Support surfaces for pressure ulcer prevention (Review)

McInnes E, Jammali-Blasi A, Bell-Syer SEM, Dumville JC, Cullum N

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[Intervention Review]

Support surfaces for pressure ulcer prevention

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ABSTRACT

Background

Pressure ulcers (i.e. bedsores, pressure sores, decubitus ulcers) are areas of localised damage to the skin and underlying tissue. They are common in the elderly and immobile, and costly in financial and human terms. Pressure-relieving support surfaces (i.e. beds, mattresses, seat cushions etc) are used to help prevent ulcer development.

Objectives

This systematic review seeks to establish:

(1) the extent to which pressure-relieving support surfaces reduce the incidence of pressure ulcers compared with standard support surfaces, and,

(2) their comparative effectiveness in ulcer prevention.

Search methods

For this third update we searched: the Cochrane Wounds Group Specialised Register (searched 8 December 2010), The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 4); Ovid MEDLINE (1950 to November Week 3 2010); Ovid MEDLINE (In-Process & Other Non-Indexed Citations December 07, 2010); Ovid EMBASE (1980 to 2010 Week 48); EBSCO CINAHL (1982 to 3 December 2010), and the reference sections of included studies.

Selection criteria

Randomised controlled trials (RCTs) and quasi-randomised studies, published or unpublished, that assessed the effects of any support surface for prevention of pressure ulcers, in any patient group or setting which measured pressure ulcer incidence.Studies reporting only proxy outcomes (e.g. interface pressure) were excluded. Two review authors independently selected studies.

Data collection and analysis

Data were extracted by one author and checked by another. Where appropriate, estimates from similar studies were pooled for meta-analysis.

Main results

One new trial was included, bringing the total of included studies to 53.

Foam alternatives to standard hospital foam mattresses reduce the incidence of pressure ulcers in people at risk (RR 0.40 95% CI 0.21 to 0.74). The relative merits of alternating- and constant low-pressure devices are unclear. One high-quality trial suggested that alternating-pressure mattresses may be more cost effective than alternating-pressure overlays in a UK context.

Pressure-relieving overlays on the operating table reduce postoperative pressure ulcer incidence, although two studies indicated that foam overlays caused adverse skin changes. Meta-analysis of three trials indicated that Australian standard medical sheepskins prevent pressure ulcers (RR 0.56 95% CI 0.32 to 0.97).

Authors' conclusions

People at high risk of developing pressure ulcers should use higher-specification foam mattresses rather than standard hospital foam mattresses. The relative merits of higher-specification constant low-pressure and alternating-pressure support surfaces for preventing pressure ulcers are unclear, but alternating-pressure mattresses may be more cost effective than alternating-pressure overlays in a UK context. Medical grade sheepskins are associated with a decrease in pressure ulcer development. Organisations might consider the use of some forms of pressure relief for high risk patients in the operating theatre.

PLAIN LANGUAGE SUMMARY

Can pressure ulcers be prevented by using different support surfaces?

Pressure ulcers (also called bed sores and pressure sores) are ulcers on the skin caused by pressure or rubbing at the weight-bearing, bony points of immobilised people (such as hips, heels and elbows). Different support surfaces (e.g. beds, mattresses, mattress overlays and cushions) aim to relieve pressure, and are used to cushion vulnerable parts of the body and distribute the surface pressure more evenly. The review found that people lying on ordinary foam mattresses are more likely to get pressure ulcers than those lying on a higher-specification foam mattress. In addition the review also found that people who used sheepskin overlays on their mattress developed fewer pressure ulcers. While alternating-pressure mattresses may be more cost effective than alternating-pressure overlays, the evidence base regarding the merits of higher-specification constant low-pressure and alternating-pressure support surfaces for preventing pressure ulcers is unclear. Rigorous research comparing different support surfaces is needed.

BACKGROUND

Description of the condition

Pressure ulcers (also known as pressure sores, decubitus ulcers and bed sores) are areas of localised damage to the skin and underlying tissue, believed to be caused by pressure, shear or friction (EPUAP-NPUAP 2009). Pressure ulcers are more likely to occur in those who are seriously ill; neurologically compromised (e.g. individuals with spinal cord injuries (Elliot 1999)); have impaired mobility (Allman 1997; Berlowitz 1990; Berlowitz 1997; Bianchetti 1993); or who are immobile (including those wearing a prosthesis, body brace or plaster cast). Other risk factors include impaired nutrition (Banks 1998; Casey 1997; Casey 1998; Ek 1990); obesity (Gallagher 1997); poor posture, which puts extra pressure on bony prominences; or using equipment that does not provide appropriate pressure relief, such as seating or beds. Pressure ulcers particularly affect older people (Hefley 1990; Krainski 1992; Orlando 1998; Pase 1998; Ronda 2002; Spoelhof 2000; Thomas 2001; Waltman 1991); but have also been reported in pregnant women (Prior 2002). Pressure ulcers have also been associated with an increased incidence of infection, including osteomyelitis (Darouiche 1994).

The development of pressure ulcers is relatively common. A review of epidemiological studies in Europe, Canada and the USA described the reported prevalence of pressure ulcers in European hospitals as ranging from 8.3% to 23% (Vanderwee 2007). In the UK, the overall prevalence of pressure ulcers within care settings was 10.2%, with 59% of these being hospital-acquired (Phillips

2009). In the USA and Canada, prevalence ranged from 12.3% in US health care facilities (VanGilder 2009), to 33% in patients in the community with spinal cord injury, and the overall estimate of pressure ulcer incidence in Canadian healthcare settings has been reported as 26% (Woodbury 2004). The presence of pressure ulcers has been associated with a two- to four-fold increase in risk of death in older people in intensive care units, however, these findings were not adjusted for other prognostic factors (Bo 2003; Clough 1994; Thomas 1996). Based on the available European data, it has been estimated that between one-in-four and one-in-five patients within an acute hospital setting (i.e. neurology, ICU, chronic and acute care units) will have had a pressure ulcer (Vanderwee 2007). Estimates on pressure ulcer incidence and prevalence from hospital-based studies vary widely according to the definition and grade of ulcer, the patient population and care setting. Within the community, the incidence rate within the UK ranges from 4.4% to 6.8%, and in the USA and Canada it is up to 16.5% (Kaltenhalter 2001).

Tthe financial cost of treating ulcers in the UK varies from GBP 1,064 for a grade 1 ulcer to GBP 10,551 for a grade 4 ulcer, with total costs in the UK estimated as being GBP 1.4 to 2.1 billion annually, which is equivalent to 4% of the total National Health Service (NHS) expenditure (Bennett 2004). National prevalence and incidence data from the US report, based on a 24 hour data collection period at each participating institution, indicate that the annual cost to the American health system of treating all hospital-acquired pressure ulcers to be between USD 2.2 and 3.6 billion (Whittington 2004).

Healthcare professionals attempt to prevent and treat pressure ulcers by using a variety of support surfaces with the aim of relieving pressure. These include - but are not limited to - mattresses, beds, overlays, cushions and chairs. A summary of the available support surfaces for pressure ulcer treatment is the subject of another Cochrane review which is in preparation (Support surfaces for treating pressure ulcers).

Description of the intervention

The aim of pressure ulcer prevention strategies is to reduce either the magnitude, or duration, of pressure between a patient and his (or her) support surface (i.e. the interface pressure), or both. This may be achieved by regular manual repositioning (e.g. two-hourly turning), or by using pressure-relieving support surfaces such as cushions, mattress overlays, replacement mattresses or whole bed replacements, which are widely used in both institutional and non-institutional settings. Often a combination of repositioning and support surface enhancement may be used. Support surfaces are used with the aim of redistributing pressure, reducing shearing forces and controlling the local microclimate. The cost of these interventions varies widely; from over GBP 30,000 for some bed replacements, to less than GBP 100 for some foam overlays. Information on the relative cost-effectiveness of this equipment is needed to inform use.

How the intervention might work

Pressure-relieving cushions, beds and mattresses either mould around the shape of the patient to distribute the patient's weight over a larger contact area (constant low-pressure devices) (CLP); or vary the pressure beneath the patient mechanically, thus reducing the duration of the applied pressure (alternating-pressure devices) (AP) (Bliss 1993). CLP devices (either overlays, mattresses or replacement beds) can be grouped according to their construction (foam, foam and air, foam and gel, profiled foam, hammocks, air suspension, water suspension and air-particulate suspension/air-fluidised). These devices fit, or mould, around the body so that the pressure is dispersed over a large area, and are mainly classified as being of a lower technological specification (i.e. "low-tech"). By comparison, air-fluidised beds, where warmed air circulates through fine ceramic beads covered by a permeable sheet, and low-air-loss beds, where patients are supported on a series of air sacs through which warmed air passes, are high-specification CLP devices.

Alternating-pressure devices generate alternating high and low interface pressures between body and support, usually by alternate inflation and deflation of air-filled cells. Such devices are available as cushions, mattress overlays, and single-or multi-layer mattress replacements. These devices are classified as being high specification (i.e. "high-tech").

Other support surfaces, such as turning beds, turning frames, net beds, and turning/tilting beds move patients who are unable to turn themselves manually or automatically. Pressure ulcer prevention is often not the reason for using turning and tilting beds, which may be used in Intensive and Critical Care Units for other reasons, e.g. to promote chest drainage.

Why it is important to do this review

Research indicates that pressure ulcers represent a major burden of sickness and reduced quality of life for patients, their carers (Franks 1999; Franks 2002; Hagelstein 1995), and their families (Benbow 1996; Elliot 1999). Often patients who develop pressure ulcers require prolonged and frequent contact with the healthcare system; and suffer much pain (Emflorgo 1999; Flock 2003; Freeman 2001; Healy 2003; Manfredi 2002), discomfort and inconvenience (Franks 1999).

The presence of a pressure ulcer creates a number of significant difficulties psychologically, physically and clinically to patients, carers and their families. Clinicians, working in a variety of clinical and non-clinical settings, including primary care and acute trusts, also face challenges when providing holistic, person-centred services for the assessment and treatment of pressure ulcers.

These challenges include clinical decisions regarding methods of assessment, and which treatments to use on individuals with an existing pressure ulcer.

Healthcare professionals attempt to reduce the incidence of severe pressure ulcers by the identification of people at high risk, and the use of preventative strategies, such as the deployment of pressure-relieving equipment. It is essential that initiatives are based on the best available clinical- and cost-effectiveness evidence, and we have, therefore, undertaken a systematic review of the evidence for the effectiveness of pressure-relieving support surfaces such as beds, mattresses, cushions, and repositioning interventions.

OBJECTIVES

This systematic review seeks to answer the following questions:

- to what extent do pressure-relieving cushions, beds, mattress overlays and mattress replacements reduce the incidence of pressure ulcers compared with standard support surfaces?
- how effective, compared to one another, are different pressure-relieving surfaces in preventing pressure ulcers?

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) and quasi-randomised trials comparing support surfaces, and which measured the incidence of new pressure ulcers. Studies that only reported subjective measures of outcome (e.g. skin condition "better" or "worse") were excluded, as were studies that reported only proxy measures such as interface pressure. Trials were eligible for inclusion if they reported an objective, clinical, outcome measure such as incidence and severity of new pressure ulcers developed.

Types of participants

People receiving health care who were deemed to be at risk of developing pressure ulcers, in any setting. Some studies involved people who had existing pressure ulcers, however, only the incidence of new pressure ulcers was examined.

Types of interventions

Studies which evaluated the following interventions for preventing pressure ulcers were included:

1. "Low-tech" CLP support surfaces

- Standard foam mattresses.
- Alternative foam mattresses/overlays (e.g. convoluted foam, cubed foam): these are conformable and aim to redistribute pressure over a larger contact area.
- Gel-filled mattresses/overlays: mode of action as above.
- Fibre-filled mattresses/overlays: mode of action as above.
- Air-filled mattresses/overlays: mode of action as above.
- Water-filled mattresses/overlays: mode of action as above.
- Bead-filled mattresses/overlays: mode of action as above.
- Sheepskins: proposed mode of action unclear.

2. "High-tech" support surfaces

- Alternating-pressure (AP) mattresses/overlays: patient lies on air-filled sacs that inflate and deflate sequentially to relieve pressure at different anatomical sites for short periods; these may incorporate a pressure sensor.
- Air-fluidised beds: warmed air circulates through fine ceramic beads covered by a permeable sheet; allowing support over a larger contact area (CLP).
- Low-air-loss beds: patients are supported on a series of air sacs through which warmed air passes (CLP).

