Appendix Table H11. Key Questions 3 and 4: data extraction of support surfaces trials

| **Author, Year Notes About Study Design, Publication Status** | **Setting Country** | **Eligibility Criteria and Exclusions** | **Patient Followup** | **Number Screened/ Enrolled/ Analyzed** | **Withdrawals** | **Loss to Followup** | **Intervention (Ns)** | **Baseline Demographics (Age, Percent Women, Race, etc.), p value** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Andersen, 198254 | Acute care Denmark | Patients at risk of pressure ulcer development using a simple risk score system, without existing sores | 10 days | 3,571/600/482 | 118 (prior to randomization); ~35% became ineligible during the course of the study | None | A. Alternating-air pressure mattress (n=166) B. Water mattress (camping mattress filled with lukewarm water) (n=155) C. Ordinary hospital mattress (n=166) | Mean age: NR (age reported by ranges within groups, majority >60 years) % Female: 63% vs. 56% vs. 53% |
| Aronovitch, 199955 Quasi-randomized trial (comparative, parallel study with weekly randomization) | Surgical units (cardiothoracic, ENT, urology, and vascular surgery) United States | Patients >18 years of age undergoing a scheduled surgery with general anesthesia for at least 4 hours (actual operative time of >3 hours). Excluded patients if they participated in a clinical trial within 30 days of baseline visit or if they had a pressure ulcer at baseline visit (n=4 patients excluded because they were discharged home before postop day 4). Patients removed from study if they requested discontinuation, experienced adverse event that precluded continued treatment, or if investigator felt it was not in the best interest of the patient to continue in the study | 7 days or until discharge (median NR) | NR/234/217 | None | None | A. Alternating pressure system intra and postoperatively (Micropulse). Micropulse is thin pad with over 2,500 small air cells in rows; 50% cells inflated at any time (n=112) B. Conventional management (gel pad in operating room and replacement mattress postoperatively) (n=105) | Mean age, years: 63.5+/11.9 vs. 64.7+/-11.8 Age distribution: < 50 years 12.7% vs. 16.3% 50-60 years 21.8% vs. 17.3% 61-70 37.3% vs. 27.9% > 70 years 28.2% vs. 38.5% % female: 28.2% (31/110) vs. 26% (27/104) Race distribution: Caucasian 95.5% vs. 92% Black 3.6% vs. 7% Hispanic 0 vs. 1%  Other 0.9% vs. 0 Mean weight, pounds: 178.7+/-40.35 vs. 168.1+/-39.79 Mean height, inches: 66.23+/-17.51 vs. 68.12+/-4.248 Smoking status: Smoker 23.8% (25/105) vs. 30.4% (21/102) Never smoked 20.0% (21/105) vs. 17.6% (18/102) Ex-smoker 56.2% (59/105) vs. 52.0% (53/102) Baseline skin risk assessment score for both groups <4 (range: 0-13) \*All data not available for all patients (p=NS for all) |
| Berthe, 200756 Randomized trial | Hospital (medical and surgical wards) Belgium | Patients admitted for at least 24 hours, free of bed sores | Until PU incidence (median and length without PU unclear) | NR/1729/1729 | 0 | 0 | A: Kliniplot foam block mattress (n=657) B: Standard hospital mattress (n=1072) | NR |
| Brienza, 201057 | Nursing homes United States | Inclusion: nursing home resident, aged 65+, Braden score ≤ 18, combined Braden Activity and Mobility subscale ≤ 5, absence of ischial area PU, tolerance for daily wheel chair sitting 6+ hours, ability to accommodate seating and positioning needs with the wheelchairs selected for study use. Exclusion: body weight > 113kg, hip width > 51 cm, various wheelchair seating requirements, current use of wheelchair cushions other than segmented foam cushions (SFCs) or their equivalent or lower-quality | 6 months or until PU incidence, discharge, or death (median NR) | NR/232/232 | Did not receive intervention: 5.3% (6/113) vs. 3.4% (4/119) Death: 11.5% (13/113) vs. 12.6% (15/119) Voluntary withdrawal: 4.4% (5/113) vs. 5.0 % (6/119) | 18.6% (21/113) vs. 17.6% (21/119) | A: Skin Protection Cushions (SPC), including Quadtro (Roho, Inc.), J2 Deep Contour (Sunrise Medical, Inc.), Infinity MC (Invacare Corporation) (n=113) B: Cross-cut 7.6cm thick, Segmented Foam Cushion (SFC) (Span-America Medical Systems, Inc., Greenville, SC) - standard care (n=119) | KiSha |
| Cavicchioli, 200758 | Hospitals Italy | Admission expected to last at least 2 weeks; had up to one grade I pressure ulcer Exclude: not at risk according to Braden scale; more than one pressure ulcer at study entry; prevalent pressure ulcer of grade 2 or greater | 2 weeks | 203 enrolled/173 analyzed | 0 | 9 died, 12 were discharged before study completion, 9 could not tolerate interventions | A: Alternating-low-pressure option on Duo2 Hillrom mattress (n=69) B: Constant-low-pressure option on Duo2 Hillrom mattress (n=71)  C: Standard mattress (n=33) | Mean age: 77 vs. 78 vs. 77 years Sex: 71% vs. 72% vs. 73% female Race: NR |
| Collier,199659 | Hospital United Kingdom | Patients with a low Waterlow score (low risk) were not excluded | Length of hospital stay (median NR) | NR/NR/90 | 9 due to one mattress manufacturer’s decision to remove the mattress from the study | NR | Comparison of 8 foam mattresses: A. New Standard Hospital Mattress (Relyon) (130 mm) (n=9) B. Clinifloat (n=11) C. Omnifoam (n=11) D. Softform (n=12) E. STM5 (n=10) F. Therarest (n=13) G. Transfoam (n=10) H. Vapourlux (n=14) | % women: 60% (59/99) |
| Conine, 199060 Modified sequential randomized trial | Extended care facility  Canada | Patients aged 18 to 55 years, with no evidence of skin breakdown for at least 2 weeks prior to the study, who were at high risk of developing pressure ulcers according to the Norton’s scale (score<14). Excluded patients if their high risk status changed during the study. | 3 months (median NR) | NR/187/148 | Discomfort: 20% (19/93) vs. 18% (17/94) Transferred: 0 vs. 1% (1/94) Total dropouts: 22% (21/93) vs. 19% (18/94)\*  \*includes 2 deaths in group A Note: Above patients were not included in analysis | See withdrawals | A. Alternating-pressure overlay, 10-cm air cells that alternately inflate and deflate by electronic pump (cycle time not reported, nor the make of overlay) (n=72) B. Silicore (Spenco) overlay; siliconized hollow fibers in waterproofed cotton placed over standard hospital mattress (spring or foam) (n=76) Note: Both groups received usual care (2-3 hourly turning; daily bed baths; weekly bath/shower; use of heel, ankle and other protectors) | Mean age, years (SD; range): 38.8 (13.0;19-55) vs. 35.6 (13.0;21-55) % female: 56.9%(41/72) vs. 61.8% (47/76) (p=NS for all) |
| Conine, 199361 | Extended care facility, wheelchair cushions Canada | Patients >60 years, free of any skin breakdown for at least 2 weeks prior to study, considered to be at high risk of pressure sores (Norton score <14), sitting in wheelchair for minimum of 4 consecutive hours for normal daily activities, and free of progressive disease which could confine them to bed. Excluded patients if they had diabetes or peripheral vascular disease, if they became confined to bed during trial for >120 consecutive hours due to reasons other than pressure sores, or if their status of high risk improved. | 3 months (median NR) | NR/288/248 | Discomfort: 1% (2/144) vs. 1% (2/144) Transferred: 3% (4/144) vs. 2% (3/144) Score change (Norton score>15): 2% (3/144) vs. 3% (4/144)  Total dropouts: 13% (19/144) vs. 15% (21/144)\*  \*includes 10 deaths in group A and 12 deaths in group B Note: Above patients were not included in analysis | See withdrawal | A. Contoured foam cushion individually customized by seating specialist, with a posterior cut out in the area of ischial tuberosities and an anterior ischial bar (n=123) B. Slab cushion made of medium-high density polyurethane foam, bevelled at base to prevent seat sling (n=125) Note: Both cushions were covered by the identical polyester covers with laminated waterproof inside. Patients assigned to wheelchairs by institutions’ personnel. All patients given equal medical, nursing, nutritional and rehabilitation care. | Mean age: 84 vs. 83.5 years % female: 79.6 (98/123) vs. 77.6% (97/125) (p>0.05 for all) |
