IDC) • No previous use of adult diapers • No cognitive impairment Exclusion criteria: • Severely ill Participant characteristics: • Mean age 49.13 years (SD 21.19) • 30% had experienced a previous PU • 60% had dual incontinence, 38% urinary incontinence only and 2% fecal incontinence only • 46% had SCI, 20% had CVA • Mean Braden scale score 15.15 (SD 2.95)	of 3-6 diapers per day for 10 weeks	in risk of PU measured on Braden scale • Outcome measures were assessed at baseline, week 2, week 6 and week 10	75%) and week 10 (risk decreased 67%, 95% CI 16 to 78%) **Change in risk of PU measured on Braden scale** No significant difference in Braden score from baseline at weeks 2 (mean difference 0.27, 95% CI –0.31 to 0.85) or week 10 (mean difference 0.19, 95% CI –0.42 to 0.79) **Author conclusions: Diapers were associated with increased HRQOL and functional ADLs while not being associated with development of PU. The risk of sustaining a PU was not significantly changed by use of diapers; however the cost was not sustainable in the setting.**		
Francis, ManPang, Cohen, Salter, & Homel, 2017	To determine difference in **hospital acquired pressure injuries and incontinence associated dermatitis (IAD) using disposable v. reusable underpads**	• Participants were recruited in four medical surgical units in USA (n=462) Inclusion Criteria: • all fecal and/or urinary incontinent adults admitted to 4 selected med/surg units • patients with heel ulcers • IAD present on admission • Exclusion Criteria: • patients with 3 or more pressure injuries on the	Participants were randomized to receive either: • Intervention: disposable waterproof underpads with super absorbent material and breathable backing for use up to 300 pounds (n=210) • Control: reusabe quilted, moderately absorptive underpad with waterproof polyvinyl chloride backing (n=252)	measurements by skin care champions educated through orientation program, 4 hour teaching module, bimonthly education sessions and education in differentiation between IAD and pressure injuries, and in data collection procedures - data submitted weekly and verified by WOC nurses - cluster randomization procedure used for patient allocation to units	**Pressure injury incidence** - Patients with disposable underpads had a lower rate of hospital acquired pressure injury occurrence (reusable 11.5% versus disposable 4.8%, p=0.02) **IAD incidence** no significant difference in IAD occurrence between groups **Use of disposable underpads reduced**	- form used to collect data on IAD and pressure injures on admission was not validated -	**Level of evidence: 1** **Quality: Low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		sacrum, buttocks, hips or ischial areas Participant characteristics: • Mean age 78-80 years • Many differences existed between groups for the use of the following: indwelling urinary catheters, fecal incontinence devices, external urinary devices, toileting programs • Intervention group had significantly fewer pressure injuries on admission (44% vs 33%, p=0.03)		- Statistical Package for the Social Sciences software for descriptive and univariate analysis - SAS version 9.4 for hierarchical analysis based on cluster randomization Staging system used - NPUAP	**hospital acquired pressure injury occurrence**		
Fecal incontinence management							
Su et al., 2015	RCT comparing a suspension positioning continence device with standard **fecal incontinence management** for reducing PUs in neurological impaired individuals	Participants were recruited in an acute care hospital in China (n=200) Inclusion criteria: • Neurogenic fecal incontinence • Aged 60 years • Conscious and alert with a stable neurological disorder • More than 8 bowel movements per day and single stool volume of 80 to 15oml • Bed bound Exclusion criteria: • Chronic neurological condition • Dementia	• All participants received timely skin care and linen changes, regular perianal cleansing with warm sterile water, disposable incontinence pads, increased fluid intake • Participants were randomized to receive: ○ Suspension positioning system (SPS) consisting of a suspension device similar to a suspension traction system with cushioned belts held on a frame to elevate perianal area 45° to 60° and used from 8am to 8pm daily (n=100)	• Fecal incontinence severity using Park's incontinence score • Bristol stool scale • Shea PU classification • 36-item Short Form (SF-36) Health Survey • Follow up was at 6 months	**PU incidence** • The experimental group had significantly less of any level of skin break down compared with normal continence care group (11% versus 39%, p<0.001) • The experimental group had significantly less Grade I PU compared with normal continence care group (6% versus 23%, p=0.001) • The experimental group had no significant difference for Grade II PU (0% versus 11%, p=0.191) or for Grade III	• Non blinded study • Skin assessment was not reported in detail but appeared to be performed after hygiene • Reduction in pressure from positioning may have contributed to outcome	**Level of evidence: 1** **Quality: High**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• Unconscious or serious cerebral, cardiopulmonary or liver disease • Gastrointestinal infection • Fecal obstruction Participant characteristics: • Mean age 69 years • No significant difference in groups for BMI, neurological condition, stool type or stool frequency	○ Routine continence care: increased dietary fiber, health education, social and psychological support (n=100)		PU (0% versus 5%, p=0.06) **Other outcomes** • Experimental group required less care time (p<0.001), less consumable costs (p<0.001) and shorter hospital stays (p<0.001) • Experimental group had significantly better scores on all items on SF-36 (p<0.01 to p<0.001)		