3. Other support surfaces

- Turning beds/frames: these work either by aiding manual repositioning of the patient, or by motor driven turning and tilting.
- Operating table overlays: mode of action as above.
- Wheelchair cushions: either conforming cushions that reduce contact pressures by increasing surface area in contact, or mechanical cushions e.g. alternating pressure.
- Limb protectors: pads and cushions of different forms to protect bony prominences.

Types of outcome measures

Primary outcomes

1. Incidence of new pressure ulcers

Many evaluations simply measure the pressure on different parts of the body in contact with the support surface (i.e. the interface pressure). This, however, is an intermediate, or surrogate, outcome measure with serious limitations as a proxy for a clinical outcome, since the process which leads to the development of a pressure ulcer almost certainly involves the complex interplay of several factors. In this review we have only considered trials that reported the clinical outcome measure of pressure ulcer incidence.

Some studies do not differentiate between those people who develop grade 1 ulcers (in which the skin is unbroken), and those who develop more severe ulcers. Studies that compare the incidence of pressure ulcers of grade 2 or greater are more likely to be reliable (see below for details of grading system), however, we included all studies irrespective of whether grade 1 ulcers were described separately.

2. Grades of new pressure ulcers

Various pressure ulcer severity classification systems are in use, including in trials of pressure relieving interventions. An example of a commonly-used grading system is presented below; this has been adapted from an EPUAP classification system (www.epuap.org.uk):
Grade 1: persistent discolouration of the skin including non-blanchable erythema; blue/purple/black discolouration.
Grade 2: partial-thickness skin loss involving epidermis and dermis.
Grade 3: full-thickness skin loss involving damage or necrosis of subcutaneous tissues, but not through the underlying fascia, and not extending to the underlying bone, tendon or joint capsule.
Grade 4: full-thickness skin loss with extensive destruction and tissue necrosis extending to the underlying bone, tendon or joint capsule.

Secondary outcomes

- Costs of the devices.
- Patient comfort.
- Durability/longevity of the devices.
- Acceptability of the devices for healthcare staff.
- Quality of life.

Search methods for identification of studies

See Appendix 1 for the search methods used in the second update of this review.

Electronic searches

For this third review update, the following databases were searched:

- Cochrane Wounds Group Specialised Register (searched 8 December 2010);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2010, Issue 4);
- Ovid MEDLINE (1950 to November Week 3 2010);Ovid MEDLINE (In-Process & Other Non-Indexed Citations December 07, 2010);
- Ovid EMBASE (1980 to 2010 Week 48);
- EBSCO CINAHL (1982 to 3 December 2010)

The following search strategy was used for CENTRAL and modified, where appropriate, for other databases:
#1 MeSH descriptor Beds explode all trees
#2 mattress*
#3 cushion*
#4 "foam" or transfoam
#5 overlay*
#6 "pad" or "pads"
#7 "gel"
#8 pressure NEXT relie*
#9 pressure NEXT reduc*
#10 pressure NEXT alleviat*
#11 "low pressure" NEAR/2 device*
#12 "low pressure" NEAR/2 support
#13 constant NEAR/2 pressure
#14 "static air"
#15 alternat* NEXT pressure
#16 air NEXT suspension*
#17 air NEXT bag*
#18 water NEXT suspension*
#19 elevation NEAR/2 device*
#20 clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or "foot waffle" or silicore or pegasus or cairwave
#21 (turn* or tilt*) NEXT (bed* or frame*)
#22 kinetic NEXT (therapy or table*)
#23 net NEXT bed*
#24 "positioning" or "repositioning"
#25 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24)
#26 MeSH descriptor Pressure Ulcer explode all trees
#27 pressure NEXT (ulcer* or sore*)
#28 decubitus NEXT (ulcer* or sore*)
#29 (bed NEXT sore*) or bedsore*
#30 (#26 OR #27 OR #28 OR #29)
#31 (#25 AND #30)
The search strategies for Ovid MEDLINE, Ovid EMBASE and EBSCO CINAHL can be found in Appendix 2, Appendix 3 and Appendix 4 respectively. The MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision)(Lefebvre 2009). The EMBASE and CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2008). There was no restriction on the basis of the language in which the study reports were written, nor publication status.

Searching other resources

Originally, experts in the field of wound care were contacted to enquire about potentially-relevant ongoing, and recently published,

trials. In addition, manufacturers of support surfaces were contacted for details of any trials they were conducting. This process was not productive, and so was not repeated for this update. However, reference lists within obtained reviews and papers were scrutinised in an effort to identify additional studies.

Data collection and analysis

Selection of studies

For this update the titles and abstracts of the search results were assessed for relevance independently by two review authors (EMcI, AJ-B). Full copies of all potentially-relevant studies were obtained. Decisions on final inclusion after retrieval of full papers was made by one review author (EMcI), and was checked by a second (AJ-B); disagreements were resolved by discussion with a third review author (NC or SB-S). Rejected studies were checked by a third review author (SB-S or NC).

Data extraction and management

Two review authors extracted details of included studies independently using a pre-prepared data extraction sheet. We resolved any disagreements over data by discussion, with referral to a third review author for adjudication if necessary. The following data were extracted from each study:

- Care setting.
- Clear description of main interventions.
- Key baseline variables by group, for example, age, sex, baseline risk of pressure ulcer development, baseline area of existing ulcers.
- Description of the interventions and numbers of patients randomised to each intervention.
- Description of any co-interventions/standard care.
- Duration and extent of follow-up.
- Acceptability and reliability of equipment within the clinical setting.
- Description of inclusion and exclusion criteria used to derive the sample from the target population.
- Description of a priori sample size calculation.
- Incident ulcers described by severity grading as well as frequency (grade 1 ulcers are not breaks in the skin and are subject to more inter-rater variation).

Assessment of risk of bias in included studies

For the update of this review, two review authors assessed each included study independently using the Cochrane Collaboration tool for assessing risk of bias (Higgins 2008). This tool addresses six specific domains, namely sequence generation; allocation concealment; blinding of either participants, or personnel or assessors, or any combination of the three; incomplete outcome data; selective outcome reporting and other issues (e.g. extreme baseline imbalance) (see Appendix 5 for details of criteria on which the judgements are based). Blinding and completeness of outcome data were assessed separately for each outcome. We completed a risk of bias table for each eligible study. We discussed any disagreement amongst all review authors to achieve a consensus. We presented an assessment of risk of bias using a risk of bias summary figure, which presents all of the judgments in a cross-tabulation of study by entry. Evaluating the validity of each study may assist the reader in interpreting and making conclusions about the study.

Dealing with missing data

When a paper provided insufficient information for full data extraction, or if conflicting data were found, we approached study authors for additional information. Where there are losses to follow and a treatment effect exists we plan to test the robustness of the result to different assumptions in dealing with the missing data, for example assuming all losses did not develop pressure ulcers. We included studies published in duplicate only once; we nominated a primary data source, although we reviewed secondary publications for additional data.

Data synthesis

For each trial, we calculated relative risk (RR) for categorical outcomes such as number of patients developing ulcers, with 95% confidence intervals (95% CI). The results were plotted on to graphs and discussed by narrative review. Individual study details are presented in the Characteristics of included studies table. Where there was more than one trial comparing similar devices using the same outcome (though possibly differing lengths of follow-up), statistical heterogeneity was assessed by means of the I^2 statistic (Higgins 2003). An I^2 value greater than 50% indicates substantial heterogeneity, and will be considered statistically significant where the P value is less than 0.10 (Higgins 2003). In the absence of significant statistical heterogeneity, studies with similar comparisons were pooled using a fixed-effect model. If heterogeneity was observed, a random-effects model was used.
For the purpose of meta-analysis we assumed that the risk ratio remained constant for different lengths of follow-up, hence studies were pooled if participants were followed-up for different lengths of time. All statistical analysis were performed on RevMan 5.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.

Results of the search

The search for the third update of this review resulted in the inclusion of one new trial (Mistiaen 2009). Seven studies that had been awaiting assessment were excluded (Büchner 1995; Defloor 1997; Geelkerken 1994; Haalboom 1994; Holzgreve 1993; Neander 1996; Zernike 1994) and their details added to the Characteristics of excluded studies table. A further 11 studies which were retrieved in full did not meet the inclusion criteria and were excluded (Della Valle 2001; Gil Agudo 2009; Gray 2008; Grisell 2008; Heyneman 2009; Huang 2009; McMichael 2008; Timmons 2008; Turnage-Carrier 2008; Vanderwee 2007; Vanderwee 2008) (see Characteristics of excluded studies table for reasons). One study remained classified as awaiting assessment, as further information has been sought from the study author (Berthe 2007); one study Allegretti 2008 was classified as awaiting assessment pending full publication of the study and five studies are awaiting full text retrieval (Demarré 2010; Mastrangelo 2010; Mayer 2008; Taccone 2009; van Leen 2011).

Included studies

The one new included study brought the total number of included trials to 53 (Mistiaen 2009) (see Characteristics of included studies and Table 1). Twenty-seven trials involved participants without pre-existing pressure ulcers (intact skin); eight trials included patients with ulcers greater than or equal to grade 1 at baseline; four trials did not specify the grading of the pre-existing ulcers, and one trial only included people with grade 4 pressure ulcers. In 12 trials the baseline skin status of the participants was unclear.

Study settings

Five studies evaluated different operating table surfaces (Aronovitch 1999; Feuchtinger 2006; Nixon 1998; Russell 2000; Schultz 1999); nine evaluated different surfaces in intensive care units (ICU) (Cadue 2008; Gebhardt 1996; Gentilello 1988; Inman 1993; Laurent 1998; Sideranko 1992; Summer 1989; Takala 1996; Theaker 2005); eight studies confined their evaluation to orthopaedic patients (Cooper 1998; Exton-Smith 1982; Goldstone 1982; Hofman 1994; McGowan 2000; Price 1999; Santy 1994; Stapleton 1986); and one involved both an Accident & Emergency and ward setting (Gunningberg 2000). Five studies were set in extended care facilities (Conine 1990; Conine 1993; Conine 1994; Daechsel 1985; Lim 1988); three studies were set in nursing homes (Geyer 2001; Lazzara 1991; Mistiaen 2009); seven studies involved two or more different hospital wards (Bennett 1998; Cavicchioli 2007; Cobb 1997; Gray 1994; Kemp 1993; Russell 2003; Vanderwee 2005). Fifteen studies did not specify the study setting (Andersen 1982; Collier 1996; Economides 1995; Ewing 1964; Gilcreast 2005; Gray 1998; Hampton 1997; Jolley 2004; Keogh 2001; Nixon 2006; Sanada 2003; Taylor 1999; Tymec 1997; Vyhlidal 1997; Whitney 1984).

Interventions

Eleven trials evaluated cushions; four evaluated the use of sheepskins; four looked at turning beds/tables; sixteen examined overlays; 27 looked at mattresses; three evaluated foam surfaces, and two examined waffle surfaces. A number of studies evaluated multiple interventions.

Small sample size

Small sample size was a major limitation of many of the studies; the median sample size was 100 (range 12 to 1972), and only 20 studies reported an *a priori* sample size estimate.

Excluded studies

In total 59 studies were excluded from the review. Two were literature reviews (Heyneman 2009; Vanderwee 2008); eight studies reported insufficient information or data to allow a complete assessment and no further information was available through contact with the study authors (Barhyte 1995; Braniff-Matthews 1997; Bliss 1995; Geelkerken 1994 Holzgreve 1993; Neander 1996; Scott 1995; Zernike 1994); 20 studies did not report clinical ulcer-related outcomes (Allen 1993; Ballard 1997; Brienza 2001; Colin 1996; deBoisblanc 1993; Della Valle 2001; Flam 1995; Gil Agudo 2009; Grindley 1996; Grisell 2008; Koo 1995; McMichael 2008; Rosenthal 1996; Scott 1999; Suarez 1995; Takala 1994; Turnage-Carrier 2008; Wells 1984; Wild 1991; Zernike 1997); 11 studies did not use an eligible study design (Bliss 1967; Büchner 1995; Chaloner 2000; Gray 2008; Gunningberg 1998; Marchand 1993; Ooka 1995; Phillips 1999; Regan 1995; Reynolds 1994; Stoneberg 1986); nine studies did not consider the intervention of interest, i.e. a support surface, (Defloor 1997; Defloor 2000; Defloor 2004; Huang 2009; Inman 1999; Jacksich 1997; Jesurum 1996; Torra i Bou 2002; Vanderwee 2007) and nine studies did not meet the inclusion criteria for the review in other ways (Andrews 1989; Conine 1991; Fleischer 1997; Haalboom 1994; Hampton 1998; Hawkins 1997; Scott 2000; Thomas 1994; Timmons 2008).