| Conine, 199462 Modified sequential randomized trial | Extended care facility, wheelchair cushions Canada | Patients aged >60 years, assessed at high risk of pressure sores (Norton score >14), free of pressure ulcer for at least 2 weeks prior to the study, sitting in a wheelchair daily for minimum of four consecutive hours, free of any progressive disease which could confine them to bed. Excluded patients if they had diabetes, or peripheral vascular disease, became confined to bed for more than 120 consecutive hours due to reasons other than pressure ulcer, or had change in high risk status during the study | 3 months (median NR) | NR/163/141 | Discomfort: 1% (1/83) vs. 7% (6/80), p=0.05 Transferred: 2% (2/83) vs. 1% (1/80) Score change (Norton score>15): 4% (3/83) vs. 3% (2/80)  Total dropouts: 12% (10/83) vs. 15% (12/80)\*  \*includes 4 deaths in group A and 3 deaths in group B Note: Above patients were not included in analysis | See withdrawal | A. Jay cushion; the Jay cushion is a contoured urethane foam base with gel pad over top (n=68) B. Foam cushion; 32 kg/m3 density foam bevelled at the bottom to prevent sling effect (n=73) | Mean age 82 years  % female: 85% |
| Cooper, 199863 | Acute care United Kingdom | Patients > 65 years, no existing pressure ulcers, and a Waterlow score >15 | 7 days | NR/100/100 | 16 | 0 | A: Sofflex immersion air mattress, 2 separate air sections and a foam section for the head, larger cells (n=51) B: Roho immersion air mattress, 3 separate air sections and a foam section for the head, smaller cells (n=49) Note: Both mattress systems are constructed with flexible interconnecting air cells manufactured from neoprene and have protective covers | Mean age: 83 vs. 83 years % female: 86% (44/51) vs. 82% (40/49) Orthopedic patients |
| Daechsel, 198564 | Long-term care Canada | Patients between 19 and 60 years old, free of skin deterioration two weeks prior to study, and considered to be high risk according to Norton Scale and independent clinical judgment | 3 months | NR/32/32 | 0 | 0 | A. Alternating-pressure mattress (n=16) B. Silicone-filled mattress (n=16) | Mean age: 42.6 vs. 38.5 years Sex: 37.5% (6/16) vs. 62.5% (10/16) All chronic neurologic patients |
| Demarre, 201265 | 25 wards of 5 hospitals Belgium | Patients >18 years of age, with a Braden score of <17, an expected stay of >3 days Exclude: Patients with prevalent ulcers of grade II-IV, a “do not resuscitate” code, or weight less than 30 kg or more than 160 kg | 2 weeks | 7393 screened/796 eligible/610 enrolled | 227 withdrawn prior to study completion due to transfer to another ward (37), discharge to home (81) or another institution (79), death (29) or withdrawal of consent (1) | 41 lost to follow-up due to technical problems (6), discomfort (27), or reason not defined (8) | A: Alternating low-pressure air mattress with single-stage inflation and deflation (n=312) B: Alternating low-pressure air mattress with multi-stage inflation and deflation (n=298) | Mean age: 76.5 vs. 76.2 years Sex: 58% vs. 63% female Race: NR |
| Donnelly, 201166 | Hospital (fracture trauma unit) United Kingdom | Patients aged > 65 with a hip fracture in the prior 48 hours Exclude: Existing heel pressure damage and/or a history of pressure ulcers | 10.8 days (control) vs. 12.2 days (intervention) | 705/239/239 | 12 (3 in control group and 9 in intervention group) | 2 (1 in each group) | A. Heelift Suspension Boot (n=120) B. Usual care (n=119) | Mean age: 80.9 vs. 80.8 years Sex: 79.2% vs. 74.8% female Race: NR Fracture patients |
| Feuchtinger, 200667 | Surgical unit Germany | Patients scheduled for cardiac surgery with extracorporeal circulation, aged >18 years, not included in another study, and written informed consent obtained. | 5 days | NR/175/175 | None | None | A. Standard configuration; Operating room (OR) table with water filled warming mattress (n=90) B. Test configuration; OR table with water filled warming mattress and a 4-cm thermo active viscoelastic foam overlay (n=85) Note: Both tables also covered with moisture keeping disposable sheet and cotton sheet | Mean age, years (SD; range): 67.6 (10.8;33-92) vs. 68 (11;34-92) Number female: 23/90 vs. 27/85 BMI, mean (SD; range): 26.6 (4.2;18.6-40.1) vs. 27.2 (4.7;19.1-48.2) (p>0.05 for all) Cardiac surgery patients |
| Gebhardt, 199668 Cluster trial | Intensive care unit United Kingdom | Patients with Norton score <13 who had been in the unit for <3 days and had no sores. Excluded patients if condition improved so that Norton score >12 and no sore was present, if they were discharged or transferred to another ward or hospital, or if they died | Mean followup: 11 vs. 12 days | NR/52/43 | Transferred or died before 2nd assessment: n=2 vs. n=3 Note: Above 5 patients plus 4 used to trial equipment were not included in analysis Note: n=6 deaths per group during trial | None | A. Alternating-pressure air mattress (shallow small cell overlays, medium depth large cell overlays, and deep mattresses) (n=23) B. Static support surfaces (foam mattresses/overlays, fiber-, air-, gel-, water-, and bead-overlays) (n=20) C. Low-air-loss mattresses (n=7, but grouped in with static support surfaces) | Mean age (range), years: 55 (23-83) vs. 60 (21-83) % female: 47.8% (11/23) vs. 35% (7/20) |
| Geyer, 200169 Pilot randomized trial | Nursing homes United States | Residents >65 years with Braden score <18, combined Braden Activity and Mobility subscale score of <5, an absence of sitting-surface pressure ulcers, tolerance for total daily wheelchair sitting time >6 hours and sitting needs that could be accommodated by the ETAC Twin wheelchair (including body weight <250 lbs) | Mean days to endpoint 99.9 vs. 76.3 days | NR/32/32 | Transferred or discharged: n=2 vs. n=3 Note: one subject per group died during study Note: all participants included in ITT analysis | See withdrawals | A. Pressure-reducing wheelchair cushion and fitted incontinence cover. No single make of cushion specified, rather this could be selected by the nurse from a group of cushions based on the participants’ clinical status (n=15) B. Generic 3-inch convoluted foam (eggcrate) cushion (Bioclinic Standard, Sunrise Medical), fitted incontinence cover, and solid seat insert (n=17) | Mean age: 85.2 vs. 84.1 years % female: 93.3% (14/15) vs. 94% (16/17) p=NS for all |
| Gilcreast, 200570 | Military tertiary-care academic medical centers United States | Patients with Braden score <14, and able to read and write English (or surrogate able). Excluded patients with hip surgery, patients anticipated to be admitted for < 72 h, patients (or surrogates) unable to provide informed consent, and patients with preexisting pressure ulcer on foot or foot deformity. Hospital discharge, changes in enrollment criteria (i.e. Braden score >14) resulted in ending subjects participation in study. Occurrence of pressure ulcer also ended enrollment. | Mean time in study 7.5 days (SD 7.4) | 5475/338/240 | 15% (36/240) said they no longer wanted to participate after 48 hours in the study | 35% (84/240) ended study because they were discharged, 24% (57/240) no longer met study criteria, 15% (36/240) said they no longer wanted to participate after 48 hours in the study, 13% (32/240) died and 5.0% (12/240) developed pressure ulcers | A. Bunny Boot (fleece) high cushion heel protector (n=77)  B. Egg crate heel lift positioner (holds the foot suspended above the bed surface with heel through a window) (n=87) C. Foot waffle air cushion (felt coated plastic inflatable plastic pillow that encircles the foot) (n=76) Note: Nurses added pillows to the bunny boot group | Mean age (SD; range), years: 63.9 (19.94;18-97) % female: 42% (101/240), p=.008;  Race: 68% (163/240) White, 15.4% (37/240) Black, 16.3% Hispanic (39/240), 1% (1/240) Asian |