Whiteley, Sinclair, Lyons, & Riccardi, 2014	A retrospective observation study **exploring the use of fecal management systems in acute care**	Participants were recruited in an acute care, non-ICU over a seven year period in New Zealand (n=50) Inclusion criteria: • Fecal management system had been inserted to manage acute diarrhea, burns, pressure ulcers or necrotizing fasciitis • Aged ≥ 18 years • Normal rectal examination • Immobile Exclusion criteria: • Chronic diarrhea or fecal impaction • Rectal inflammation, anal stricture • Colorectal surgery • Allergies to silicone • Ambulant • Participant characteristics: • Mean age 63 years (range 21 to 90)	• Individuals were examined medically before use of system • All individuals were managed with a Convatec Flexi-Seal® Fecal Management System	• Adverse events associated with fecal management system	**Duration of use** • Mean duration of use for fecal management system was 17.4 days (range 1 to 74) • 86% of individuals with PI used the fecal management system for 17 days or more • Individuals with a PI required the fecal management system for significant longer than those with acute diarrhea (p=0.007) **Adverse events** • 74% of individuals had no adverse events • 14% over-inflation of rectal balloon • 8% anal atony occurred • 4% excessive leaks • Complication rate was significantly greater for individuals using system	• Relies on retrospective data • Small sample size with limited diagnoses so hard to compare outcomes for PU patients to other types of patients • Does not compare complications with and without a fecal management system, or healing rates	**Indirect evidence (reports complications from fecal management systems, not PU outcomes)**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		• 62% had acute diarrhea • 14% had PIs • 20% had burns • 4% had necrotizing fasciitis			for 17 days or more versus less than 17 days (44% versus 15%, p=0.024) **Author conclusions: Although complications are low, individuals with a PI are at greater risk of complications from fecal management system because their condition generally requires longer use of the system**		
Pittman, Beeson, Terry, Kessler, & Kirk, 2012	RCT comparing three **bowel management programs** for preventing development of PU	Participants were recruited from a critical care unit (n=56) (n=59 for analysis) Inclusion: aged >17 years incontinent of at least 2 stools/24 hours no contraindications to internal bowel management devices Characteristics: 60% of sample was female mean age 59.9 ± 12 years mean BMI 33.2 mean baseline IAD score 11.7 ± 10.1 BMS group had significantly lower Braden score at baseline 18/56 participants had a PU at entry	Participants were randomized to: a) Bowel management system (BMS) catheter (n=21) b) Rectal trumpet (RT) utilized as a rectal fecal incontinence device (n=20) c) Usual care consisting of barrier creams and/or a fecal pouch collector (n=18)	Skin status measured using Incontinence Associated Dermatitis and Its Severity Instrument (IAD score) PU measured using NPUAP staging Clinician satisfaction (measured using a Likert survey) Follow up was until device failure (>3 stools incontinence/24 hours, complications or discharge from critical care)	• Three PUs developed during the study and three resolved during the study, but it was not reported to which groups these participants were assigned. • There was no significant difference between the groups on the presence of PUs at any time in the study (BMS 42.9% vs RT 35% vs usual care 27.8%, p=0.63). • Clinicians preferred the RT (82%) over the BMS (78%) and usual care (0%). • Usual care group experienced greatest reduction in IAD. • Withdrawal from the study due to complications (including rectal bleeding) or failure of device was higher in RT group.	• Insufficient participants to meet power calculation • Most participants had short entry period in the study • Some participants (n=3) enrolled in the study twice • Mean duration in study ranged from 2 days to 60 days.	**Level of evidence: 1** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					• **Conclusions: use of a BMS or RT was not associated with a significant decrease in PUs, but was preferred by clinical staff**		
Clinical question 5: Are low friction or microclimate control fabrics effective for preventing pressure injuries?							