Of the 20 studies which did not report clinical ulcer-related outcomes, 14 recorded only interface pressure (Allen 1993; Brienza 2001; Della Valle 2001; Gil Agudo 2009; Grisell 2008; Koo 1995; McMichael 2008; Rosenthal 1996; Scott 1999; Suarez 1995; Takala 1994; Turnage-Carrier 2008; Wells 1984; Wild 1991; two reported comfort data (Ballard 1997; Grindley 1996); Colin 1996 measured transcutaneous oxygen tension; deBoisblanc 1993 reported pneumonia as the outcome, Flam 1995 skin temperature and moisture level and Zernike 1997 did not report the incidence of pressure ulcers

Risk of bias in included studies

Details of the risk of bias of each individual study are included in Characteristics of included studies and shown in Figure 1 and Figure 2.

Figure 1. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

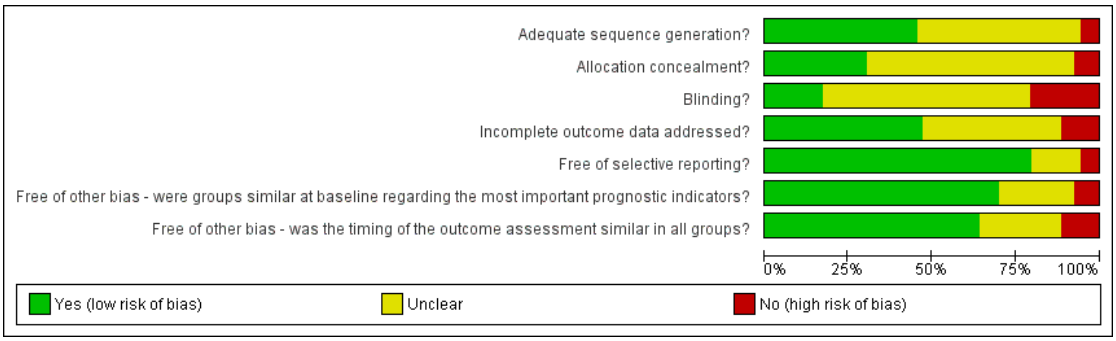
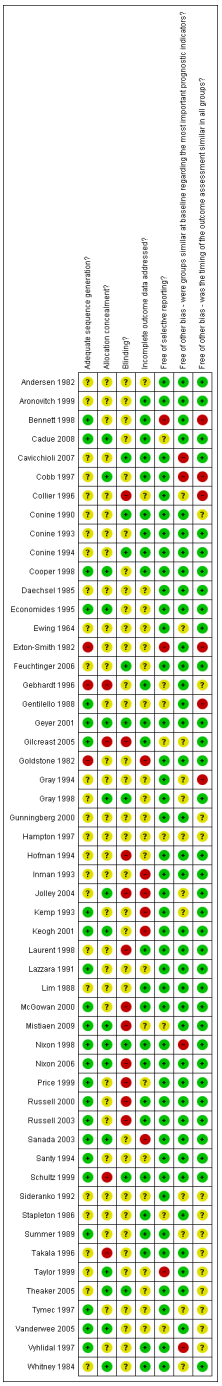


Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.



Allocation

The method of randomisation was unclear in 27 of the 53 (51%) included studies. Although the majority of trials reported patient eligibility criteria, fewer than half of the reports gave information that indicated patients were allocated with concealed allocation (16 of the 53 trials or 30%).

Blinding

Blinded outcome assessment is rarely used in wound care studies, and this was the case in these evaluations of support surfaces. It can be difficult or impossible to disguise the surface that a patient is on for assessment of outcome, and patients are often too ill to be removed from their beds for assessment of their pressure areas. Nevertheless, some studies minimise bias in outcome assessment by having a second assessor and presenting inter-rater reliability data, or by presenting photographic evidence of pressure area status which can then be assessed by an independent assessor blinded to treatment. Of the 53 RCTs in this review, we could be confident that blinded outcome assessment had been used in only eight trials (15%).

Incomplete outcome data

Assessment of whether incomplete outcome data had been adequately addressed in each study involved examining whether reasons for attrition or exclusion were reported; whether there was re-inclusion of participants; and whether the completeness of data for each main outcome was described. Twenty-five of the 53 studies reviewed (i.e. 47%) adequately addressed incomplete outcome data. Six of the remaining studies did not address incomplete outcome data adequately, and, for the final 22 studies it was unclear or unstated. High attrition rates and lack of an intention-to-treat analysis were also common.

Selective reporting

For a study to have demonstrated it was free of selective outcome reporting, a study protocol stating all pre-specified outcomes needed to have been reported, or, if the study protocol was not available, clear inclusion of all expected outcomes (including pre-specified outcomes). We were satisfied that forty-two out of 53 (79%) of the studies were free of selective outcome reporting. Three studies were not free of selective outcome reporting due to: pre-specified outcomes not being completely reported, incomplete reporting of outcomes, or reporting of outcomes that were not pre-specified (Bennett 1998; Exton-Smith 1982; Taylor 1999). For eight studies, there was insufficient information to classify whether there was or was not selective outcome reporting (Cadue 2008; Gebhardt 1996; Gentilello 1988; Gilcreast 2005; Hampton 1997; Mistiaen 2009; Stapleton 1986; Vanderwee 2005). We cannot exclude the possibility that we have introduced some level of bias by excluding studies which did not report 'pressure ulcer outcomes', this issue will be explored in more detail in the next update.

Other potential sources of bias

Other potential sources of bias included assessing whether the timing of outcomes under investigation were similar in both groups, and whether the groups under investigation were similar at baseline regarding the most important prognostic indicators. Timing of outcomes under investigation were similar in both groups under investigation in 33 (62%) of the 53 studies. In studies of pressure ulcer prevention, it is extremely important for trialists to report the baseline comparability of the intervention groups for important variables such as baseline risk. Amongst the included studies, risk of pressure ulcer development was measured by a variety of tools including the Norton (Norton 1979), Waterlow (Waterlow 1985), Gosnell (Gosnell 1973) and Braden (Bergstrom 1998) scales. Some of the studies reviewed here did not present such baseline data, nor explain what the various cut-offs for inclusion in the studies meant in terms of whether study participants were at low, medium or high risk for the development of pressure ulcers. Baseline characteristics were similar between the groups under investigation in 37 (70%) of the 53 studies. Another shortcoming was that trial reports were unclear about whether grade 1 pressure ulcers were included in the study sample or the analysis, or both.

Risk of bias was not used to weight the studies in the analysis using any statistical technique, however, methodological quality is discussed in relation to the interpretation of the results. Methodological flaws for each study are presented in Characteristics of included studies.

Effects of interventions

How the results are presented and what the terms mean

Results of dichotomous variables are presented as risk ratio (RR) with 95% confidence intervals (CI). Risk ratio has been used rather than odds ratios as it is easier to interpret than odds ratios (Deeks 1998). Risk ratio is the pressure ulcer incidence rate in the experimental group divided by the incidence rate in the control group and indicates the likelihood of pressure ulcer development on an experimental device compared with a comparison device. As, by definition, the risk of an ulcer developing in the control group is one, then the relative risk reduction associated with using the experimental bed is one-minus-RR. The risk ratio indicates the

relative benefit of a therapy, but not the actual benefit, i.e. it does not take into account the number of people who would have developed an ulcer anyway. The absolute risk reduction (ARR) can be calculated by subtracting the incidence rate in the experimental group from the incidence rate in the control group. The ARR tells us how much the reduction is due to the support surface itself, and its inverse is the number needed to treat, or NNT. Thus an incidence rate of 30% on a control mattress reduced to 15% with an experimental mattress translates into an ARR of 30-15 = 15% or 0.15, and an NNT of seven, in other words seven patients would need to receive the experimental mattress to prevent the development of one additional pressure ulcer.

Methods for measuring secondary outcomes such as comfort, durability, reliability and acceptability were not well developed. Where data were presented they appear in the Characteristics of included studies, but were not incorporated in the analysis.

1. "Low-tech" constant low-pressure (CLP) supports

This section considers comparisons of standard foam hospital mattresses with other low specification (low-tech), constant low-pressure (CLP) supports. We regarded the following as low-tech CLP: sheepskin, static air-filled supports; water-filled supports; contoured or textured foam supports; gel-filled supports; bead-filled supports; fibre-filled supports, and alternative foam mattresses or overlays. It should be emphasised, however, that there is no international definition of what constitutes a standard foam hospital mattress, and, indeed, this changes over time within countries, and even within hospitals. Where a description of the standard was provided it is included in the Characteristics of included studies table. We have assumed that standard mattresses are likely to vary less within countries than between countries, and undertook subgroup analysis by country, although this was not pre-specified.

1.1 Standard foam hospital mattress compared with other "low-tech" CLP

Eight RCTs compared 'standard' mattresses or surfaces with "low-tech" supports for the prevention of pressure ulcers (Andersen 1982; Collier 1996; Goldstone 1982; Gray 1994; Gunningberg 2000; Hofman 1994; Russell 2003; Santy 1994).

When compared with standard hospital mattresses, the incidence and severity of pressure ulcers in patients deemed to be high risk were significantly reduced when patients were placed on either the cubed foam mattress (Comfortex DeCube) (RR 0.34; 95% CI 0.14 to 0.85) (Hofman 1994); the bead-filled mattress (Beaufort bead bed) (RR 0.32; 95% CI 0.14 to 0.76) (Goldstone 1982); the Softfoam mattress (RR 0.2; 95% CI 0.09 to 0.45) (Gray 1994); or the water-filled mattress (RR 0.35; 95% CI 0.15 to 0.79) (Andersen 1982) (Analysis 1.1).

In an unpublished British study of older people with hip fractures admitted to orthopaedic trauma wards, patients allocated to receive the then NHS standard foam mattress (manufactured by Relyon) experienced over three times the rate of pressure ulcers experienced by those using one of a number of foam alternatives (Clinifloat, Therarest, Transfoam and Vaperm) (RR 0.36; 95% CI 0.22 to 0.59) (Santy 1994). Another study found a significant decrease in the incidence of grade 1 pressure ulcers from 26.3% to 19.9% (P value 0.0004), and a non-significant decrease in the incidence of pressure ulcers grade 2 to 4 from 10.9% to 8.5% in patients allocated to the high-specification foam mattress/cushion (CONFOR-med) (RR 0.78; 95% CI 0.55 to 1.11) (Russell 2003). No patient developed a pressure ulcer in the Collier 1996 trial which involved a comparison of eight different foam mattresses (Reylon, Clinifloat, Omnifoam, Softform, STM5, Therarest, Transfoam and Vapourlux). The comparisons were considered too heterogeneous, and so we did not pool these seven studies (Analysis 1.1).

Gunningberg 2000 examined the effects of a viscoelastic foam trolley mattress and subsequent overlay on 101 patients with a suspected hip fracture in the Accident & Emergency (A&E) and ward setting. There was no significant difference in pressure ulcer incidence between those assigned a visco-elastic foam trolley mattress on arrival in A&E followed by a viscoelastic foam overlay on the standard ward mattress (4/48, 8%) and those assigned a standard trolley mattress and then a standard hospital mattress on the ward (8/53, 15%).

The five trials comparing foam alternatives with the standard hospital foam mattress were pooled using a random-effects model (I^2 = 77%) (Collier 1996; Gray 1994; Hofman 1994; Russell 2003; Santy 1994). These trials were of mixed quality; they all provided evidence of allocation concealment, but none used blinded outcome assessment. To avoid double counting the control patients in the trials with more than two comparisons, and in the absence of major differences between the effects of different foams, the foam alternatives were pooled. This approach maintains the randomisation, but resulted in comparison groups of unequal size. This analysis yielded a pooled risk ratio of 0.40 (95% CI 0.21 to 0.74), or a relative reduction in pressure ulcer incidence of 60% (95% CI 26% to 79%) (Analysis 2.1). Concern regarding the heterogeneity in standard hospital mattress between these trials led us to undertake a separate meta analysis of UK-based studies (where variation in the standard hospital mattress is likely to be lower). Pooling the four studies which compared alternative foam supports with standard foam mattresses in the UK resulted in the significant benefit of alternative foam over standard foam being maintained (RR 0.41; 95% CI 0.19 to 0.87) (Analysis 2.2) (Collier 1996; Gray 1994; Russell 2003; Santy 1994). However, the heterogeneity remained high (I^2= 84%; P value 0.002), and Russell 2003 was removed as it was the only study that clearly included grade 1 ulcers as incident ulcers, thereby potentially inflating its results compared with the other trials. This resulted in I^2 being reduced to 39% (P value 0.20), and the results still favoured the alternative foam support over standard support (RR 0.29 95% CI 0.16 to

0.52). Therefore, foam alternatives to the standard hospital mattress significantly reduce the incidence of pressure ulcers in at-risk patients, including patients with fractured neck of femur, when compared with the standard hospital foam.