| Goldstone, 198271 | Hospital United Kingdom | Patients aged >60 y who arrived in the accident and emergency department with a suspected femur fracture | Unclear | NR/NR/75 Patients who did not suffer a fracture, or who requested to be removed from the intervention mattress, or who died before reaching the post operative ward were excluded from the analysis | NR | NR | A. Beaufort bead bed system overlay, renamed as “Neumark-Macclesfield Support System” (includes polystyrene bead-filled mattress on A&E trolley; bead-filled operating table overlay; bead-filled sacral cushion for operating table; bead-filled boots to protect heels on operating table (n=32) B. Standard supports in A&E, operating room, ward (n=43) | Age: >60 y  % women: 90.6% and 83.7%  Fracture patients |
| Gray, 199472 | Hospital United Kingdom | Patients were recruited from the following specialties: orthopaedic trauma, vascular and medical oncology. To be included, patients had to be assessed using the Waterlow Score and have a score >15 (high risk) and were required to have intact skin on admission | 10 days | NR/NR/170 | NR | NR | A. Softform mattress (n=90) B. Standard 130 mm NHS foam mattress (n=80) | Mean age: 76 vs. 74 years % women: 63.3% vs. 58.8% p=NS for all |
| Gray, 200073 | Surgical, orthopedic, and medical wards  United Kingdom | Emergency or list admission for bed rest or surgery, less than 353 lbs, skin intact, no existing skin conditions, no terminal illness | 10 days | NR/100/98 | 0 | 2 (post-randomization exclusions due to torn mattresses) | A. Transfoamwave pressure-reducing mattress - trial (n=50) B. Transfoam pressure-reducing mattress (n=50) | Mean age: 69 vs. 61 years % women: 40% vs. 38% |
| Gunningberg, 200074 | Hospital, surgery Sweden | Patients aged over 65 years with a suspected hip fracture on arrival in assessment and emergency (A&E) | Until discharge, or 14 days postoperative | 119/101/101 | None | None | A: Visco-elastic foam mattress (A&E 10cm; Ward 7cm) (n=48) B: Standard mattress (A&E 5cm; Ward 10cm) (n=53) Note: While all patients received standard prevention protocols, those with grade I pressure ulcers in the usual care group received more preventive interventions than those in the intervention group (confound); results not reported for other pressure ulcer grades so unknown | Mean age: 84 years vs. 85 years  % women: 79% vs. 81% p=NS for all Fracture patients |
| Hampton, 199975 | Hospital United Kingdom | Patients without pressure damage, with a Waterlow score of less than 25 | NR (study ran 6 months, but no comment on length of stay) | 407 enrolled | NR | NR | A. Stepped approach on Thermo contour foam mattress (step 1) or an air mattress (step 2) (n=199) B. Stepped approach with usual care (step 1) or an air mattress (step 2) (n=208) | Mean age: 70 vs. 67 years Sex: NR Race: NR |
| Hofman, 199476 Randomized trial, stopped early | Surgery Netherlands | Patients with femoral neck fracture and concomitant high risk (score >8 per 1985 Dutch consensus meeting criteria) for the development of pressure sores. Patients with existing pressure sores of > grade 2 were excluded. | Post-operative period of 14 days | 46/44/42 at week 1; 36 at week 2  2 excluded due to inadequate randomization | 3 deceased; 5 discharged | None | A. Cubed foam mattress (Comfortex DeCube mattress) - allows removal of small cubes of foam from beneath bony prominences (n=21) B. Standard hospital mattress, polypropylene SG40 hospital foam mattress (n=23) | Age: 85.0 years vs. 83.9 years  % women: 76.2% (16/21) vs. 95.7% (22/23) p=NS for all Fracture patients |
| Hoshowsky, 199477 Quasi-experimental study | Surgery United States | Patients from weekday operative schedule of a large university teaching hospital. Placement in the supine or prone positions while undergoing surgery, older than 12 years of age, and possession of symmetrical lower limbs | Post-operative | NR/NR/505 people (1,010 legs) | None | None | Six combinations of the below mattresses using patients right and left heels or knees as controls; each person served as their own control:  - Standard vinyl covered 2-inch thick foam OR table mattress (SFM)  - Nylon fabric covered 2-inch thick foam and gel OR table mattress (FGM - Akros®, American Sterilizer Co.) - Viscoelastic dry polymer mattress overlay (VEO-Action®, Action Products Inc.)  A. SFM vs. FGM (n=91) B. VEO above SFM vs. FGM (n=92) C. SFM vs. VEO above FGM (n=62) D. VEO above SFM vs. VEO above FGM (n=113) E. SFM vs. VEO above SFM (n=73) F. FGM vs. VEO above FGM (n=74) | Mean age: 47 years (17.1 SD) % women: 63.6% (321/505) Preexisting vascular disease: 6.3% (32/505) Preexisting hypertension: 20.4% (103/505) Preexisting diabetes mellitus: 7.5% (35/505) Current smokers: 23.8% (120/505) Past smokers: 2.4% (12/505) |
| Inman, 199378 | Intensive care Canada | Critically ill patients admitted to the Critical Care Trauma Centre of Victoria Hospital, London, Ontario from March 1989 to November 1990. Eligible patients were >17 years of age, had an admission Acute Physiology and Chronic Health Evaluation II (APACHE II) score >15, and had an expected stay in the ICU of at least 3 days. Excluded patients with myocardial infarction, vascular and cardiac surgery, and drug overdoses | 18.8+18.1 days vs. 15.4+13.9 days | NR/NR/100 | None | None | A. Air suspension bed, (KinAir, Kinetic Concepts, Inc, San Antonio, Texas); smooth, low-friction, low shear surface with a high moisture vapor transmission rate; each section of the bed has separate air-controlled settings (n=49) B. Standard ICU bed (undefined), plus repositioning every 2 hours (n=49) | Age: 63.4+14.4 years vs. 65.4+13.9 years % women: 40.8% (20/49) vs. 55.1% (27/49) |
| Jesurum, 199679 Quasi-experimental pilot study | Hospital  United States | Adult cardiovascular surgery patients with intra-aortic balloon pump | Post-operative period | NR/NR/39 | 0 | 5 eligible patients missed due to protocol breach | A. Low-air-loss mattress, 16 compartmentalized, separately controlled air sacs with a nylon quilted fabric cover (n=16) B. Standard foam mattress (n=20) | Mean age: 67 vs. 69 years % Female: 44% vs. 15% Race: 81% vs. 80% White  13% vs. 15% Hispanic 6% vs. 0 Black 0 vs. 5% East Indian Cardiovascular surgical patients |
| Jolley, 200480 Open label randomized trial | Hospital Australia | Patients admitted to hospital during study period at low to moderate risk of developing a pressure ulcer on Braden scale. Excluded patients if they were assessed at “no risk” (requiring no intervention) or “high risk” (requiring more complex intervention), had any pre-existing ulcer, were <18 years old, had expected length of stay <48 hours, had darkly pigmented skin, making Stage 1 ulcer difficult to detect | 7-7.9 days average | ~1900/539/441 | 14/270 vs. 8/269 requested withdrawal after receiving intervention; 0 vs. 2 withdrew before receiving intervention Note: 10 patients in group A complained about discomfort and requested removal of sheepskin  The following were followed up and included in analysis: 178/218 vs. 194/223 discharged; 2/218 vs. 5/223 died; 7/218 vs. 1/223 became high risk; 6/218 vs. 5/223 ward staff intervention; 11/218 vs. 10/223 other reason (e.g. Incontinence) | 52/270 vs. 46/269 were randomized but did not receive intervention Note: Above were not included in analysis | A. Sheepskin mattress overlay: leather-backed with a dense, uniform 25 mm wool pile. Used as a partial mattress overlay. Pressure points that were not covered by sheepskin were protected by a second sheepskin, or specific sheepskin elbow and heel protectors. Overlays were changed 3 times a week (unless required). Received usual care including repositioning (n=218)  B. Usual care as determined by ward staff. Included repositioning and any other PRD or prevention strategy with/without low-tech constant pressure relieving devices (n=223) | Mean age (range), years: 63.2 (18-97) vs. 61.1 (18-99) % female: 49% vs. 52% Note: Groups differed substantially by admission type with more emergency admissions in group A, but did not differ on other baseline demographic and clinical characteristics |