Richardson, Peart, Wright, & McCullagh, 2017	Cohort study comparing silk like fabric to standard linen for preventing pressure injuries	Participants were two cohorts of individuals in two ICU in US (n=2153 prior to intervention vs n=1647 post intervention) Inclusions: All admissions to the units (9 months of admissions for each cohort) Characteristics: • Mean age 60.42 years (range 18-101) • Mean ICU of stay 4.66 (SD 7.05) days (range 1-125) • 1.8% had very high Braden risk, 14.8% had high Braden risk 17.7% had moderate risk, 39.4% had mild risk and 26.3% had low risk • Hospital length od stay was significantly short in second cohort (p<0.001) but not the ICU length of stay	Cohort with usual care: Cotton blend linen Blue pads with plastic backing (no backing for specialty beds) Cohort with intervention: • Education and operational plan • Incorporated plans for storage, collection and laundering of linen • Synthetic silk like linen (DermaTherapy) • Staff and family education • Techniques for bed making and using chairs • Tips included placing a bath blanket under the sheet on the chair to prevent slippage and raising the knee of the bed to prevent sliding	• Unit acquired pressure injuries • Unit acquired posterior pressure injuries	**Pressure injury incidence (unit acquired)** • Overall 6.6% (not different between the two units) • Significant decline over time associated with interventions (7.71% vs 5.26%, p=0.002) **Posterior pressure injury incidence** • Overall 4.14% (not different between the two units) • Significant decline over time associated with interventions (5.25% vs 2.82%, p<0.001) **Cost saving** • $3 929 312 (US 2015) based on reduction in hospital length of stay by preventing a pressure injury • Specialty linen cost $50/set vs $22/set	• Relied on medical records • Methods of identifying and assessing pressure injuries not stated • Unclear when or how often skin inspections performed or if this was blinded • Participants primarily had mild -low risk of pressure injuries • Authors suggest microclimate was affected, but there was no measure of microclimate features • Does not report a full cost analysis breaking down costs of care	**Level of evidence: 3** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					for cotton blend • Specialty linen lasts 3 times longer		
Twersky et al., 2012	RCT comparing silk like fabric compared to cotton/polyester bedding	Participants were recruited in a nursing home in US (n=46) Inclusion: Expected stay in facility >30 days Characteristics: • Median age 72.7 years (range 54 to 95) in intervention and 69.5 (range 51 to 91) in control group • No significant differences between groups	Participants were randomized to: • Intervention: silk-like textile bed sheets, reusable bed pads, and pillowcases (Derma Therapy®, Precision Fabrics Group, Inc, Greensboro, NC) plus adult incontinence briefs • Custom sheets for specialized beds (n=26, n=13 completed) Control: usual care textiles were a plain-weave textile fabric and a different incontinence brief (n=20)	• New pressure injuries with weekly skin assessment • Falls • Follow up 20 weeks	**Pressure injury incidence** Significantly fewer in intervention group (6 versus 20, hazard ratio 0.31, 95% CI 0.12 to 0.78) Category Stage II or greater pressure injuries (hazard ratio 0.23, 95% CI 0.078 to 0.69, p=0.0084) **Adverse events** No significant difference Falls from bed not significantly different (4 versus 5, p=0.76)	• Non blinded outcome measurement • 19% of intervention group and 15% of control group participants withdrew •	**Level of evidence: 1** **Quality: moderate**
Smith & Ingram, 2010	Cohort comparative study **investigating effectiveness of low friction fabrics in preventing PU**	Participants were recruited from 2 medical wards and an orthopaedic ward in a UK hospital (n=650 reviews, n=204 included cases and n=165 controls) Inclusion: • Waterlow score ≥15 (high or very high risk of PU) • Unable to reposition independently • With or without PU Exclusion: • Waterlow <15 • PU in location other than	Participants were in two consecutive cohorts. All patients were cared for on pressure relieving mattresses. All care and nutrition was identical except: • Cohort 1: regular hospital garments (n=204 included cases) • cohort 2 participants at high risk of sacrum or heel/ankle breakdown wore the low friction fabric Parafricta®	• PU incidence and grading (scale not reported) • PU outcome at discharge reported as deteriorating, the same or improving.	• From participants who had no PU on admission, the incidence of hospital- acquired PU was significantly less in cohort 2 (25% versus 41%, 16% difference, p=0.02) • From participants who had a PU on admission, there was no difference in the incidence of hospital acquired PU (17% in cohort 2 versus 26% in cohort 1, p=0.184)	• Demographics of participants not reported so comparison is unknown • Prevalence of PU in each cohort was determined by auditing approx. 20% of cases. • No blinding • Drop out rate, number of participants in his cohort at commencement were not reported • Wound management was not reported	**Level of evidence: 3** **Quality: low**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
		sacrum or heel Characteristics: • Demographics (e.g. age, morbidity) not reproted	undergarments or bootees (n=165 included cases)		• From participants admitted with PU, there was a lower rate of PU deterioration in cohort 2 (6% versus 27%, 21% difference, p=0.001) • Cost-effective model suggested 63,000 pound per 100 at-risk patients • **Study conclusions: The use of low friction garments was associated with a reduced incidence of PU in patients presenting without a PU who had a high risk. In patients who did acquire a PU, the low friction undergarments were associated with fewer PUs deteriorating in condition.**		