1.2 Comparisons between alternative foam mattresses

This section covers results of head-to-head comparisons between high-specification foam products (i.e. contoured foam, support surfaces comprising foam of different densities). Five RCTs compared different foam mattresses (Analysis 3.1) (Collier 1996; Gray 1998; Kemp 1993; Santy 1994; Vyhlidal 1997).

No patients developed a pressure ulcer in the Collier 1996 trial, reported in the section above, which compared eight different foam mattresses. Santy 1994 and colleagues compared five alternative foam mattresses (Clinifloat, Vaperm, Therarest, Transfoam, NHS standard foam), and found significant reductions in pressure ulcer incidence associated with Clinifloat, Therarest, Vaperm and Transfoam compared with standard foam; and Vaperm compared with Clinifloat (RR 0.36; 95% CI 0.22 to 0.59). Vyhlidal 1997 compared a 4-inch thick foam overlay (Iris 3000) with a foam and fibre mattress replacement (Maxifloat), and reported a significant reduction in pressure ulcer incidence with the mattress replacement (RR 0.42; 95% CI 0.18 to 0.96), however, this trial did not state the methods used for allocation concealment nor blinded outcome assessment clearly.

Kemp 1993 compared a convoluted foam overlay with a solid foam overlay in only 84 patients, and found no significant difference in pressure ulcer incidence rates, however, this may be a Type 2 error, as the small sample size may have precluded detection of a clinically important difference as statistically significant (RR 0.66; 95% CI 0.37 to 1.16). Gray 1998 compared the Transfoam and Transfoamwave foam mattresses, however, only one patient in each group (50 in each arm) developed an ulcer. Analysis 3.1.

In summary, existing evidence is inadequate to guide choice between alternative foam mattresses.

1.3 Comparisons between "low-tech" constant low-pressure supports

This section covers head-to-head comparisons of the following types of support: foams; static air-filled supports (including dry flotation); water-filled supports; gel-filled supports; silicore-filled supports; heel elevators and sheepskins (Analysis 4.1). These devices and support surfaces feature particular or specialised technologies and therefore are considered in a separate category. [NB: 'Silicore' fibres are said to resist matting down and to provide insulation against heat or cold]

Eleven RCTs compared different "low-tech" CLP devices (Cadue 2008; Cooper 1998; Ewing 1964; Gilcreast 2005; Jolley 2004; Lazzara 1991; McGowan 2000; Sideranko 1992; Stapleton 1986; Takala 1996; Tymec 1997). Most of these trials were underpowered with, or without other methodological flaws.

- **Static air-filled supports (including dry flotation); water-filled supports; gel-filled supports; silicore-filled supports**

A trial from Finland (Takala 1996), compared a constant low-pressure mattress (Optima, Carital) - that consists of 21 double air bags on a base - with the standard hospital mattress and found that significantly more patients (37%) developed ulcers on the standard mattress than on the CLP mattress (on which nobody developed an ulcer) (RR 0.06; 95% CI 0 to 0.99). The report of this study did not describe either allocation concealment or blinded outcome assessment.

The remaining trials were all unique comparisons with low power (Cooper 1998; Lazzara 1991; Sideranko 1992; Stapleton 1986), and none found statistically significant differences between the surfaces tested (Analysis 4.1).

- **Heel devices**

One trial (52 patients) compared a proprietary heel elevation device (Foot Waffle) comprising a vinyl boot with built-in foot cradle, against elevation of the heels using a hospital pillow (Tymec 1997). The study reported that more heel ulcers developed in the group using the Foot Waffle (n = 6) compared with the group using a hospital pillow) (n = 2) although this difference was not statistically significant, the number of people in each group was not clearly reported, and, therefore, data were not plotted.

Gilcreast 2005 assessed three heel pressure relief devices: a fleece cushion heel protector (the Bunny Boot); the egg-crate heel lift positioner and the foot waffle air cushion. There were no statistically significant differences between the devices in terms of incidence of pressure ulcers (3/77 (4%) for the Bunny boot; 4/87 (4.6%) for the egg crate and 5/76 (6.6%) for the foot waffle). However, it was not clear from the trial whether the number of incident ulcers or number of participants with incident ulcers was being reported. Furthermore, the analysis of this trial was not by intention-to-treat, and 30% of data were not included in the analysis due, in part, to non-compliance. Therefore this result is at high risk of bias.

- **Sheepskins**

Four trials examined the effects of sheepskins on pressure ulcer incidence. The first, which compared the standard hospital mattress with, and without, sheepskin overlays (Ewing 1964), was considered too small and suffering from risk of bias to the extent that its results could not be regarded as valid. The second involved 297 orthopaedic patients (McGowan 2000), and found that pressure ulcer incidence was significantly reduced in those assigned an Australian medical sheepskin (RR for sheepskins relative to standard treatment was 0.30; 95% CI 0.17 to 0.52). The third, by Jolley 2004, was a study on a mixed inpatient population of a metropolitan hospital comparing a sheepskin mattress overlay with 'usual care' that included repositioning and any other pressure-relieving devices with, or without, "low-tech" constant pressure relieving devices. It seems that analysis by intention-to-treat was not used,

as 539 participants were randomised, but only 441 analysed. The study stated that any patient whose risk increased to high, as measured by a Braden score of less than 12 for 48 hours, was no longer followed-up. The rationale for this was not clear. The results, in terms of incidence of new pressure ulcers of grade 2 or above, were 12/218 (5.5%) for the sheepskin group and 20/223 (9%) for the 'usual care' group (reported denominators). A study by Mistiaen 2009 investigated the use of an Australian medical sheepskin for use 48 hours after admission, compared with usual care. The 543 patients, mainly from aged care rehabilitation facilities, were followed-up for 30 days. Pooling the trials by McGowan 2000; Jolley 2004 and Mistiaen 2009 using a random-effects model, and including data for patients who developed pressure ulcers of all grades (including grade 1), showed there were statistically significantly fewer pressure ulcers among those allocated sheepskins (RR 0.48 95% CI 0.31 to 0.74)(Analysis 4.1). These three trials were then pooled using only data for patients with pressure ulcers grade 2 or above using a fixed-effect analysis as the heterogeneity was low (I^2 = 3%). This analysis also showed statistically significant fewer pressure ulcers in the group using sheepskins (RR 0.56 95% CI 0.32 to 0.97) (Analysis 4.2).

- **Foam body support**

One trial, with 70 intensive care unit participants (Cadue 2008), compared a foam body support plus usual care (half-seated position, water mattress and preventative massage six times a day) with usual care alone for the prevention of heel ulcers. In total 8.6% (3/35) of participants in the support group developed heel ulcers (all grades) compared with 55.4% (19/35) in the control group, this difference was statistically significant (RR 0.16 95% CI 0.05 to 0.49) (Analysis 4.1). This study was at low or unclear risk of bias (unclear because we could not ascertain whether outcome assessment was blinded, nor whether there was risk of selective outcome reporting).

Summary: Foam alternatives to the standard hospital foam mattress reduce the incidence of pressure ulcers in people at risk, although one large trial found no difference between high-specification foam mattress and use of standard mattress (Russell 2003).

Three trials investigating the effectiveness of a specific sheepskin product in preventing pressure ulcers showed that sheepskin overlays are effective in reducing the incidence of pressure ulcers. Other evidence about competing CLP devices did not show clear differences between the effectiveness of products.

2. "High-tech" pressure supports

This section outlines three main groups of supports; alternating-pressure (AP) supports, low-air loss beds and air-fluidisedLow beds.

Alternating-pressure supports

A variety of alternating-pressure (AP) supports is used in hospital and community locations. The depth of the air-cells, cell cycle time and mechanical robustness vary between devices, and these factors may be important in determining effectiveness. It is worth emphasising that most of the RCTs of AP supports did not describe the equipment being evaluated adequately, including the size of the air cells and cell cycle time.

Sixteen RCTs of AP supports for pressure ulcer prevention were identified: these included the following comparisons:

a) alternating-pressure compared with standard hospital mattress (three studies);

b) alternating-pressure compared with constant low-pressure (11 studies) including:

- static air;
- water;
- foam;
- continuous low-pressure;
- silicore.

c) Comparison between different AP devices (five studies).

2.1 Alternating-pressure compared with standard hospital mattress

Andersen 1982 reported that the use of alternating-pressure surfaces significantly reduced the incidence of pressure ulcers compared with standard hospital mattresses. The report of this large trial, involving 482 patients who were defined by the authors as being at high-risk of pressure ulcers, gave no indication that either allocation concealment or blinded outcome assessment had been used. In an underpowered and unblinded study conducted on patients requiring head elevation, Sanada 2003 compared a single layer air cell overlay (the Air Doctor), a double-layer cell overlay (the Tricell) (both with five-minute alternating air pressure) and a standard hospital mattress (Paracare). In the Sanada trial, both the experimental groups and control group had a two-hourly change of position and skin care. In the Air Doctor group 4/29 (13.8%) participants developed grade 2 pressure ulcers, in the Tricell group 1/26 (3.8%) participants developed grade 2 pressure ulcers; and in the standard hospital mattress group 6/27 (22%) participants developed grade 2 pressure ulcers. The number of grade 1 ulcers was also reported in the study.The denominators are numbers presented by the authors after withdrawals and attrition, and the study was not analysed by intention-to-treat (in that withdrawals were excluded from the analysis). For the purpose of meta-analysis, this three-armed trial was merged into two groups receiving AP overlay.

These two trials were pooled using a fixed-effect model (I^2 = 0%). There was a statistically significant reduction in development of pressure ulcers with the AP surface compared with the standard hospital mattress (RR 0.31; 95% CI 0.17 to 0.58), however, it should be recognised that these trials were at unclear or high risk of bias (Andersen 1982 was poorly reported for randomisation,

allocation concealment and blinding and Sanada 2003 was at high risk of attrition bias) (Analysis 5.1).

Summary: Results of two studies comparing AP devices with standard mattresses showed some evidence in favour of the AP support surfaces, however these studies were at high risk of bias.

2.2 Alternating-pressure compared with constant low-pressure

Ten trials compared AP devices with various constant low-pressure (CLP) devices, however, there was conflicting evidence regarding their relative effectiveness. A two-armed trial compared a range of AP supports with a range of CLP supports in a range of specialties in acute care settings (Gebhardt 1996), and reported significantly more pressure ulcers in patients in the CLP group (34% compared with 13% in the AP group) (RR 0.38; 95% CI 0.22 to 0.66) (Analysis 6.1). This trial was difficult to interpret because of the wide variety of surfaces it used; there is currently insufficient evidence to support a 'class effect' for all alternating-pressure devices and all constant low-pressure devices.

In contrast, nine RCTs comparing different types of AP supports and a variety of CLP devices, such as the Silicore overlay (Conine 1990; Daechsel 1985; Stapleton 1986); a water mattress (Andersen 1982; Sideranko 1992); a foam pad (Stapleton 1986; Whitney 1984); and static air mattresses (Price 1999; Sideranko 1992); a visco-elastic foam mattress (including four-hourly turning and a sitting protocol with a cushion) (Vanderwee 2005); and CLP mode of the Hill-Rom Duo mattress (Cavicchioli 2007); individually reported no difference in effectiveness, although some were too small to be able to detect clinically important differences as statistically significant. In the Vanderwee study, a sub-group analysis on the location of pressure ulcers reported that there were significantly more heel pressure ulcers in the control group using the viscoelastic mattress (P value 0.006 Fischer's exact test). The study authors also noted that patients nursed on the experimental equipment (Huntleigh APAM, Alpha X-cell) seemed to develop more severe ulcers (Analysis 6.1).

Four studies that compared AP with Silicore or foam overlays were pooled (Conine 1990; Daechsel 1985; Stapleton 1986; Whitney 1984). To avoid double counting of the patients in the AP arm of the Stapleton three-arm trial, and in the absence of obvious heterogeneity in the outcomes for Silicore and foam, the Silicore and foam arms were pooled against the AP arm (maintaining the randomisation, avoiding double counting, but resulting in unequal comparison groups). Overall the pooled relative risk of pressure ulcer development for AP compared with Silicore or foam overlays (using a fixed-effect model; I^2 = 0%) was 0.91 (95% CI 0.72 to 1.16), indicating no statistically significant difference between Silicore or foam overlays and AP (Analysis 6.1).