| Kemp, 199381 | Hospital and long-term care United States | Patients without pressure ulcers, at least 65 years old, with Braden score <16 (increased likelihood of developing pressure ulcer) | 1 month | 994/84/84 | None | None | A. Convoluted foam overlay, 3 or 4 inches thick, depending on acute care or long-term care setting (n=45) B. Solid foam overlay, 4 inches thick, sculptured (n=39) Note: Standard nursing practice was to reposition patient every 2 hours if at risk of pressure ulcers and to apply moisture repelling ointments to protect skin of incontinent patients. Hospital setting used disposable under pads for incontinent patients while long term facility used reusable cloth under pads | Mean age (SD), years: 79.31 (7.54) vs. 82.64 (8.60) % women: 68.8% (31/45) vs. 93.1% (27/29) Race: 23/45 vs. 22/39 black, 21/45 vs. 17/39 white, 1/45 vs. 0/39 Hispanic p=NS for all |
| Keogh, 200182 | Hospital United Kingdom | Patients age >18 years, with a Waterlow score of 15-25, no tissue damage greater than grade I, and expected to stay in bed at least 12 hours/day Exclude: Patients with terminal illness, weighing more than 120 kg, or posing a manual-handling risk | Mean follow-up: 7.4 vs. 6.8 days | 100 eligible/70 randomized | 30 recruited patients excluded due to stays <5 days (13), Waterlow score exceeding 25 (2), discharged or transferred (10), or refused to complete questionnaire (5) | 0 | A: Non-profiling standard hospital bed with variety of pressure relieving/reducing mattresses (alternating air [n=10] or foam [n=25]) (n=35) B: Electrically operated, four-sectioned profiling bed with foam (Pentaflex) pressure relieving/reducing mattress (n=35) | Mean age: 71 vs. 69 years Sex: 60% vs. 30% female Race: NR |
| Lazzara, 199183 | Nursing homes United States | Residents determined to be at risk for pressure ulcer development | 6 months | 74 enrolled | 0 | 2 refused to give consent, 19 died  \*Numbers do not add up | A: Gel mattress (n=33) B: Air-filled overlay (n=33) | NR |
| Lim, 198884 | Extended care facility Canada | Residents >60 years, free of any pressure ulcer for at least 2 weeks prior to the study, considered to be at high risk for developing ulcers (Norton Scale <14), using a wheelchair for >3 hours daily. Excluded residents if they had a progressive disease that could confine them to bed or if they became confined to bed for >120 consecutive hours due to reasons other than pressure ulcer | 5 months | NR/62/52 | n=1 in group A refused to continue Note: patient was not included in analysis | n=1 in group B transferred  Note: 8 deaths during trial (2 in group A, 6 in group B) Note: Above were not included in analysis | A. Contoured foam cushion, cut into a customized shape to relieve pressure on ischial tuberosities (n=26) B. Foam slab cushion, 2.5 cm medium density foam glued to 5 cm firm chipped foam (n=26) Note: Both groups also received usual care | Mean age (SD; range), years: 83.0 (7.7;65-103) vs. 84.6 (8.2;70-104) % female: 76.9% (20/26) vs. 69.2% (18/26) p=NS for all |
| McGowan, 200085 | Hospital (orthopedic wards) Australia | Patients aged >60 years, admitted with an orthopedic diagnosis, assessed at low or moderate risk of developing a pressure ulcer on the Braden scale, patient or significant other able to give informed consent. Excluded patients if patients assessed as no risk (requiring no intervention) or high risk (requiring more complex intervention) for developing pressure ulcers, patients with pre-existing pressure ulcer, non-English speaking patients (unless interpreter present), patients with anticipated stay <48 hours, colored skin patients where stage 1 ulcer detection is difficult | Post-operative period until discharge | NR/297/290 (unclear) | n=2 (one from each group) withdrew prior to data collection; n=6 in group A withdrew before completion of data collection due to discomfort; n=7 in group B vs. n=3 in group A withdrawn due to protocol violations Note: above included in ITT analysis | See withdrawals | A. Australian Medical Sheepskin overlay; sheepskin heel and elbow protectors as required on top of standard hospital mattress and sheet. Sheepskins were changed as required (at least every 3 days) (n=155) B. Standard hospital mattress and sheet with or without other low tech constant pressure devices as required (n=142) | Mean age: 73.6 vs. 74 years % female: 54% (83/155) vs. 61% (87/142) Note: More patients in Group A were male and more were admitted for total knee replacement compared to Group B Orthopedic patients |
| Mistiaen, 201086 | Long-term care facility Netherlands | Newly admitted to one of eight nursing homes for primarily physical impairments, age ≥ 18 years, expected stay > 1 week, free of PU on sacrum Exclusion: darkly pigmented skin, allergy to wool, admitted for a primarily psycho-geriatric reason | 30 days | 1066/588/543 | NR | 8.1% (24/295) vs. 7.2% (21/293) | A. Australian Medical Sheepskin on top of the mattress in the area of the buttocks (n=271) B. Control (n=272) Note: Both groups received usual care (includes all other pressure-reducing interventions; varied per group) | Mean age: 78 (26-97) years vs. 78 (27-98) years % women: 71% vs. 67% (p=NS for all) Somatic nursing home patients 40.5% cardiovascular disease 38% fracture patients |
| Nixon, 199887 | Hospital United Kingdom | Patients scheduled for elective major general, gynecological, or vascular surgery, >55 years old and position to be supine or lithotomy. Excluded patients with pressure damage of > Grade 2a pre-operatively, ward staff provision of pre-operative alternating pressure mattress, dark skin pigmentation which precludes reliable identification of Grade 1 and Grade 2a skin assessments, and skin conditions over the sacrum, buttocks, or heels which preclude reliable identification of Grade 1 and Grade 2a skin assessments | 8 days | 720/446/416 | 30 | 30 | A. Dry visco-elastic polymer pad (torso area and heels) on standard operating table mattress (n=222) B. Standard operating table mattress plus heel support (Gamgee pad) (n=224) Note: Both groups received usual care (warming mattress) | Aged 55-69: 56% (124/222) vs. 57% (128/224) Aged >70: 44% (98/222) vs. 43% (96/224) % women: 45% (101/222) vs. 48% (107/224) <90 min operation: 23% (50/222) vs. 18% (40/224) 90-179 min operation: 49% (108/222) vs. 49% (110/224) >180 min operation: 28% (62/222) vs. 33% (73/224) p=NR |
| Nixon, 200688 RCT  Same data as in Nixon, 2006 Health Technology Report | Hospital United Kingdom | Aged >55 years; admitted to vascular orthopaedic, medical, or care of elderly wards; expected length of stay >seven days; limited mobility or activity or an existing grade 2 pressure ulcer. Elective surgical patients without limitation of activity or mobility also included if average length of stay for their type of surgery >7 days or expected Braden activity or mobility scores of 1 or 2 for at least 3 days post-operatively Exclude: pressure ulcers of grade 3 or greater; planned admission to intensive care after surgery; admitted to hospital >4 days prior to surgery; slept at night in a chair; or weighed more than 140 kg or less than 45 kg | 60 days | 6,155 screened/1,972 randomized/1,971 analyzed | 1 patient randomized twice | 6.6% (66/990) vs. 5.2% (51/982) | A: Alternating-pressure overlay (n=990) B: Alternating-pressure mattress (n=982) | Mean age: 75.4 vs. 75.0 years Sex: 63.1% vs. 64.8% female Race: NR |
| Russell, 200089 | Hospital and Surgery Canada | Patients > 18 years, undergoing cardiothoracic surgery under general anesthesia, surgery of > 4 hours duration, and free of pressure ulcers | 7 days | NR/198/198 | 2 | None | A. MicroPulse system (multi-cell dynamic mattress) in the OR and postoperatively (n=98) B. Conventional care (gel pad in OR, standard mattress postoperatively) (n=100) | Mean age: 65.2 (10.9 SD) vs. 65.2 (10.6 SD) % women: 23.5% (23/98) vs. 25% (25/100) Smoker: Never 37.1% (36/98) vs. 33.3% (33/100), Past 45.4% (44/98) vs. 51.5% (51/100), Current 17.5% (17/98) vs. 15.2% (15/100) Race: Caucasian 94.9% (93/98) vs. 87.0% (87/100), African-American 0 vs. 1.0% (1/100), Asian 2.0% (2/98) vs. 2.0% (2/100), Hispanic 0 vs. 3.0% (3/100), Other 3.1% (3/98) vs. 7.0% (7/100) Mean hours in surgery: 4.1 (1.0 SD) vs. 4.2 (1.1 SD) p=NR for all Cardiovascular surgery patients |