Smith, McNichol et al., 2013	Retrospe ctive cohort study (record review)	Participants were recruited from telemetry, urology and ICU in a US hospital. control time period (n= 659) intervention time period (n= 768) Inclusion: • Admitted or transferred to the study units during the study period	• All participants received the same standard pressure ulcer care including daily skin assessment, incontinence management, regular repositioning, nutritional management and moist wound healing strategies for existing PU • Intervention group received a silk like fabric	• Record review to determine development of Stage I to IV PU during the 3 month time frame for each group	• The control group experienced significantly greater Stage I PUs than the intervention group (5.6% versus 2.3%, p<0.001) • The control group experienced significantly greater Stage II or greater PUs (5.95 versus 0.8%, p<0.001).	• Record review relies on accurate documentation	**Level of evidence: 3 Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
			for bedding and gowns				
Coladonato, Smith et al., 2012	Prospective, non-randomized controlled trial investigating **the effectiveness of silk-like fabrics in preventing PU**	Participants were recruited in a medical renal unit (n=307) and a surgical ICU (n=275) Inclusion: • Admitted to the unit for a minimum of 2 consecutive days • Not nursed on a pressure-relieving surface or bariatric bed Exclusion: • Hospital stay overlapped the control and intervention periods Medical renal unit characteristics: • No significant difference in weight, age (mean approx. 63 yrs), albumin levels, Braden scores (mean approx. 17) or PU on admission (13.6% control, 17% intervention). • Intervention group had lower prevalence of anaemia (51% versus 65.6%, p=0.005), higher prevalence of drugs/alcohol use	• All participants received standard pressure care including repositioning, nutritional management, moist wound dressings and continence management. • Control period: In both units there was an 8 week control period, with all participants nursed on cotton-blend linen. Control period was repeated after the intervention period. • Intervention period: An 8 week intervention period in which silk-like linen was used was introduced after the control period. • In the surgical ICU in the control period, participants assessed as having early signs of a PU were nursed directly on a mattress overlay without sheeting.	Primary endpoint was the development of a new PU	**Medical Renal Unit** • Incidence of new PUs was significantly less in the intervention period (4.6% versus 12.3%, p=0.01) • Average length of stay was significantly shorter in the intervention period (5.31 days versus 5.97 days, p=0.07) • 36.8% fewer participants were discharged with a PU during the intervention period (p=0.05) **Surgical ICU** • Incidence of new PUs significantly lower in the intervention period (0% versus 7.5%, p=0.01) • Average length of stay was not significantly different (4.33 days in intervention period versus 4.5 days in the control period, p=0.33) • **Study conclusions: the silk-like linen was associated with a**	• Intervention items were easily distinguishable from the control (i.e. no blinding) • No randomization	**Level of evidence: 2** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					lower incidence of PU in medical and surgical units compared with cotton-blend linen. Hospital stays were shorter for medical		
Yusuf, Okuwa et al., 2013	Prospective cohort study **investigating the relationship between PU development and microclimate**	Participants were recruited in an Indonesian hospital (n=86, 71 completed study) Inclusion: • Braden score of 18 or lower • Aged ≥ 18 years • No history of PU Exclusion: • Pain, pre-existing PU or skin maceration • Critical health condition	• Standard care in the facility. Influences on microclimate and pressure ulcer prevention: ○ Dry season in Indonesia (high humidity) ○ Average room temperature 30°C ○ Foam mattress with synthetic fiber or 100% cotton sheets	• Microclimate measured at the sacrum and periumbilicum (skin temperature, skin moisture (only from 8am until midnight) • Room temperature • Daily skin inspections and EPUAP staging • Observations by a single observer	• 28% participants developed PU or superficial skin changes, primarily Stage II PU • There was no significant difference in skin temperature at the sacrum between those who did and did not develop PU (p=0.07) • Multivariate analysis found the type of sheet (cotton versus synthetic fiber) and total Braden score were significant factors in the development of PU ○ Sheet (more likely with cotton sheets): p=0.053, OR 0.11, 95% CI 0.012 to 1.032 ○ Braden score: p=0.00, OR 0.347, 95% CI 0.206 to 0.585 • **Study conclusions: Although the authors conclude that skin temperature could be used to detect**	• High humidity of ward environment decreases reliability of skin temperature measures • Exclusion criteria were not established apriori • No randomization (unclear how many patients received synthetic sheets) • Non-blinded	**Level of evidence: 3** **Quality: moderate**