The studies that compared AP with static water, or static air mattresses, were also considered together (Andersen 1982; Price 1999; Sideranko 1992). The Sideranko trial also had three comparison groups, and, for the purposes of the meta-analysis, the water and static air arms of this study were considered sufficiently similar to pool together against AP to avoid double counting of the AP patients. Pooling these three trials to answer the question of whether AP is associated with fewer incident ulcers than air- or water-filled mattresses using a random-effects model (I^2 = 25%) yielded a pooled RR of 1.31 (95% CI 0.51 to 3.35), indicating no statistically significant difference (Analysis 6.3). It is worth emphasising, however, that some of these studies were small, and, even when pooled, were too underpowered to detect clinically important differences in effectiveness as statistically significant.

All nine RCTs comparing the various CLP devices and AP devices were pooled to try to determine whether AP is more effective than CLP in pressure ulcer prevention. Double counting was avoided for the Sideranko and Stapleton trials as before. In view of the different devices evaluated in the studies, the I^2 of 34% and the Chi ^{2} statistic of 13.69 (df = 9), a random-effects model was applied. This yielded an overall relative risk of 0.85 (95% CI 0.64 to 1.13), which suggested no statistically significant difference between the rates of pressure ulcer incidence with AP compared with CLP (Analysis 6.1). Further trials are needed to determine whether the CLP and AP devices are associated with a clinically important difference in risk of pressure ulceration.

One trial used a complex factorial design to compare various combinations of standard, constant low-pressure (Tempur) and alternating-pressure (Nimbus) support in surgical intensive care patients intra- and post-ICU. This trial (which involved only 75 to 80 patients in each group) did not identify any significant benefit associated with using alternating-pressure in the ICU (Laurent 1998) (Analysis 7.1).

Summary: The relative merits of alternating- (AP) and constant low-pressure (CLP) devices, and of the different AP devices for pressure ulcer prevention are unclear with most trials comparing AP with CLP devices and showing no significant difference between treatment groups. One large, high quality study found no significant differences between an AP overlay with an AP mattress. However, the AP mattresses were associated with an 80% probability of reducing costs, due to a delay in pressure ulceration and reduced length of stay in hospital when they were used.

2.3 Comparisons between different alternating-pressure devices

AP devices differ somewhat in structure, for example, the size of the inflatable air cells. One early study of pressure ulcer prevention compared two large-celled alternating-pressure devices (Pegasus Airwave and the Large Cell Ripple - similar except that the Airwave has two layers of cells) (Exton-Smith 1982). The authors reported that the Airwave system was significantly more effective than the Large Cell Ripple in preventing and reducing severity of pressure ulcers in a high risk group of elderly patients. However, the allocation was not truly random, and an analysis which

regarded losses to follow-up as having not developed pressure ulcers did not show a statistically significant difference in the rate of pressure ulcers (16% versus 34%; P value > 0.05; Analysis 8.1).

Hampton 1997 compared the Pegasus Airwave mattress with a new Cairwave Therapy system by the same manufacturer, in 75 patients. No patients developed an ulcer within the 20-day follow-up in either arm of this study.

Taylor 1999 compared the Pegasus Trinova three-cell alternating-pressure air mattress plus a pressure redistributing cushion (intervention) with a two-cell alternating-pressure air mattress plus a pressure redistributing cushion (control). This study was underpowered and so could not detect important differences (22 patients in each group), and, whilst two patients developed a superficial ulcer in the control group and none in the intervention group, this difference was not statistically significant (RR 0.20; 95% CI 0.01 to 3.94) (Analysis 8.1).

In another underpowered trial, Theaker 2005 examined two AP devices in an ICU setting. The KCI Therapulse, a stand-alone unit that incorporates a mattress into a bed frame and uses optional pulsation technology and low-air-loss to reduce tissue interface pressure, and the Hill-Rom Duo mattress (control), which is designed to lie directly on most standard hospital frames and uses either continuous or alternating low-pressure modes. Details of the alternating cycle were not provided. Pressure ulcer incidence (restricted to grade 2 ulcers or greater) was 3/30 (10%) in the experimental group and 6/32 (19%) in the control group (no statistically significant difference).

In a large trial, at low risk of bias, Nixon 2006 compared an AP overlay with an AP mattress, the primary outcome was incidence of pressure ulcers (grade 2 or above). An intention-to-treat analysis was conducted on data from 1971 participants (989 in the overlay group and 982 in the mattress group). One-hundred and six (10.7%) people in the overlay group and 101 (10.3%) in the mattress group developed one or more new grade 2 pressure ulcers. The majority of incidence ulcers were grade 2. There was no significant difference between the two groups in terms of development of a new pressure ulcer of grade 2 or greater (RR 1.04; 95% CI 0.81 to 1.35). More participants on the overlay requested a change to another device due to their dissatisfaction (23.3%), compared with patients allocated to the AP mattress (18.9%), this difference was statistically significant.

Nixon 2006 also conducted a full cost-effectiveness analysis from the perspective of the UK NHS and Personal Social Service. Calculation of cost information was based on length of hospital stay and pressure-relieving surface used. Benefits were measured as the number of pressure-ulcer-free days. In the base case analysis the mean cost per patient of the AP mattress was GBP 6509.73, and the mean cost per patient of the AP overlays was GBP 6793.33. The mattress cost on average GBP 283.6 less per patient, (95% CI, GBP 377.59 to GBP 976.79), and also conferred greater benefits (a delay in mean time to ulceration of 10.64 days (95% CI 24.40 to 3.09). Whilst neither the difference in costs nor benefits reached statistical significance, the assessment of uncertainty around the cost-effectiveness decision indicated that, on average, AP mattresses were associated with an 80% probability of being a cost saving. This was because the mattress was associated with a delay in ulceration (measured by Kaplan Meier estimates), and reduced costs as a consequence of shorter length of hospital stay. The conclusions of the base case analysis was not altered when challenged in sensitivity analyses.

Low-air-loss (LAL) beds

Three studies evaluated the use of low-air-loss beds. Such devices provide a flow of air that assists in controlling the microclimate of the patient's skin (NPUAP 2007).

2.4 Comparisons between LAL and other support surfaces

Inman 1993 reported that low-air-loss beds were more effective at decreasing the incidence of pressure ulcers in critically-ill patients than a standard (but poorly described) ICU bed (RR 0.24; 95% CI 0.11 to 0.53) (Analysis 9.1).

A second trial of 98 participants, compared low-air-loss hydrotherapy (LAL-hydro) with standard care (some patients received alternating-pressure in this group); more patients developed ulcers of grade 2 ulcer or greater in the LAL-hydro group (19%) than the standard care group (7%) though this difference was not statistically significant (Analysis 9.1) (Bennett 1998).

A third trial with 123 participants recruited from hospital wards and intensive care units compared a low-air-loss bed (KinAir) with a static air overlay in the prevention of pressure ulcers (Cobb 1997). Three people developed grade 1 ulcers on the low-air-loss bed (3/62) compared with one on the static air overlay (1/61). However, three people developed grade 2 ulcers on the low-air-loss bed (3/62) compared with 11 on the static air overlay (11/61). Comparing the incidence of all ulcers showed no statistically significant difference between the two groups (Analysis 9.1).

Cobb and Inman were pooled as they investigated LAL beds with alternatives in the ICU setting. This showed a statistically significant difference in favour of the low-air-loss bed (RR 0.33; 95% CI 0.16 to 0.67) (random-effects, I^2 = 26%) (Analysis 9.2) (Cobb 1997; Inman 1993). Inman 1993 also reported that low-air-loss beds reduced the incidence of patients developing multiple pressure ulcers compared with the standard ICU mattress (RR 0.08 95% CI 0.01 to 0.62) (Analysis 9.3).

Air-fluidised beds

2.5 Comparison between air-fluidised bed and dry flotation mattress

One small trial that investigated 12 patients after plastic surgical repair of pressure ulcers showed no difference between an air-

fluidised bed and the Roho dry flotation mattress in postoperative tissue breakdown rates (Economides 1995) (Analysis 10.1).

3. Other pressure supports

Other pressure supports included Kinetic turning tables, profiling beds, operating table overlays and seat cushions. Turning beds contain motors which constantly turn and tilt the patient. This includes kinetic beds and profiling beds. They are used in critical care settings, primarily to prevent pneumonia and atelectasis (collapsed lung). Operating table overlays are used as pressure relief during surgery.

Kinetic turning tables

3.1 Comparison between kinetic beds and conventional beds

Four RCTs were identified in a meta-analysis of kinetic therapy (Choi 1992), however, full copies of only two of the individual trials could be obtained for this systematic review (Gentilello 1988; Summer 1989). These two trials evaluated kinetic bed against conventional beds. Sample sizes in all the trials were small, and no beneficial effect of kinetic therapy on incidence of pressure ulcers was detected (Analysis 11.1).

Profiling beds

3.2 Comparison between profiling bed and flat-based bed

Keogh 2001 recruited 70 participants, and found that no pressure ulcers developed in either the group assigned to the profiling bed with a pressure-reducing foam mattress or cushion combination or the group assigned to a flat-based bed with a pressure-relieving/redistributing foam mattress or cushion combination. Patients were followed-up for five to 10 days, however, the extent of the follow-up was difficult to ascertain

Operating table overlay

3.3 Comparison with viscoelastic polymer pad with standard table

Five RCTs evaluated different methods of pressure relief on the operating table. The first compared a viscoelastic polymer pad with a standard table (Nixon 1998), and found a relative reduction in the incidence of postoperative pressure ulcers of 47% associated with using the polymer pad for patients undergoing elective, major general, gynaecological or vascular surgery (supine or lithotomy) (RR 0.53; 95% CI 0.33 to 0.85) (Analysis 12.1). It is important to note that the majority of incident pressure ulcers were grade 1 (i.e. early ulcers with no break in the skin), and the length of follow-up was eight days.

Two further RCTs compared the Micropulse alternating system (applied both during surgery and postoperatively) with a gel pad during surgery and a standard mattress postoperatively. We pooled these two trials (I^2 = 0%), and derived a pooled risk ratio (fixed-effect) of 0.21 (95% CI 0.06 to 0.7) in favour of the Micropulse system (Aronovitch 1999; Russell 2000). It is not clear from these two trials whether the effect was due to the intra-operative or the postoperative pressure relief, or both (Analysis 13.1).

Schultz 1999 compared an operating theatre mattress overlay with usual care (which included padding as required, e.g. gel pads, foam mattresses). People in the overlay group were more likely to experience postoperative skin changes, and six patients in the overlay group developed ulcers of grade 2, or worse, compared with three people in the control group. No attempt was made to gather information on the patients' postoperative skin care. Details regarding stage of ulcer by group and of the unnamed product were sought unsuccessfully from the study authors. In the absence of this information, the clinical importance of the findings is difficult to assess.

Gunningberg 2000 examined the effects of a viscoelastic foam trolley mattress and subsequent overlay on 101 patients with a suspected hip fracture in the A&E and ward setting, this trial is dealt with in the review in the section: *1.1 Standard foam hospital mattress compared with other low-tech CLP*.

Summary: Pressure-relieving overlays on the operating table and in the postoperative period reduce the incidence of postoperative pressure ulcers, although there is some evidence that certain operating room overlays may result in postoperative skin changes.

3.4 Comparison of water-filled warming mattress and thermoactive viscoelastic foam overlay with an operating theatre table with water-filled warming mattress

Another trial compared an operating theatre table that included a water-filled warming mattress and a 4-cm thermoactive viscoelastic foam overlay, with an operating theatre table with water-filled warming mattress only (Feuchtinger 2006). The trial was terminated before the full sample was recruited because more patients in the experimental group with the 4-cm thermoactive viscoelastic foam overlay developed pressure ulcers (all were grades 1 to 2), with 15/85 (18%) in the experimental group and 10/90 (11%) in the control group. For grade 2 pressure ulcers only, there were two in the experimental group and one in the control group. There was no statistically significant difference between the two groups at the point at which the trial was terminated (Analysis 12.1).