| Russell, 200390 | 3 hospitals United Kingdom | Patients aged >65 years, with a Waterlow score of 15 to 20 Exclude: Patients weighing >155 kg | Median follow-up: 12 vs. 11 days | 1168 enrolled/1166 analyzed | 2 excluded post-randomization due to placement on incorrect mattress | 0 | A: Standard hospital mattress (primarily King’s Fund, Linknurse, Softfoam, or Transfoam) (n=604) B: Viscoelastic and polyurethane foam (CONFOR-Med) mattress (n=562) | Median age: 83 years Sex: 67% female Race: NR |
| Sanada, 200391 | Hospital  Japan | Braden score < 16, bed bound, free of pressure ulcers at study admission, and required head elevation | Unclear | 123/108/82 | 41 | NR | A. Double-layer air cell overlay (Tri cell): two layers consisting of 24 narrow cylinder air cells, cell pressure alternated at 5 minute intervals (n=37) B. Single-layer air cell overlay (Air doctor): single layer consisting of 20 round air cells, cell pressures alternated at 5 minute intervals (n=36) C. Standard hospital mattress (Paracare) (n=35) Notes: All groups had change of body position every 2 h, and special skin care to guard against friction and sheer. Nutritional intervention was given where required | Mean age: 69.5 (14.7 SD) vs. 73.9 (10.4 SD) vs. 70.6 (10.7 SD), p=NS % women: 51.7 (15/29) vs. 42.3 (11/26) vs. 51.9 (14/27), p=NS All patients required head elevation, including stroke patients, recovering from surgery, and terminally ill |
| Schultz, 199992 | Operating room United States | Patients scheduled for inpatient care, >18 years old, with surgery scheduled to last longer than 2 hours in the lithotomy or supine position. Excluded patients with an existing pressure ulcer, patients with severe chronic skin problems, or patients receiving only local anesthesia. | 6 days | NR/NR/413 | None | None | A. Experimental mattress overlay in operating room made of foam with a 25% indentation load deflection (ILD) of 30 lb and density of 1.3 cubic feet (n=206) B. Standard perioperative care (padding as required, including gel pads, foam mattresses, ring cushions [donuts] etc.) (n=207) | Mean age: 65.68 (11.66 SD) vs. 65.73 (12.87 SD)  % women: 35.4% (73/206) vs. 35.7% (74/207) BMI: 27.06 (4.97 SD) vs. 27.03 (4.51 SD) Smoker: Never 26.2% (54/206) vs. 24.6 % (51/207), Past 49.5% (102/206) vs. 52.2% (108/207), Current 23.3% (48/206) vs. 22.2% (46/207) Diabetes: 21.8% (45/206) vs. 24.1% (50/207) (p=NS for all) Without pressure ulcers vs. with pressure ulcers: No significant difference for patient type (same day admit vs. inpatient), gender, smoking status, preoperative albumin levels, OR time, or time to first position change. |
| Sideranko, 199293 | Surgical intensive care unit United States | Patients with surgical ICU stay >48h, presence of ventilatory support or some form of hemodynamic support on admission to surgical ICU. Exclude any evidence of existing skin breakdown upon admission to the surgical ICU. | Mean followup: 9.4 days | NR/NR/57 | NR | NR | A. Alternating air mattress: 1.5-inch thick Lapidus Airfloat System (n=20) B. Static air mattress: 4-inch thick Gay Mar Sof Care (n=20) C. Water mattress: 4-inch thick Lotus PXM 3666 (n=17) | Mean age: 67.9 (11.1 SD) vs. 63.6 (16.6 SD) vs. 66.1 (15.6 SD) Mean days of surgical ICS stay: 10.0 (10.9 SD) vs. 9.4 (8.8 SD) vs. 8.9 (7.1 SD) Mean days on mattress: 20.3 (21.4 SD) vs. 19.8 (14.7 SD) vs. 20.5 (17.5 SD) % women (reported for whole group): 42.1% (24/57) (p=NS for all) |
| Stapleton, 198694 | Hospital United Kingdom | Female patients aged >65 years with fractured femur, without existing pressure ulcers, with a Norton score of <14 | Unclear | NR/100/98 | 2 | 2 | A. Large Cell Ripple (canvas or plastic) pads (“Talley”) (n=32) B. Polyether foam pad 2 feet x 2 feet x 3-inch thickness (n=34) C. Spenco pad (n=34) Note: these materials were all already in use, but not systematically | Mean age: 60 years vs. 63 years % female: 43% vs. 32%  Acute respiratory organ failure patients |
| Takala, 199695 | Hospital Intensive care unit Finland | Admitted to hospital with expected stay in ICU exceeding five days Exclude: patients with accidental injuries | 14 days | 1,489/40/24 | 0 | 16 (10 patients excluded due to early discharge or death, 6 patients excluded due to unavailable intervention mattress) | A. Carital Air-float System (Carital Optima, Carital Ltd.): constant, static low pressure mattress comprising 21 double air bags (one inside the other), which can be adjusted for the head, middle, and feet areas (n=21) B. Standard hospital foam mattress: 10 cm thick foam density 35 kg/m3 (n=19) | Mean age: 60 years vs. 63 years % female: 43% vs. 32%  Acute respiratory organ failure patients |
| Taylor, 199996 | Hospital United Kingdom | Inpatients aged >16 years, with intact skin, requiring a pressure-relieving support, and expected hospital stay of >7 days | Mean days: 10.5 vs. 11.6 days | NR/44/44 | None | None | A. Alternating air pressure mattress (Pegasus Trinova), 19 cells that inflate and deflate in a 3-cell cycle over a 7.5 minute period; along with alternating air pressure redistributing chair cushion, 4 cells inflating and deflating over a 7.5 minute cycle (n=22) B. Alternating air pressure system (unnamed), cells inflating and deflating over a 10 minute cycle - control (n=22) | Mean age: 66.50 (2.20 SD) vs. 70.27 (2.73 SD), p=NS % women: 45.5% (10/22) vs. 40.9% (9/22), p=NS |
| Theaker, 200597 | Hospital, Intensive care  United Kingdom | Patients in ICU aged > 18 years, deemed at high risk of pressure ulcer development (based on 5 factors, no details provided). Excluded those with pressure sores on admission and those transferred from hospitals or other ward areas and had been nursed on a pressure-relieving device other than the control mattress | 14 days | 68/62/62 | None | None | A. KCI TheraPulse pulsating air suspension mattress (n=30) B. Hill-Rom Duo, constant low pressure or alternating-air options in same mattress (n=32) Note: Both consist of cells that are connected to a pump that inflate and deflate either a at a 5-10 minute time cycle or continuously | Mean age: 53 (range: 38-75) vs. 57 (range: 35-77) vs. 59 (range: 26-80) vs. 66 (range: 30-85) % women: 33% (10/30) vs. 41% (13/32) |
| Tymec, 199798 | Hospital United States | Patients of select nursing units, with a Braden score <16 and intact skin on the heels | Unclear | NR/NR/52 | NR | NR | A. Foot Waffle ([EHOB Inc.] FDA approved, non-abrasive vinyl boot with built-in foot cradle and inflated air chamber). B. Hospital pillow under both legs from below knee to the Achilles tendon (n=52 total) | Mean age: 66.6 (16.5 SD) years % women: 44% (23/52) Race: 61% (32/52) African American, 37% (19/52) Caucasian, 2% (1/52) Asian |
| van Leen, 2011 99 | Long-term care nursing facility Netherlands | Patients aged > 65 years, living in the nursing home with a Norton score < 13 Exclude: Pressure ulcer in the previous 6 months | 6 months | NR/83/83 | 9 (died, 5 in cold foam group and 4 in the static air group, for reasons not related to the study [none developed ulcers]) | None | A. Static air overlay on top of cold foam mattress (n=41) B. Standard cold foam mattress - control (n=42) Note: Repositioning was only begun when signs of developing a pressure ulcer of >grade 2 occurred | Mean age: 81.1 vs. 83.1 years % women: 78.6% vs. 82.9%  p=NS for all Dementia: 73.8% vs. 75.6% |
| Vanderwee, 2005100 | 7 Hospitals Belgium | Patients aged >18 years, with an expected stay of >3 days, no grade II or greater pressure ulcers, no contraindication for turning, body weight <140 kg, and in need of pressure ulcer prevention (judged by Braden score <17 or presence of non-blanchable erythema) | 20 weeks | 2608 screened/570 eligible/447 enrolled | 0 | 0 | B: Alternating-pressure mattress (n=222)  A: Viscoelastic foam mattress and repositioning every 4 hours (n=225) | Mean age: 81 vs. 82 years Sex: 61% vs. 66% female Race: NR |