Ref	Type of Study	Sample	Intervention(s)	Outcome Measures & Length of Follow-up	Results	Limitations and comments	
					increased risk of PU in patients with dark skin tones, the temperature of skin was not significant in development of PU. The		

APPRAISALS

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

QUASI EXPERIMENTAL STUDIES

	Author/year	Focussed question	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measurement	Per cent drop out in study arms is reported and acceptable	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
11035	Byrne et al., 2016	Y	N	U	N	Y	N	N	Y	N	Y	2	low
9806	Teerawattananon et al., 2015	Y	N	N/A	N/A	Y	Y	N	U	N	U	3	low
7029	T. S. d. Souza, M. T. Reichembach Danski, D. A. Johann, L. S. Marques De Lazzari, & P. Mingorance, 2013	Y	N	Y	Y	Y	N/A	Y	N/A	N	U	2	low
16681	Yoshimura et al., 2016	Y	N	Y	Y	U	Y	Y	NA	Y	Y	2	High
2951	Park, 2014a	Y	N	Y	Y	Y	Y	Y	NA	Y	Y	2	High
6368	Park, 2014b	Y	N	Y	Y	Y	y	y	NA	Y	Y	2	High
3103	Park & Kim, 2014	Y	N	Y	U	U	N	U	NA	N	Y	2	Low