Seat cushions

3.5 Comparisons between different cushions

Four RCTs compared different types of seating cushion for preventing pressure ulcers; one study compared slab foam with bespoke contoured foam and found no difference between the groups (RR 1.06; 95% CI 0.75 to 1.49) (Lim 1988). The second study compared contoured foam over a gel pad (Jay gel) plus a foam wheelchair cushion with a foam cushion alone in 141 people (Conine 1994), and found fewer ulcers in the gel pad plus cushion group, though this was not statistically significant (RR 0.61; 95% CI 0.37 to 1.00). The third study found no difference in pressure ulcer incidence between those assigned a slab foam cushion bevelled at the base and those assigned a contoured foam cushion with an area cut out to accommodate the patient's bottom (Conine 1993) (RR 1.00; 95% CI 0.81 to 1.18) (Analysis 14.1). The fourth study was a small pilot trial of 32 wheelchair-users that compared a standard foam (eggcrate) cushion with a pressure-reducing wheelchair cushion (Geyer 2001). The trial did not differentiate between patients with grade 1 ulcers or higher grades of ulcer. In total, 40% of participants on the pressure-reducing cushion developed an ulcer (6/15) compared with 58.5% (10/17) on the foam cushion (RR 0.68; 95% 0.33 to 1.42); this difference was not statistically significant (Analysis 14.1).

Summary: There is insufficient evidence to determine the value of seat cushions, various CLP devices and A&E trolley overlays as pressure ulcer prevention strategies.

Summary of results

- Foam alternatives to the standard hospital foam mattress reduce the incidence of pressure ulcers in people at risk, although one large trial found no difference between high-specification foam mattress and use of standard mattress (Russell 2003).
- The relative merits of alternating- (AP) and constant low-pressure (CLP) devices, and of the different AP devices for pressure ulcer prevention are unclear with most trials comparing AP with CLP devices and showing no significant difference between treatment groups. One large, high quality study found no significant differences between an AP overlay with an AP mattress. However, the AP mattresses were associated with an 80% probability of reducing costs, due to a delay in pressure ulceration and reduced length of stay in hospital when they were used.
- Results of two studies comparing AP devices with standard mattresses showed some evidence in favour of the AP support surfaces, however these studies were at high risk of bias.
- Three trials investigating the effectiveness of a specific sheepskin product in preventing pressure ulcers showed that sheepskin overlays are effective in reducing the incidence of pressure ulcers. Other evidence about competing CLP devices did not show clear differences between the effectiveness of products.
- Pressure-relieving overlays on the operating table and in the postoperative period reduce the incidence of postoperative pressure ulcers, although there is some evidence that certain operating room overlays may result in postoperative skin changes.
- There is insufficient evidence to determine the value of seat cushions, various CLP devices and A&E trolley overlays as pressure ulcer prevention strategies.

DISCUSSION

The confidence with which we can draw firm conclusions from the studies detailed in this review is greatly tempered by (a) the poor quality of many of the trials; (b) the lack of replication of most comparisons; and (c) that the "standard" mattress is often not clearly defined. The clearest conclusion that can be drawn is that standard hospital mattresses have been consistently outperformed by a range of foam-based, low-pressure mattresses and overlays, and also by higher-specification pressure-relieving beds and mattresses in the prevention of pressure ulcers.

The application of this conclusion to current clinical practice is, however, hampered by the fact that the "standard" was poorly described in many of these studies, and what is standard varies by hospital, country and with time. This factor leads to major difficulties in interpretation of trial results and the importance of providing clear descriptions of all interventions in future studies cannot be overemphasised. In view of this, and because we thought there would be less variation within a country, a subgroup analysis of UK-based studies was undertaken, which showed that the advantage of alternative foam was maintained.

Many of the trials reviewed did not provide convincing reassurance that manual repositioning was provided equally to each group of participants. This is a possible confounder, as care providers were not blinded to treatment allocation in any of the trials, and may have moved patients in one group more frequently if they perceived a particular mattress to be less effective. As experimental evidence of the effectiveness of manual repositioning is lacking, it is difficult to say what impact this has. In addition, in many studies the definitions of pressure ulcer free, low-risk, moderate-risk and high-risk varied widely. Also, it is often difficult to ascertain whether study participants with grade 1 ulcers have been accepted into the sample and included in the analyses, or not, and this needs to be taken into account when interpreting findings. Some of the included studies did recruit participants with pressure ulcers worse than grade 1 therefore only the incidence of *new* pressure ulcers was reported.

The results of three of the five trials evaluating the use of pressure-relieving overlays on the operating table suggest that these are beneficial in reducing subsequent pressure ulcer incidence in high-risk surgical patients. These three trials were of reasonable or good quality; in particular the Nixon 1998 trial was adequately powered, with allocation concealment and blinded outcome assessment lending further weight to the result. At present, the most

effective means of pressure relief on the operating table is unclear; Nixon and colleagues found a gel-filled overlay to be significantly better than a standard operating table, whilst a gel-filled overlay on the operating table was less effective than an alternating-pressure overlay intra- and postoperatively (the Micropulse system) in the other two trials (Aronovitch 1999; Russell 2000). The Micropulse trials were confounded by their provision of a standard mattress postoperatively in the gel overlay arm, and an alternating-pressure overlay postoperatively in the Micropulse arm. Thus whilst there is clearly a reduction in pressure ulcer incidence associated with the alternating-pressure system, it is not clear whether this is merely a result of better postoperative pressure relief. Two other trials showed that postoperative skin changes occurred as a result of different operating theatre overlays (Feuchtinger 2006; Schultz 1999), but the clinical importance of these results is difficult to determine in the absence of further details about pressure ulcer grading and products used.

Previously the evidence for different alternating-pressure devices was unclear due to the poor quality and small size of existing studies. This review includes a large, robust trial which suggests that AP mattresses are clinically as effective as overlays, but likely to be more cost effective, and more acceptable to patients (Nixon 2006).

Trials published in the early 1980s found that water-filled and bead-filled mattresses were both associated with reductions in the incidence of pressure ulcers when compared with standard hospital mattresses, however, the products evaluated are no longer available.

There are tentative indications that four interventions may be harmful. Firstly, Tymec 1997 found that Foot Waffle heel elevators were associated with a trebling in the incidence of pressure ulcers, though this was not statistically significant and the study was small (52 patients) (Tymec 1997). Secondly, Bennett 1998 evaluated low-air-loss hydrotherapy (LAL-hydro) in a trial in which 19% LAL-hydro patients developed ulcers compared with 7% of standard care patients, though again this was not a statistically significant difference and the study was underpowered (98 participants). Thirdly, Schultz 1999 investigated the effectiveness of an alternative foam overlay used in the operating theatre; the results suggested that patients placed on the intervention devices were significantly more likely to experience postoperative skin changes (i.e. mainly grade 1 pressure ulcers). It is difficult, however, to separate out the role of postoperative care and padding, which was used as a concomitant intervention, either of which may have caused the skin changes (mainly found on buttock and coccyx). Lastly Feuchtinger 2006 terminated the trial comparing an operating theatre table that included a water-filled warming mattress and a 4-cm thermoactive viscoelastic foam overlay with an operating theatre table with a water-filled warming mattress only. The trial was terminated before the full sample was recruited because more patients ii the group receiving the 4-cm thermoactive viscoelastic foam overlay developed pressure ulcers (all were grades 1 to 2). It is important to note, however, that two of the above studies did not provide clear information to indicate that the groups under investigation were similar at baseline for the most important prognostic factors (Bennett 1998; Tymec 1997).

Few comparisons have been replicated, and, as most of the completed trials were under-powered there is little information from which to draw firm conclusions. For example, air-fluidised therapy has only been compared with dry flotation as a prevention strategy, and low-air-loss only with standard care. There remain gaps in the knowledge base to which a rational research agenda could be addressed. It is always important to consider publication bias and its potential influence on the population of studies on a topic. Whilst equipment manufacturers appear to have contributed funding to many of the trials identified, it is difficult to see what the impact of this has been. For example, whilst bias in favour of positive results cannot be discounted, most of the studies published did not find a statistically significant difference. It is also important for the reader to be aware of the development of materials used in the production of support surfaces over the past 30 years, and how this may impact on the effectiveness of such devices. A systematic review of RCTs and quasi-randomised studies investigating the prevention of heel pressure ulcers conducted by Junkin 2009 reported similar conclusions regarding the current state of the evidence, and the need for further rigorous research in this area.

Common methodological flaws which increase the risk of bias in trials investigating support surfaces include lack of allocation concealment, lack of baseline comparability, high attrition rates, lack of intention-to-treat analysis, lack of blind - or independently verified - outcome assessment. Specific to pressure ulcer intervention research, other flaws include failing to report on whether or not participants were free from pressure ulcers on study entry, and providing an adequate definition for pressure ulcer status. These deficiencies further reduce the confidence with which we can regard many of the individual study findings. It is, however, heartening that the recently included studies have improved reporting of some study details to enable quality assessment. It is important to acknowledge that the different follow-up times amongst the trials contribute to both clinical and statistical heterogeneity, and this needs to be taken into account when reading this review.

Future trials should continue to address these deficiencies and collect data on aspects of equipment performance such as reliability. It is hoped that future studies will be reported in line with current international standards for trial reporting (Moher 2001).

AUTHORS' CONCLUSIONS

Implications for practice

For people at high risk of developing pressure ulcers, higher-spec-

ification foam mattresses rather than standard hospital foam mattresses should be used, where possible. Organisations should consider the use of selected pressure relief devices for high risk patients in the operating theatre, as this is associated with a reduction in postoperative incidence of pressure ulcers. Medical grade sheepskins are associated with a decrease in pressure ulcer development. The relative merits of higher-tech constant low-pressure and alternating-pressure for prevention are unclear, however, alternating-pressure mattresses may be more cost effective than alternating-pressure overlays in the UK context. Seat cushions have not been adequately evaluated.

Implications for research

Independent, well-designed, multi-centre RCTs are needed to compare the clinical and cost-effectiveness of different types of pressure-relieving devices for patients at different levels of risk in a variety of settings. Particular gaps, include comparisons of:

(a) alternating-pressure devices with other "high-tech" equipment (such as low-air-loss and air-fluidised beds) for prevention in very high risk groups;

(b) alternating-pressure devices with "lower-tech" alternatives (such as different types of high-specification foam mattresses and other constant low-pressure devices).

The evaluation of alternating-pressure devices is given emphasis as they are viewed as standard preventive interventions in some areas, but not others, and may vary widely in cost (from less than GBP 1000 to more than GBP 4,000).

Research is needed into valid and reliable methods of detecting early skin damage that is prognostic of pressure ulcer development, and of the impact of pressure ulcers on quality of life. Future research must address the methodological deficiencies associated with much of the research described in this review.

Patients should be truly randomised (with concealed allocation), trials should be of sufficient size to detect clinically-important differences, and have clear criteria for measuring outcomes which, ideally, should be assessed without knowledge of the intervention received (blinded). Interventions under evaluation should be thoroughly and clearly described. Researchers should be encouraged to develop measures to assess patient experiences of pressure-relieving equipment e.g. comfort. The studies should also have adequate follow-up and appropriate statistical analysis. The CONSORT statement should be used as a guideline for reporting (Moher 2001).

Given the high costs associated with the prevention of pressure ulcers in general, and of pressure-relieving surfaces specifically, emphasis should be given to robust economic evaluations to be conducted concurrently with trials.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Andersen 1982

Methods	RCT with 10 day follow-up. Method of allocation unclear.
Participants	Patients in acute setting at high risk of pressure ulcer development (Andersen scale), and without existing pressure ulcers
Interventions	1. Standard hospital mattress (n = 161). 2. Alternating air mattress (AP) (n = 166). 3. Water-filled mattress (air mattress for camping filled with water) (n = 155)
Outcomes	Incidence of pressure ulcers (skin examined on alternate days): 1. Standard mattress: 13.0% (21/161). 2. Alternating mattress: 4.2% (7/166). 3. Water mattress: 4.5% (7/155).
Notes	118 out of 600 selected patients dropped out during first 24 h. A priori sample size calculation. AP easily punctures and in this study was not always set at optimum pressure. Water bed is heavy and time-consuming to fill. Patients more satisfied with ordinary bed: complained of the noise and pressure changes of AP

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Patients "were allotted to one of the three group". Method of randomisation not reported
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Unclear	Only participant drop-out pre-randomisation reported.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"The distribution showed no significant difference between the three groups according to age, sex, body weight, or risk score"

Andersen 1982 (*Continued*)

Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Observation took place on alternate days for 10 days.