| Vyhlidal, 1997101 | Skilled nursing facility United States | Patients newly admitted to the skilled nursing facility with an estimated stay of at least 10 days, free of existing pressure ulcers, at-risk for pressure ulcer development (Braden score <18 with a subscale score of <3 in sensory perception, mobility, or activity levels) | 10-21 days | 492/40/40 | None | None | A. MAXIFLOAT (BG Industries, Northridge, CA), a foam replaceable parts mattress with 4 primary parts: a water repellent antibacterial cover, a 1.5-inch thick 2.4 lb antimicrobial foam dual indentation force load deflection, a foam center core with heel pillow, and waterproof antibacterial bottom cover (n=20) B. IRIS 3000 (Bio Clinic of Sunrise Medical Group, Ontario, CA), a 4-inch thick 1.8 lb foam overlay with a dimpled surface (n=20) Note: Subjects in both groups received standards of care according to the protocols of the organization | Mean age: 74.3 vs. 80.2 years, p=0.19 % women: 55% (11/20) vs. 55% (11/20), p=1.0 Most common admitting diagnoses: musculoskeletal 45%, cardiovascular disease 27.5% |

| **Author, Year Notes About Study Design, Publication Status** | **Baseline Ulcer Risk Score, p-value** | **Risk Level, Per General Cutoffs\*** | **Baseline Pressure Ulcers, Defined as >10% of Population? (Y/N/unclear)** | **Results - Incidence and Characteristics (Number patients with Ulcers or Number Ulcers, varies)** | **Results – Severity (Number Patients with Ulcers or Number Ulcers, varies)** | **Results – Resource Utilization** | **Harms** | **Quality** | **Funding Source** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Andersen, 198254 | Scores ranged from 2 to 7 (total scale range 0-11), p=NS Study’s own risk assessment tool, score of >2 indicates at risk | At risk | No | Incidence (number pressure ulcers): 4.2% (7/166) vs. 4.5% (7/155) vs. 13.0% (21/161), p<0.01 A vs. C: RR = 0.32, 95% CI 0.14-0.74 B vs. C: RR = 0.35, 95% CI 0.15-0.79 | NR | NR | NR | Poor | NR |
| Aronovitch, 199955 Quasi-randomized trial (comparative, parallel study with weekly randomization) | Modified Knoll Risk Scores for both groups: <4 (range 0-13) Modified Knoll Risk Assessment Tool ranges from 0-33, with a score of >12 indicating a greater risk for the development of alternations in skin integrity | Low risk | No | Incidence: 1% (1/112) vs. 7% (7/105); p<0.005 Note: For patients that developed ulcers in group B vs. group A, there was significant differences between groups on vascular surgery (p=0.02), previous history of pressure ulcer (p=0.02) and age (p=0.03). Significant difference in incidence of pressure ulcers between groups, even when these factors were controlled (p=0.04). Note: Analysis with only vascular surgery patients, controlled for age and baseline skin assessment and looking at type of device, found a statistical significance associated with device and presence of pressure ulcers (p=0.023) | Severity: 7 patients in group B only developed 11 pressure ulcers (stage of 6 of these could not be determined because of eschar) Grade 1: 1 Grade 2: 4 | NR | NR | Poor | Partially funded by an educational grant from MicroPulse |
| Berthe, 200756 Randomized trial | Modified Ek score: 1: 42 vs. 47, 2: 54 vs. 71, 3: 96 vs. 149, 4: 465 vs. 805. No significant differences between groups | Low risk | No | Incidence of pressure ulcers: 3.2% (21/657) vs. 1.9% (21/1072); RR = 1.63, 95% CI 0.90-2.96) | NR | NR | NR | Poor | NR |
| Brienza, 201057 | Mean Braden score: 15.4 (SD ± 1.4) vs. 15.5 (SD ± 1.5) | At risk | No | Incidence (number ischial tuberosity pressure ulcers): 0.9% (1/113) vs. 6.7% (8/119), p=0.04, RR = 0.13, 95% CI 0.02-1.04 p=0.054 Incidence (number combined ischial tuberosity and sacral pressure ulcers): 10.6% (12/113) vs. 17.6% (21/119), p=0.14 | Severity: Stage 1: 1, Stage 2: 7, Ungradable: 1 | NR | NR | Fair | Eunice Kennedy Shriver National Institute on Child Health and Human Development Grant |
| Cavicchioli, 200758 | All had Braden score <17 Both treatment groups at greater risk than control (p<0.001) | High risk | Baseline ulcers: 8.7% (6/69) vs. 4.2% (3/71) vs. 18% (6/33) | Any pressure ulcer: 2.1% (3/140) vs. 36% (12/33); RR 17 (95% CI 5.1 to 57)  Alternating low pressure vs. constant low pressure, in patients randomized to Duo2 Hill-Rom mattress  Any pressure ulcer: 2.9% (2/69) vs. 1.4% (1/71); RR 2.1 (95% CI 0.19 to 22) | Stage 1 ulcer: 0.7% (1/140) vs. 36% (12/33); RR 0.02 (95% 0.003 to 0.15)  Stage 2 or 3 ulcer: 1.4% (2/140) vs. 0% (0/33); RR 1.2 (955 CI 0.06 to 24) | NR | NR | Poor | Hill-Rom provided the intervention surfaces |
| Collier,199659 | Waterlow score range: 3 to 25 | Various risk levels | Unclear, but appears prevention is the intention of the study | Incidence: No patients developed a pressure ulcer of any grade during the study | Not relevant | NR | NR | Poor | NR |
| Conine, 199060 Modified sequential randomized trial | Conine, 199060 Modified sequential randomized trial | At risk | No | Incidence: 133 ulcers in 54% (39/72) patients in group A vs. 148 ulcers in 59% (45/76) patients in group B, p=NS RR = 0.91, 95% CI 0.69-1.21 | Severity: Grade 1: 64% (95/133) vs. 41% (91/148) Grade 2: 12% (15/133) vs. 13% (19/148) Grade 3: 24% (33/133) vs. 14% (36/148) Grade 4: 0 vs. 1% (2/148) (p=NS for all) | NR | NR | Poor | British Columbia Health Care Research Foundation |
| Conine, 199361 | Mean Norton score at baseline: 11.5 vs. 12.1 | At risk | No | Incidence: 175 sores in 84/123 patients vs. 184 sores in 85/125 patients, p=NS RR = 1.0, 95% CI 0.84-1.18 | Severity: Grade 1: 57% (105/184) vs. 56% (98/175) Grade 2: 24% (45/184) vs. 27% (48/175) Grade 3: 17% (32/184) vs. 15% (27/175) Grade 4: 1% (2/184) vs. 1% (2/175)  p=NS | NR | NR | Fair | Department of Health and Welfare Canada National Health Research and Development Program Grant |
| Conine, 199462 Modified sequential randomized trial | Mean Norton score of patients at baseline: 12 | At risk | No | Incidence (3 patients): 30/73 vs. 17/68, RR = 0.61, 95% CI 0.37-1.00; p=0.049 | Severity: Grade 1: 77% (20/26) vs. 57% (24/42)  Grade 2: 11.5% (3/26) vs. 29% (12/42)  Grade 3: 11.5% (3/26) vs. 14% (6/42)  p=NS   Grade 2 or 3: 8.8% (6/73) vs. 26% (18/68); RR 0.36, 95% CI 0.15 to 0.85 | NR | Withdrawals due to discomfort: 8% (6/80) vs. 1% (1/83); RR 6.23, 95% CI 0.77 to 50.56 | Fair | NR |
| Cooper, 199863 | Waterlow score on admission: 17 vs. 16 | At risk | No | Incidence:  7% of patients (3/51) developed an ulcer vs. 12% (5/49) of patients developed an ulcer; p=NR | Severity: Only 1 pressure ulcer involved a break in the skin (Stirling grade 2.4, Group A Sofflex group) | NR | NR | Poor | Raymar research grant |
| Daechsel, 198564 | Mean Norton score: 13.4 vs. 13.0 | At risk | No | Incidence:  25% (4/16) of patients developed 5 ulcers vs. 25% (4/16) of patients developed 5 ulcers, p=NS RR = 1.0, 95% CI =0.30-3.32; p=NS | Severity: Mean Exton-Smith scores: 2.25 (0.82 SD) vs. 2.75 (0.74 SD), p=0.39 | NR | NR | Poor | Gaymar Industries; Pearson Hospital |
| Demarre, 201265 | Median Braden score: 14 vs. 14 Grade I ulcer at baseline: 15.4% (48/312) vs. 15.4% (46/298) | High | Grade I ulcer at baseline: 15.4% (48/312) vs. 15.4% (46/298) | Pressure ulcer grade II-IV: 5.8% (18/312) vs. 5.7% (17/298); RR 1.01 (95% CI 0.53-1.92); p=0.97 Pressure ulcer grade I: 12.2% (38/312) vs. 17.1% (51/298); RR 0.71 (95% CI 0.48-1.05); p=0.08 | NR | NR | Discontinued intervention due to discomfort: 5.1% (16/312) vs. 3.7% (11/298) | Fair | Hill-Rom provided the intervention surfaces; Ghent University |
| Donnelly, 201166 | Mean Braden score: 14.8 vs. 15 Mean Barthel score: 16.4 vs. 17.4 (p=0.08) | At risk | No | Incidence (number patients):  7% (8/120) of patients vs. 26% (31/119) of patents, p<0.001 RR = 0.26, 95% CI 0.12-0.53; p<0.001 Incidence (number heel, foot, or ankle pressure ulcers):  0% (0/120) vs. 24.4% (29/119); p<0.001 | Severity (number pressure ulcers): Grade 1: 0 vs. 18 Grade 2: 4 vs. 16; RR 0.25, 95% CI 0.09 to 0.72 Ungraded: 5 vs. 5  Note: Excluding Grade 1 ulcers did not change results | NR | Adverse events: 20\* vs. 23\*; p=0.69 (5 deaths, 21 life-threatening, 9 severe, 2 moderate, and 8 mild events - none deemed to be treatment-related)  \*Denominator unclear; text reported 45 adverse events but only accounted for 43 | Good | Special Nursing Research Fellowship funded by the Research and Development Office for Health and Social Care in Northern Ireland |