RCTS

Endnote ID	Author/year	Focussed question	Assignment randomised	Adequate concealment method	Subjects and investigators blinded	Groups comparable at commencement	Only difference btw groups was treatment	Valid, reliable outcome measure	% drop out in study arms is reported and acceptable	Intention to treat analysis	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
8107	Lupianez-Perez et al., 2015	Y	Y	Y	U	Y	Y	U	Y	Y	N/A	U	N	1	low
8397	Dutra et al., 2015	Y	Y	Y	N	N	Y	Y	U	U	NA	Y	N	1	low
8955	Su et al., 2015	Y	Y	U	N	Y	Y	U	Y	Y	NA	Y	Y	1	high
14802	Walker et al., 2017	Y	Y	Y	N	Y	U	U	Y	Y	NA	Y	N	1	low
16046	Francis et al., 2017	Y	Y	U	N	N	N	Y	U	Y	NA	Y	N	1	Low
16206	Kalowes et al., 2016	Y	Y	Y	N	Y	Y	Y	Y	Y	NA	Y	Y	1	High
16782	Aloweni et al., 2017	Y	U	N	N	Y	Y	Y	N	Y	NA	Y	Y	1	Moderate
	Santamaria, Gerdtz, Kapp, Wilson, & Gefen, 2018	Y	N	N	N	Y	U	Y	Y	N	NA	Y	Y	1	Low

CASE SERIES

	Author/year	Focussed question	Participant characteristics reported	Inclusion criteria defined	Consecutive recruitment	Participants entered at same disease stage	Intervention clearly reported	Outcomes relevant and defined apriori	Valid, reliable outcome measurement	Per cent drop out reported and acceptable	Estimates of random variability	Comparable results for multiple sites	Minimal bias	Reliable conclusions	Level of evidence	Quality
1309	Bateman & Roberts, 2013	Y	N	N	U	U	Y	N	N	NA	N	U	N	N	4	Low

ECONOMIC EVALUATIONS

	Author/year	Focussed question	Economic importance of question is clear	Choice of study design is justified	All costs are included and measured and valued appropriately	Outcome measures to answer study question are relevant and measured and valued appropriately	Discounting of future costs and outcome measures is performed correctly when appropriate	Assumptions explicit and a sensitivity analysis conducted	Results provide information relevant for policy providers	Minimal bias	Reliable conclusions	Level of evidence	Quality
12067	Inoue & Matsuda, 2015	Y	Y	N	N	U	N	N	N	N	N	N/A	Low
3165	Santamaria et al., 2014; Santamaria & Santamaria, 2014	Y	Y	Y	Y	Y	NA	Y	Y	Y	Y	N/A	High
14724	Padula, 2017	Y	Y	Y	U	Y	NA	N	Y	U	Y	NA	Low

COHORT STUDIES

	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	Minimal bias	Reliable conclusions	Level of evidence	Quality
14316	Richard-Denis et al., 2017	Y	Y	Y	U	N	U	Y	N	Y	Y	Y	N	Y	N	3	Low
9806	Teerawattananon et al., 2015	Y	NA	N	N	N	NA	Y	N	Y	Y	Y	Y	Y	Y	3	Moderate
14725	Padula, 2017	Y	Y	N	N	NA	NA	Y	N	Y	U	N	N	Y	Y	3	Low
8189	Santamaria et al., 2015b	Y	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	N	Y	Y	3	High
1453	Cubit et al., 2013	Y	Y	Y	Y	N	N	Y	N	Y	Y	N	N	Y	N	3	Low
15159	Freeman et al., 2017	Y	Y	Y	N	NA	NA	Y	U	U	U	N	N	Y	Y	3	Low

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 included studies[6]	Risk of bias assessed[7]	Source of funding reported[8]	Appropriate meta-analysis including weighting and adjustment for heterogeneity	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
12114	Huang et al., 2015				Y			N		Y		N		Y	N	N	Exclude
2854	Clark et al., 2014				Y			N		N		N		N	N		Exclude
16794	Beeson, Eifrid, Pike, & Pittman, 2017				Y			N		N		N		N	N		Exclude

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