Aronovitch 1999

Methods	Quasi-randomised trial with 7 day follow-up.
Participants	> 18 y; free of pressure ulcers; undergoing elective surgery under GA, of > 3 h operative time. No significant differences between groups for age, sex, race, weight, height, smoking status at baseline, but patients in conventional management group were at greater risk of pressure ulcer development as defined by Knoll score
Interventions	1. AP system intra and postoperatively (Micropulse) (n = 112). Micropulse is thin pad with over 2,500 small air cells in rows; 50% cells inflated at any time. 2. Conventional management (n = 105): consisted of use of a gel pad in the operating room and a replacement mattress postoperatively
Outcomes	Occurance of pressure ulcer within 7 days of surgery: number/size/grade of ulcers on each postoperative day: 1. MicroPulse system 1% (1/90), however, ulcer was due to a foreign body and considered "not related to the bed". 2. Conventional management 9% (7/80) (7 patients developed 11 pressure ulcers; the stage of 6 of these could not be determined because of eschar). Grade 1: 1; Grade 2: 4
Notes	1. MicroPulse system: device was inadvertently turned off during treatments of 4 patients. 4 patients asked to withdraw for various unreported reasons. 3 patients withdrew due to back pain. 12 patients assigned to this group were placed on another surface postoperatively for reasons unrelated to the surface. 2. Conventional management: 6 patients were placed on the MicroPulse postoperatively. Analysis was on an ITT basis

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Quasi-randomised: "randomisation was performed by week rather than by patient to decrease protocol error"
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Yes	All reasons/numbers for attrition/exclusions reported.

Aronovitch 1999 (*Continued*)

Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	It was stated, however, that all data were not available for all patients
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Outcomes assessed on days 1, 4 and 7.

Bennett 1998

Methods	RCT with 60-day follow-up. Median length of follow-up (days): Group 1: 4 (1-60). Group 2: 6 (1-62) P value <0.017.
Participants	Acute and long-term care patients incontinent of urine and/or faeces, in bed >16 h/day, with pressure ulcers grade 2 or below (or none). If urinary catheter present, this was removed in the LAL group (not control group). Most common diagnoses: sepsis; malignancy; fractured neck of femur; hypovolaemia; dementia
Interventions	Group 1. Low-air-loss Hydrotherapy (LAL) (n = 42) Clensicair (SSI/Hill Rom). Permeable fast drying filter sheet over low-air-loss cushions (circulating air). Urine collection device integral to bed. Group 2. Standard care (n = 56) comprised standard bed or foam, air, alternating-pressure mattresses. Skin care not standardised
Outcomes	Number of patients who developed any kind of skin lesion more than 1 day after enrolment: Group 1: 64% (27/42); Group 2: 18% (10/56). Number of patients who developed pressure ulcers Grade 2-4: Group 1: 19% (8/42); Group 2: 7% (4/56) P value 0.11; NS. Number of patients with non-blanchable erythema (Grade 1): Group 1: 14% (6/42); Group 2: 0/56 P value 0.008. Only 26 ulcers present on enrolment, and only 3 were Grades 3 or 4, so no healing data presented
Notes	The first 68 patients were discounted, and a further 26 out of 116 withdrew. No ITT analysis. Nurses received special extra training for the LAL bed. LAL patients were interviewed about satisfaction, control patients were not. There were many nurse complaints about the LAL; firmly held belief that it was associated with more ulceration. Two subjects in the LAL group developed hypothermia. Findings may not relate to subsequent products developed since

Risk of bias

Bennett 1998 (*Continued*)

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"Randomization of subject to low-air-loss hydrotherapy or standard care was done by unblocked allocation using a table of random numbers stratified by pressure sore and by setting"
Allocation concealment?	Unclear	Method of concealment not described.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Yes	Shown in Table 2 and reported in text.
Free of selective reporting?	No	"Because too few patients with pressure sores at enrolment were enrolled long enough to have changes in pressure sore size, grade, or status, no data on change in pressure sores present at enrolment are presented herein"
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"There were no statistically significant differences in enrolment characteristics between the two groups"
Free of other bias - was the timing of the outcome assessment similar in all groups?	No	"For all subjects, the study treatment period commenced on the day of enrolment and continued until withdrawal of consent, discharge from the hospital, transfer to a critical care unit from a medical-surgical ward or to the acute hospital from the chronic hospital ward, death, cessation of incontinence, bed use less than 16 hours per day, enrolment for more than 60 days, or end of the overall study"

Cadue 2008

Methods	RCT with maximum follow-up 30 days.
Participants	Patients in an intensive care setting with a Waterlow Score >10, no existing heel pressure ulcers, ≥18 y or over. Participants seemed generally matched at baseline
Interventions	1. Foam body support and standard pressure prevention protocol (half-seated position, water mattress preventative massage 6 times/day) (n = 35). 2. Standard pressure ulcer protocol (as above) (n = 35).

Cadue 2008 (*Continued*)

Outcomes	Number of participants developing non-blanching pressure ulcer or worse on the heel: 1. Foam body support 8.6% (3/35); 2. Usual care 55.4% (19/35).
Notes	Full paper not available in English.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	From English summary. Quote: "a randomisation table was used to allocate 70 patients into 2 groups". The two groups were formed randomly by following a randomisation table
Allocation concealment?	Yes	Quote: "envelope cachetee" translated as sealed envelope.
Blinding? Pressure ulcer incidence	Unclear	"le masseur-kinesitherapeute et l'infirmiere" translated to: *t*he physiotherapist and nurse assessed the stage of the lesion daily - but it is not clear if they were blinded
Incomplete outcome data addressed? All outcomes	Yes	70 patients were included, 35 in each group. Table 2 presents the principle results and notes that "n = 35" which has been interpreted that data were presented on 35 patients in each group. No mention was found of any withdrawals
Free of selective reporting?	Unclear	The judgement has been recorded due to the difficulty in making this assessment in a trial that has been published in French and partially translated
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"a l'inclusion il n'existait pas de difference significative entre les 2 groupes au niveau du risque theorique de developper des escarres ni au niveau des principaux facteurs connus pour favoriser la survenue d'escarres", was translated to: at inclusion there was no significant difference between the 2 groups in the theoretical risk of developing pressure ulcers or any of the main factors known to contribute to the occurrence of bedsores

Cadue 2008 (*Continued*)

Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	The physiotherapist and nurse assessed the stage of the lesion daily? it is assumed this was done for both experimental and control groups

Cavicchioli 2007

Methods	RCT with follow-up of 2 weeks.
Participants	Acute and long-term care participants deemed at risk of pressure ulceration (Braden score < 17 activity or mobility sub-scales < 3 respectively). Patients had an expected admission of at least 2 weeks. Patients could have 1 grade 1 pressure ulcer at baseline, but were excluded if they had more; or the ulcer was grade 2 or above. Baseline balance for age, sex and Braden score in the randomised groups
Interventions	1. High-tech (Duo 2, Hill Rom) mattress on alternating low-pressure setting (n = 86). 2. High-tech (Duo 2, Hill Rom) mattress on continuous low-pressure setting (n = 84)
Outcomes	Number of participants with Incidence pressure ulcer (blinded outcome assessment at study end): Grade 1: 1. Alternating low-pressure 1% (1/69); 2. Continuous low-pressure 0/71. Grade 2: 1. Alternating low-pressure 1% (1/69); 2. Continuous low-pressure 1% (1/71).
Notes	This was a 3-armed study. There was a 2-armed RCT, as described, and a control group (standard mattress), which was not formed by randomisation and not included here Blinded outcome assessment was conducted for the randomised groups Follow up figures were: 1. 69 (4 deaths, 8 participants discharged before final assessment, and 5 classed as not having completed the study due to non-concordance); 2. 71 (5 deaths, 4 discharged and 4 classed as non-concordant). Not ITT

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Participants not randomly allocated to the 3 groups from same pool of patients. Controls from another hospital. Only patients in high tech groups appeared to be randomised "by means of a sealed envelope"
Allocation concealment?	Unclear	Unclear.

Cavicchioli 2007 (*Continued*)

Blinding? Pressure ulcer incidence	Yes	External observer was blinded to which treatment mattress was in use
Incomplete outcome data addressed? All outcomes	Yes	Reasons for attrition and exclusion reported.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	No	"The two treatments groups were assessed as at greater risk of pressure ulceration than the control group both at baseline ($p < 0.001$) and the study end ($p < 0.005$)."
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	2-week study period with assessments taking place at the beginning and end of the study

Cobb 1997

Methods	RCT with 40-day follow-up.
Participants	Recruitment in hospital wards and intensive care units. Participants > 18 y of age, ≤ 290 pounds, without pre-existing pressure ulcer, an expected length of stay of 1-2 weeks and considered at "high risk" on the basis of the Braden Scale. Patients allocated through the selection of a treatment card by an independent nurse. Some baseline imbalance observed with older participants; more participants with co-morbidities in the KinAir group
Interventions	1. Low loss air bed (KinAir Bed) (n = 62). 2. Static air mattress overlay (EHOB waffle) (n = 61).
Outcomes	Number of participants with incidence pressure ulcer (ICU participants assessed daily, ward patients assessed every 48 h): Grade 1 1. KinAir Bed 5% (3/62); 2. EHOB waffle 2% (1/61). Grade 2. 1. KinAir Bed 5% (3/62); 2. EHOB waffle 18% (11/61) Eschar 1. KinAir Bed 3% (2/62); 2. EHOB waffle 0/61.
Notes	No higher grades reported. No loss to follow-up reported.

Risk of bias

Item	Authors' judgement	Description

Cobb 1997 (*Continued*)

Adequate sequence generation?	Unclear	"Patients were placed into one of the study groups by random selection of a treatment card". Method of randomisation unclear
Allocation concealment?	Yes	The use of an independent nurse picking a treatment card.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Yes	No numbers/reasons given for exclusions/attrition.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	No	EHOB waffle group had more participants in younger age bracket; KinAir group had more with diabetes and cancer
Free of other bias - was the timing of the outcome assessment similar in all groups?	No	"Patients in the ICUs had skin assessments daily and those on the wards were assessed every 48 hours"

Collier 1996

Methods	RCT comparing 8 different foam mattresses; length of follow-up not clear but patients assessed weekly. Allocation as follows: mattresses assigned to beds and coded numerically with only the principal investigator and ward link nurse aware of identity of each mattress. Mattresses then allocated to patients "as available"
Participants	Patients on a general medical ward; no further details given
Interventions	Comparison of 8 foam mattresses: 1. New Standard Hospital Mattress (Relyon) (130 mm) (n = 9). 2. Clinifloat (n = 11). 3. Omnifoam (n = 11). 4. Softform (n = 12). 5. STM5 (n = 10). 6. Therarest (n = 13). 7. Transfoam (n = 10). 8. Vapourlux (n = 14).
Outcomes	Incidence of pressure ulcers. Patients assessed at least weekly throughout hospital stay. No patient developed a pressure ulcer of any grade during whole study
Notes	9 patients allocated the Cyclone mattress, however, this group was withdrawn from the study at manufacturer's request and data not presented. All mattresses assessed for "grounding", deterioration of cover and contamination of inner foam core, interface pressures. No "grounding" of any mattresses during the evaluation period; softening of

Collier 1996 (*Continued*)

	the centre of the foam base in Standard and Omnifoam mattresses on completion of study (detected using a "fist test" of unknown reliability). All mattress covers remained intact and inner foam protected

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Only information provided: "Mattresses were randomly allocated to patients on admission as available"
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	No	"Only the principal investigator and the ward link nurse knew the identification of each mattress"
Incomplete outcome data addressed? All outcomes	Unclear	9 patients missing from data in Table 2 as their treatment, Cyclone mattress, was removed during the evaluation process at the request of the manufacturer. No other raw data presented in the paper to evaluate if incomplete outcome data addressed
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	Not reported.
Free of other bias - was the timing of the outcome assessment similar in all groups?	No	"Frequency of assessment was determined by each patient's condition, but in all cases was conducted at least weekly throughout their period in hospital"

Conine 1990

Methods	Sequential RCT with 3-month follow-up. Method of allocation unclear
Participants	Patients with chronic neurological diseases aged 18-55 y with no evidence of skin breakdown for at least 2 weeks prior to the study. Patients in the 2 groups were well matched at baseline for key variables e.g. Norton score; sex; age; underweight/overweight; diagnoses; years as a wheelchair user; history of previous pressure ulcers; incontinence. Setting extended care facility for chronic neurological conditions

Conine 1990 (*Continued*)

Interventions	1. Alternating-pressure overlay (n = 72); 10-cm air cells. Cycle time not reported, nor the make of overlay. 2. Silicore (Spenco) overlay (n = 76); siliconised hollow fibres in waterproofed cotton placed over standard hospital mattress (spring or foam). All patients received usual care including 2-3 hourly turning; daily bed baths; weekly bath/shower; use of heel, ankle and other protectors
Outcomes	Incidence of pressure ulcers (including grade 1). Pressure ulcer status was checked by another researcher blind to the study. Inter-rater reliability high. Included grade 1 ulcers: 1. Alternating air overlay: 54% (39/72); 2. Spenco overlay: 59% (45/76). The alternating air overlay group had a slightly lower than average 'Exton-Smith severity score' (1.59 vs 1.69); a shorter than average healing duration (25 days vs 29 days); NS
Notes	Alternating air overlay needed frequent monitoring and expensive prolonged repairs. Reported that patients sank into the Silicore overlay and found it difficult to move. Patients complained of build-up of bad odour, instability (especially Silicore), and noise of the alternating-pressure motor. High dropout rate due to discomfort

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Only information given: a modified sequential clinical trial as described by Pocock (1981) was used to assign subjects randomly to one of the two mattress groups of 20
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Yes	"The Norton's scale was administered by a blind experienced occupation therapist who was external to the institution" and "The research nurse...was responsible for the assessment of all outcome measures. She was not associated with the institution and was not informed about the study"
Incomplete outcome data addressed? All outcomes	Yes	As shown in Table 1.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No statistically significant differences between the 2 groups as shown in Table II

Conine 1990 (*Continued*)

Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Timing not specified.