| Feuchtinger, 200667 | Norton score preoperatively, mean (SD; range): 22.2 (2.4;13-26) vs. 22.6 (1.9;17-25), p=0.43 | Lower Risk | Preoperative incidence 2.3% (4 patients had grade 1 pressure ulcers) | Incidence (pressure ulcers): Total post-operative pressure ulcer incidence was 14.3% for both groups; 11.1% vs. 17.6%, p=0.22 | Severity: Grade 1 ulcers postoperative days 0-5: 10% (9/90) vs. 15.3% (13/85) Grade 2 ulcers postoperative day 0-5: 1% (1/90) vs. 2.4% (2/85) | NR | NR | Fair | NR |
| Gebhardt, 199668  Cluster trial | Norton score >8: n=5 vs. n=1 Norton score <8: n=18 vs. n=19 | At risk | No | Incidence (number pressure ulcers): Grade 1: 1 vs. 3 Grade 2: 0 vs. 4 Grade 3: 0 vs. 2 RR = 0.08, 95% CI 0.01-0.56  Excluding Grade I ulcers: RR = 0.06, 95% CI 0.00-0.96 | NR | NR | NR | Fair | North East Thames Regional Hospital Board research grant |
| Geyer, 200169 Pilot randomized trial | Initial Braden score, mean: 12.5 vs. 13.4 | At risk | No | Incidence (patients): 40% (6/15) vs. 59% (10/17), p=NS RR = 0.68, 95% CI 0.33-1.42 | NR | NR | NR | Fair | National Institute on Disability and Rehabilitation Research grant; authors received “assistance” for the study from ETAC USA, Crown Therapeutics, and Sunrise Medical |
| Gilcreast, 200570 | Braden score at baseline not reported for groups, but inclusion of only patients with Braden score <14 | At risk | Not on foot but patients had pressure ulcers on other parts of body | Incidence (heel pressure ulcers; unclear whether the unit was number of ulcers or number of patients): Total 5% (12/240) incidence in both groups over 3 years; 1.68% per year 4% (3/77) vs. 5% (4/87) vs. 7% (5/76), p=0.416 | NR | NR | NR | Poor | Tri Service Nursing Research Program grant |
| Goldstone, 198271 | Mean Norton score at admission: 13 | At risk | Unclear, but states prevention is the intention of the study | Incidence (overall pressure ulcers): 15.6% (5 lesions in 5 patients) vs. 48.8% (35 lesions in 21 patients), p<0.005 RR = 0.32, 95% CI 0.14-0.76 Heel pressure ulcers: 0% vs. 32.6% | Severity Overall maximum width of broken skin (mean): 6.4 mm vs. 29.5 mm, p=0.03 Buttocks maximum width (mean): 5.7 mm vs. 23.9 mm, p=0.018 Sacrum, maximum width (mean): 7.5 mm vs. 56.0 mm, p=NR | NR | NR | Poor | NR |
| Gray, 199472 | Waterlow score: 18.03 (3.23 SD) vs. 16.01 (2.58 SD), p=NS | At risk | Unclear, intact skin required, but this may include a grade 1 pressure ulcer | Grade 2 or greater ulcer incidence (number ulcers): 7% vs. 34%, p<0.001 | NR | NR | NR | Fair | Research grant from Medical Support Systems |
| Gray, 200073 | Waterlow score on admission: 13 vs. 14 | At risk | No | Incidence of pressure ulcers: 4% (2/50) vs. 4% (2/50), p=NS | Grade 1: 1 vs. 1 Grade 2: 1 vs. 0 Grade 4: 0 vs. 1 | NR | NR | Fair | NR |
| Gunningberg, 200074 | Mean Modified Norton Scale (MNS) at ward admission: 19 vs. 19 % MNS <21: 69% (33/48) vs. 64% (34/53)   Score of <21 considered at risk | At risk | No | Incidence (patients): 25% (12/48) vs. 32% (17/53), p=NS | Severity: Grade I: 17% (8/48) vs. 17% (9/53), p=NS Grade II: 8% (4/48) vs. 14%, (7/53), p=NS Grade III: 0% (0/48) vs. 0% (0/53), p=NS Grade IV: 0% (0/48) vs. 2% (1/53), p=NS Grade II-IV: 8% (4/48) vs. 15% (8/53), p=NS | NR | NR | Poor |  |
| Hampton, 199975 | Mean Waterlow score: 14.6 vs. 12.8 | Low risk (30%), at risk (20%), high risk (20%, and very high risk (22%) | Any ulcer at baseline: 2.4% (5/208) vs. 1.5% (3/199) | Any pressure ulcer: 2.9% (6/208) vs. 0%; RR 0.08 (95% CI 0.00-1.46); p=0.09 | NR | NR | NR | Poor | NR |
| Hofman, 199476 Randomized trial, stopped early | Mean score (per 1985 Dutch consensus meeting criteria): 21 (10.3, 1.6 SD) vs. 23 (10.4, 1.4 SD) High risk | At risk | No | Incidence of at least grade 2 ulcers (number patients): 24% (4/17) vs. 68% (13/19), p=0.008% (Includes withdrawals) | Grade 0: 11 vs. 5 Grade 1: 2 vs. 1 Grade 2: 1 vs. 5 Grade 3: 3 vs. 5 Grade 4: 0 vs. 3 p=0.0067 (1985 Dutch consensus meeting grading scale, 0-4) | Mean length of stay: 21 vs. 23 days | NR | Poor | NR |
| Hoshowsky, 199477 Quasi-experimental study | Baseline NR  Adapted Hemphill’s Guidelines for Assessment of Pressure Sore Potential (Scale 0-34, with 0-12 low, 13-25 moderate, 26-34 high) | Unclear risk (lower) | Unclear | Incidence per mattress: Stage I pressure ulcer, A. vs: B: OR 0.16 (95% CI 0.1 to 0.24; p<0.001) C: OR 0.49 (95% 0.34 to 0.72; p<0.001) Incidence per patient characteristics: Age 41-70 years: OR 2.13, CI 1.16 to 3.89, p<0.01 Age >70 years: OR 3.37, CI 1.46 to 7.81, p<0.0005 Vascular disease: OR 2.37, CI 1.10 to 4.89, p<0.02 Hemphill scale rating >4: 2.89, CI 1.25 to 6.69, p<0.01 | NR | NR | NR | Poor | NR |
| Inman, 199378 | Unclear, but requirement to be critically ill for inclusion | At risk | Unclear, but prevention is the intention of the study | Incidence\* Overall: 16.3% (8/49) vs. 79.6% (39/49); RR 0.21, 95% CI 0.11 to 0.39 Effect of air suspension bed on presence of pressure ulcers: OR 0.18 (0.08-0.41), p=0.0001 Single pressure ulcers: 12% (6/49) vs. 51% (25/49) Multiple pressure ulcers: 2% (1/49) vs. 24% (12/49) Effect of air suspension bed on presence of pressure ulcers: OR 0.11 (0.02-0.54), p=0.007 \*Estimated from figure. All significant differences. | Incidence\* Severe (>1 on Shea grading assessment) pressure ulcers:  4.1%% (2/49) vs. 28.6% (14/49)  Effect of air suspension bed on presence of pressure ulcers: OR 0.16 (0.06-0.44), p=0.0005 \*Estimated from figure. All significant differences. | Mean length of stay: 18.8 vs. 15.4 days | NR | Fair | Kinetic Concepts Inc, San Antonio, Texas, maker of the KinAir air suspension bed |
| Jesurum, 199679 Quasi-experimental pilot study | Braden score: 9.68 vs. 9.45 | At risk | - | Incidence\* Overall: 16.3% (8/49) vs. 79.6% (39/49); RR 0.21, 95% CI 0.11 to 0.39 Effect of air suspension bed on presence of pressure ulcers: OR 0.18 (0.08-0.41), p=0.0001 Single pressure ulcers: 12% (6/49) vs. 51% (25/49) Multiple pressure ulcers: 2% (1/49) vs. 24% (12/49) Effect of air suspension bed on presence of pressure ulcers: OR 0.11 (0.02-0.54), p=0.007 \*Estimated from figure. All significant differences. | Incidence\* Severe (>1 on Shea grading assessment) pressure ulcers:  4.1%% (2/49) vs. 28.6% (14/49)  Effect of air suspension bed on presence of pressure ulcers: OR 0.16 (0.06-0.44), p=0.0005 \*Estimated from figure. All significant differences. | Mean length of stay: 18.8 vs. 15.4 days | NR | Fair | Kinetic Concepts Inc, San Antonio, Texas, maker of the KinAir air suspension bed |
| Jolley, 200480 Open label randomized trial | Mean Braden score (range): 15.7 (13-18) vs. 15.9 (13-18) | At risk | No | Incidence of pressure ulcers (number patients): 9.6% (21/218) of patients developed 27 ulcers vs. 16.6% (37/223) patients developed 58 ulcers Rate ratio 0.42, 95% CI, 0.26 to 0.67) | Incidence of pressure ulcers:  All ulcers (grade 1 and 2; no grade 3 or 4 recorded)  Number of incident grade 2 ulcers (% of all ulcers): 12 (44%) vs. 20 (34%) | Mean bed days: 7.9 vs. 7.0 | Withdrawals due to heat-related discomfort: 5% (10/218) vs. 0% (0/223); RR 21, 95% CI, 1.3 to 364 | Fair | National Health and Medical Research Council of Australia grant; CSIRO Textile and Fibre Technology, Leather Research Center |
| Kemp, 199381 | Mean Braden score on admission (SD): 14.00 (1.73) vs. 13.85 (1.1), p=NS | At risk | None | Incidence (number of patients): 46.7% (21/45) vs. 30.8% (12/39), p=0.18 RR = 0.50, 95% CI 0.28-0.87 | Severity: Grade 1: 10 Grade 2: 47 | NR | NR | Fair | AARP Andrus Foundation; Gamma Phi Chapter of Sigma Theta Tau International |
| Keogh, 200182 | Waterlow score: NR Nutritional assessment score: 11.9 vs. 11.7 Mobility score: 3.4 vs. 3.7 | High | Grade I ulcers at baseline: 28.5% (10/35) vs. 11.4% (4/35) | Any pressure ulcer: 0% vs. 0% | NR | NR | NR | Fair | NR |
| Lazzara, 199183 | All had Norton score >15 | High risk | Ulcers at baseline: 21% (7/33) vs. 6% (2/33) | Incidence of pressure ulcers in patients without ulcers at baseline: 31.7% (8/26) vs. 32.3% (10/31); RR 0.95 (95% CI 0.44-2.06) | Improvement in severity: 58% (7/12) vs. 60% (9/15)  \*No differences between groups | NR | NR | Poor | Gaymar Industries |
| Lim, 198884 | Baseline Norton <14 for inclusion in study Mean Norton score (SD; range) of patients completing trial: 12.3 (1.4;10-16) vs. 12.3 (1.8;9-16) | At risk | No | Incidence of ulcers: By ulcer: 35 vs. 37, p>0.05 By patient: 69% (18/26) vs. 73% (19/26), p>0.05 | Severity Overall: 60% (44/72) of ulcers were grade 1; none progressed past grade 3 (Exton-Smith scale) number ulcers per group: 35 vs. 37, p>0.05 | NR | NR | Fair | Grant from the National Health Research and Development Program, Health and Welfare Canada |
| McGowan, 200085 | Mean Braden score: 13.9 vs. 14.01 | At risk | No | Incidence: 9% (14/155) patients developed 21 ulcers vs. 30.3% (43\*/142) patients developed 67 ulcers, p<0.0001 Rate Ratio 0.28 (95% CI, 0.16 to 0.46) \*40 with valid data | Severity Grade 1: All others Grade II: 4 Grade IV: 2 (both in same patient) | NR | Heat-related discomfort reported in unspecified number of group A patients; no incidence in group B (no data reported) | Poor | Sir Edward Dunlop Medical Research Foundation; Nurses Memorial Center Western Australia |
| Mistiaen, 201086 | Braden score ≤20: 70% vs. 71%, p=0.79 Braden score ≤18: 47% vs. 47%, p=0.84 | At risk | No, free of pressure ulcers at the sacrum at admission | Incidence (number sacral pressure ulcers): 8.9% (24/271) vs. 14.7% (40/272), p=0.035 RR = 0.60, 95% CI 0.37-0.97  After adjustment for baseline patient characteristics, differences between groups shows protective effect of sheepskin: OR 0.53 (95% CI, 0.29 to 0.95) Incidence (number ulcers elsewhere than sacral area; intervention only covers sacral area): 16.4% vs. 15.1%, p=0.69 | Severity, number sacral pressure ulcers (EPUAP grades): Grade 1 = 50 Grade 2 = 12 Grade 3 = 2 p=NS between groups | NR | One-third of group A patients complained of heat-related discomfort, leading to withdrawal for 2/3 of these patients; no incidence in group B (no data reported) | Fair | - |
| Nixon, 199887 | Pre-operative Braden score  10-14: 0% (1/222) vs. 0% (0/224) 15-19: 8% (17/222) vs. 10% (23/224) 20-23: 91% (202/222) vs. 89% (200/224) | Lower risk | Unclear, excludes grade 2 or above (may include grade 1) | Incidence (number of patients that failed Torrance scale):  11% (22/205) vs. 20% (43/211), p=0.01, OR = 0.46 (95% CI 0.26-0.82) | Severity: 56/65 ulcers conversions of grade 0 to grade 1 4/65 ulcers conversions of grade 0 to grade 2A 5/65 ulcers conversions of grade 0 to grade 2B | NR | NR | Fair | Northern and Yorkshire Regional Health Authority |
| Nixon, 200688 RCT  Same data as in Nixon, 2006 Health Technology Report | Mean Braden score: NR Bedfast: 81.3% vs. 76.8% | High risk | Grade 1b ulcers: 18.2% (180/989) vs. 14.8% (145/982) Wound (including ulcers and surgical wounds): 5.8% (57/989) vs. 6.1% (60/982) | Incidence of grade 2 or greater pressure ulcers: 10.7% (106/989) vs. 10.3% (101/982); Adjusted OR 0.94 (95% CI 0.68-1.29) | Median ulcer area: 1.2 sq. cm vs. 1.1 sq. cm | NR | 23.3% (230/990) vs. 18.9% (186/982) discontinued intervention for comfort or device-related reasons | Good | UK Department of Health |
| Russell, 200089 | Mean Modified Knoll risk score 3.6+1 vs. 3.8 +1, p=NS The highest attainable score is 33; a score of >12 indicates a greater risk for altered skin integrity | Lower risk | No | Incidence (number of patients that developed ulcers):  2.2% (2/98) vs. 7% (7/100), p=NS Incidence (number of ulcers):  2 vs. 10, p=NR | Severity (number of ulcers), p=NR Grade 1: 0 vs. 2 Grade 2: 2 vs. 5 Grade 3: 0 vs. 3 | NR | Adverse events: no difference between groups; no adverse events were treatment-related (no data reported) | Good | MicroPulse, Inc, Portage, Michigan |
| Russell, 200390 | Mean Waterlow score: 17 vs. 17 | High | Grade I ulcers at baseline: 12.4% (145/1168) | Any pressure ulcer (nonblanching erythema or worse), patients without prevalent erythema: 6.9% (34/494) vs. 9.3% (49/527); RR 0.74 (95% CI, 0.49 to 1.1) Any pressure ulcer, all patients: 15% (74/494) vs. 22% (115/527); RR 0.78 (95% CI 0.55 to 1.1) | NR | Mean bed days utilized per patient: 17.7 vs. 16.7 Number of dressings: 47.8 vs. 44.3 | NR | Good | NR |
| Sanada, 200391 | Mean Braden scale: 12.5 (1.7 SD) vs. 12.1 (1.4 SD) vs. 12.7 (1.7 SD), p=NS | At risk | No | Incidence (number patients that developed pressure ulcers): 3.4% (1/26) vs. 19.2% (5/29) vs. 37.0% (10/27), p<0.01 A vs. B: RR = 0.22, 95% CI 0.03-1.79 A vs. C: RR = 0.10, 95% CI 0.01-0.76 | Grade 1 (number ulcers): 0% (0/26) vs. 3% (1/29) vs. 15% (4/27), p=NR Grade 2 (number ulcers): 4% (1/26) vs. 14% (4/29) vs. 22% (6/27), p=NR | NR | NR | Poor | NR |
| Schultz, 199992 | Admit Braden score: 22.15 (1.98 SD) vs. 22.41 (1.34 SD) | Lower Risk | No | Incidence: 26.7% (55/206) vs. 16.4% (34/207), p=0.0111 | Severity, grade 2 or greater (number people): 2.9% (6/206) vs. 1.4% (3/207), p=NR | NR | NR | Good | Partially funded by Devon Industries, in conjunction with the AORN Foundation |
| Sideranko, 199293 | Unclear | Unclear risk | No | Incidence (number of patients that developed ulcers):  25% (5/20) vs. 5% (1/20) vs. 12% (2/17), p=NS | NR | Mean length of stay: 10 vs. 9.4 vs. 8.9 days | NR | Poor | NR |
| Stapleton, 198694 | Mean Norton scores: 12 vs. 12.8 vs. 12.9 | At risk | No | Incidence (number patients that developed ulcers): 34% (11/32) vs. 41% (14/34) vs. 35% (12/34), p=NR Incidence in patients >80 years:  63% (12/19) vs. 32% (7/22), p=0.055 RR = 1.99, 95% CI 0.98-4.00 | Severity (Border grading scale): Grade A: 2 vs. 1 vs. 2 Grade B: 9 vs. 5 vs. 8 Grade C: 0 vs. 3 vs. 2 Grade D: 0 vs. 5 vs. 0 | NR | NR | Poor | NR |
| Takala, 199695 | All patients <8 on Norton Scale | High risk | No | Incidence: 0 vs. 37% (7/19 patients) developed 13 ulcers, p<0.005 | Grade 1A: 9  Grade 1B: 4 (all in control group) | NR | NR | Poor | Ahlstrom Medical |
| Taylor, 199996 | Waterlow score: 19 vs. 17 | At risk | Unclear, intact skin but may have grade 1 ulceration | Incidence (number of patients that developed ulcers):  0% (0/22) vs. 9% (2/22), p=NR RR = 0.20, 95% CI 0.01-3.94 | Both “superficial” | Mean length of stay: 10.5 vs. 11.6 days | NR | Fair | NR |
| Theaker, 200597 | High risk, details NR | High risk | No | Incidence (number of patients that developed ulcers):  10% (3/30) vs. 19% (6/32), p=0.35 RR = 0.53, 95% CI 0.15-1.94 | Grade II: 8 Grade III: 1 | Mean duration on mattresses: no differences between groups | NR | Fair | NR |
| Tymec199798 | Mean Braden score: 11.8 | High risk | Unclear, intact skin on heel, but may have grade 1 ulceration | Incidence (ulcers):  6 vs. 2, p=NS | NR | NR | NR | Poor | EHOB Incorporated provided the Foot Waffles |
| van Leen, 2011 99 | Norton score between 5-8 at baseline: 61.9% vs. 53.7% Norton score between 9-12 at baseline: 38.1% vs. 46.3% | At risk, high risk | No | Incidence (number patients with ulcers):  4.8% (2/42) vs. 17.1% (7/41), p=0.088 RR = 0.28, 95% CI 0.06-1.26; p=0.0978 | Severity (number patients with ulcers): Grade 2: 1 vs. 2 Grade 3: 1 vs. 5 | NR | NR | Fair | NR |
| Vanderwee, 2005100 | Mean Braden score: 14.6 vs. 14.2 | High | Grade I ulcers at baseline: 33% (74/222) vs. 34% (76/225) | Pressure ulcer grade II-IV: 15% (34/222) vs. 16% (35/225); RR 0.98 (95% CI 0.64 to 1.5) | Stage 2 ulcer: 12% (26/222) vs. 15% (33/225); RR 0.80 (95% CI 0.49 to 1.3)  Stage 3 or 4 ulcer: 3.6% (8/222) vs. 0.9% (2/225); RR 4.1 (95% CI 0.87 to 19) | NR | NR | Good | Ghent University and Huntleigh Healthcare |
| Vyhlidal, 1997101 | Admission mean Braden scale: 14.7 vs. 14.5, p=0.75 | At risk | No | Incidence (number patients with ulcers): 25% (5/20) vs. 60% (12/20), p=0.025 Incidence (number ulcers): 5 vs. 16 RR = 0.42, 95% CI 0.18-0.96 | Severity (number patients): Stage 1: 2 vs. 4 Stage 2: 3 vs. 8 | NR | NR | Fair | NR. BG Industries (manufacturer) and Baxter Corporation (distributor) provided the MAXIFLOAT mattresses for the study. |