Conine 1993

Methods	Trial with 3-month follow-up.
Participants	Extended care patients > 60 y; free of skin breakdown for at least 2 weeks prior to study; considered to be at high risk of pressure ulcers; sitting in wheelchair for a minimum of 4 consecutive h; free of any progressive disease which could lead to bed confinement
Interventions	1. Slab cushion bevelled at base to prevent seat sling (n = 144). 2. Contoured foam cushion with a posterior cut out in the area of ischial tuberosities and an anterior ischial bar (n = 144)
Outcomes	1. Slab cushion 68% (85/125); 2. Contoured foam cushion 68% (84/123).
Notes	No ITT analysis.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Method of randomisation unclear, only information given: "the patients were entered into the trial in sequential groups of 40, 20 on each cushion type"
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	"The Exton-Smith scale was used weekly by a blinded research assistant who was a registered nurse (RN)", but, "A sore was declared to be healed by the patient's primary nurse with the joint agreement of the research RN" - unclear if the primary nurse was blinded to treatment groups
Incomplete outcome data addressed? All outcomes	Yes	Shown in Table 3.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"No significant differences were found between the slab and contoured groups in the reasons for drop-outs or between the group characteristics of the 248 remaining patients"

Conine 1993 (*Continued*)

Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	It is reported that the occupational therapist conducted monthly checks for change in status. The checking of ulcers was carried out 30 minutes after returning to bed by the patient's primary nurse with the joint agreement of the research RN

Conine 1994

Methods	RCT of 2 wheelchair cushions with 3-month follow-up. Method of randomisation unclear as patients were described as "randomly allocated by the principal investigator"
Participants	Elderly patients (mean age 82 y) in an extended care hospital deemed at high risk of pressure ulcers (Norton Score $\leq$ 14); sitting in a wheelchair for minimum of 4 consecutive h/day; free of progressive disease likely to confine to bed. Excluded if diabetic, had peripheral vascular disease; confined to bed for more than 120 consecutive h (except if to heal a pressure ulcer). There were no statistically significant differences between groups at baseline for Norton scores; age; hours in bed/day; sex; diagnosis; sensory loss; history of previous ulcers; weight; nutritional status; oedema; incontinence; hours in wheelchair/day
Interventions	1. Jay cushion (n = 68); the Jay cushion is a contoured urethane foam base over gel pad. 2. Foam cushion (n = 73); 30 kg/m^3 density foam bevelled at the bottom to prevent sling effect. Both cushions fitted with identical Jay air-exchange covers of knitted polyester. Patients assigned to their specific wheelchairs by a seating specialist according to a local policy unaffected by the trial
Outcomes	1. Jay Cushion 25% (17/68); 2. Foam Cushion 41% (30/73). Pressure ulcer incidence data presented as number of ulcers and number of affected patients for all grades of ulcer, but only as number of ulcers by grade (and there were cases of multiple ulcers on the same patient). Therefore impossible to present the incidence data as number of patients affected by ulcers of grade 2 or above
Notes	13% attrition; not analysed by ITT.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	"Qualified patients were randomly assigned to either foam or Jay cushions in groups of 40 by the principal investigator" Method of randomisation not reported
Allocation concealment?	Unclear	Not reported.

Conine 1994 (*Continued*)

Blinding? Pressure ulcer incidence	Yes	"The principal investigator was blind to all data" and "A research assistant, an experienced registered nurse (RN), examined the patients weekly, blind, and classified the status of any skin lesions"
Incomplete outcome data addressed? All outcomes	Yes	Shown in Table 3.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"No statistically significant differences were found between groups"
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Weekly for 3 months.

Cooper 1998

Methods	RCT with 7-day follow-up. Allocation by consecutively-numbered, sealed, opaque envelopes
Participants	100 patients > 65 y, with no pressure ulcers, from 3, 24-bedded mixed emergency orthopaedic trauma wards. All patients at risk of pressure ulcers with Waterlow Risk scores of $\geq$15. Baseline variables similar for each group (age, sex, mobility, Waterlow scores)
Interventions	1. Dry flotation mattress (Roho) (n = 49) (data supplied for only 43). 2. Dry flotation mattress (Sofflex) (n = 51) (data supplied for only 41)
Outcomes	Grade 2 ulcers and above: 1. Roho mattress: 5% (2/43); Sofflex mattress: 2% (1/51). Grade 1 ulcers: 1. Roho mattress: 12% (5/43); 2. Sofflex mattress 5% (2/41)
Notes	Roho mattress: 79% patients found it comfortable or very comfortable, 5 found it uncomfortable. Sofflex mattress: 90% patients found it comfortable or very comfortable. Staff had difficulty setting the level of inflation correctly; this can now be done automatically. 16% attrition; no ITT analysis

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"The subjects were then randomly allocated to one of two types of mattress using consecutively numbered sealed opaque envelopes"

Cooper 1998 (*Continued*)

Allocation concealment?	Yes	See above.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Yes	No missing outcome data. Reasons for attrition reported: death, change in care circumstances, transferred and discharged, however, not specified for each intervention group
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	As seen in Table 1.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	24 h post admission and at 7 days.

Daechsel 1985

Methods	RCT with 3-month follow-up. Method of allocation unclear.
Participants	32 patients with chronic neurological conditions in a long term care hospital. All aged 19-60 y, free from skin breakdown on entry, considered at high risk of pressure ulcers
Interventions	1. Alternating-pressure mattress (Gaymar Inc) (n = 16). 2. Silicore overlay (JW Westman Inc) (n = 16).
Outcomes	Included grade 1 ulcers: 1. Alternating overlay: 25% (4/16); 2. Spenco overlay: 25% (4/16). No statistically significant differences were found between the 2 groups with regard to location and severity of pressure ulcers
Notes	100% follow-up. Patients' satisfaction was similar for both devices

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	"All qualified subjects were entered into the trial for a period of three months and all were randomly assigned to one of the two types of mattress". Method of randomisation not reported

Daechsel 1985 (*Continued*)

Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Unclear	No reasons/numbers for exclusions/attrition given.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"Statistical tests of significance indicated that the groups were comparable on the factors that are considered to be associated with the development of DU"
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Daily observations and weekly skin checks over 3 months.

Economides 1995

Methods	RCT with 2-week follow-up. Allocation by sealed envelope.
Participants	12 patients with grade 4 pressure ulcers needing myocutaneous flap closure. 10/12 participants paraplegic or quadriplegic. Groups appeared broadly comparable at baseline, except the Roho group seem to have slightly better nutritional status (not tested for significance)
Interventions	1. Roho dry flotation mattress (n = 6) - bed overlay consisting of 720 air cells that conform to the body to provide maximum support area and a "floating" environment. 2. Air-fluidised Clinitron bed (n = 6) - ceramic microspheres through which warm pressurised air is blown, covered by a polyester sheet. The bed forms a dry-fluid environment on which the patient floats, thus distributing body weight away from bony prominences
Outcomes	Wound breakdown: 33% (2/6) on Roho vs 33% (2/6) on Clinitron. No significant difference between 2 support surfaces in the prevention of flap breakdown in the immediate postoperative period
Notes	Do not appear to have had any withdrawals.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"The patients were assigned to a support surface by using a table of random numbers"

Economides 1995 (*Continued*)

Allocation concealment?	Yes	"The names of the two support surfaces were placed in envelopes that were sealed and numbered sequentially"
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Unclear	No reasons/numbers for exclusions/attrition reported.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Table 1.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Daily assessments for 2 weeks.

Ewing 1964

Methods	RCT with 6-month follow-up. Mode of allocation unclear - reported as random selection
Participants	Elderly patients, average age 72.5 y, confined to bed, with reduced mobility in legs due to neurological disorder, fixed joints, or peripheral vascular disease. No baseline data given and baseline comparability not described. Setting was geriatric unit of a convalescent hospital
Interventions	1. Sheepskins adjusted so that both legs were supported on the woolly fleece (n = 18). 2. Control, without sheepskins (n = 18). All were submitted to the same 4-hourly routine skin care involving washing, drying, powdering, light massage of pressure areas, bed cradle
Outcomes	The study was too small and poorly designed to detect a difference. No reports of withdrawals. Outcomes not clearly described or reported in terms of numerator and denominator. Reports incidence of pressure ulcers areas of 'reddened' skin. Grading of outcomes not done
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	"The patients were studied for a period of six months, and were allotted to a 'treated' or a 'control' group by random selection"'.

Ewing 1964 (*Continued*)

		Method of randomisation not reported
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Unclear	No reasons/numbers for attrition/exclusions reported.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	No patient demographics given.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	At the end of the study period - at six months

Exton-Smith 1982

Methods	Trial with 2-week follow-up. Allocation by alternation, and, where surface of choice was not available, patients were given an available surface
Participants	Newly-admitted geriatric patients, with fractured neck of femur, and long-stay patients; without pressure ulcers of grade 2 or greater. Norton score <14. Patients were matched in pairs for sex and Norton score. Where a match was not possible, the Airwave patient was matched with a Large Cell Ripple patient with a higher risk score. Groups appear well matched at baseline
Interventions	1. Pegasus Airwave system (AWS) (n = 31) 2 layers of air cells; pressure alternated by deflating every 3rd cell in a 7.5 minute cycle. Mattress ventilated by pinholes through which air passes to keep patient's skin dry. 2. Large Cell Ripple (LCR) mattress (n = 31) large cell ripple not described
Outcomes	Grade 2 ulcer or greater: 1. AWS: 16% (5/31); 2. LCR: 39% (12/31).
Notes	During the trial period, no breakdowns with AWS, 10 breakdowns on LCR, 4 patients withdrawn; 94% follow-up

Risk of bias

Item	Authors' judgement	Description

Exton-Smith 1982 (*Continued*)

Adequate sequence generation?	No	"Patients were alternately allocated the AWS or the LCM unless the appropriate mattress was not available: in that case the patient was allocated the mattress not in use". Proper randomisation not completed
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Unclear	No reasons/numbers for exclusions/attrition reported.
Free of selective reporting?	No	Not all of the study's pre-specified primary outcomes were reported i.e. the reliability and acceptability of both types of apparatus.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"There was no significant difference between the two groups"
Free of other bias - was the timing of the outcome assessment similar in all groups?	No	"Each patient remained on the allocated regimen for 2 weeks unless he died or was discharge from hospital, or the clinic score rose to 17 or more"

Feuchtinger 2006

Methods	RCT with 5-day follow-up (postoperative).
Participants	Recruitment from a Department of Cardiovascular Surgery. Eligible patients > 18 y, scheduled for cardiac surgery with extracorporal circulation. Not required to be free of pressure ulcers; 4 patients had grade 1 pressure ulcers as they went into surgery. Participants well matched at baseline
Interventions	1. Operating table with waterfilled warming mattress and a 4-cm thermoactive viscoelastic foam overlay (Thermo) (n = 85). 2. Standard OR table configuration (OR table with waterfilled warming mattress) (n = 90)
Outcomes	Number of participants with incidence pressure ulcer (assessed day 1, 3 and 5 postoperatively; blinded outcome assessment): Grade 1 ulcers postoperative days 0-5: 1. Thermo 15.3% (13/85); 2. Standard 10% (9/90). Grade 2 ulcers postoperative day 0-5:

Feuchtinger 2006 (*Continued*)

	1. Thermo 2.4% (2/85); 2. Standard 1% (1/90).
Notes	No higher grades of ulcers reported. No participant loss reported. The study was stopped after interim analysis due to the 11.1% total incidence in the standard group compared with 17.6% in the treatment group

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	"Included patients were randomised to either the standard operating table configuration or the test configuration". Method of randomisation unclear
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Yes	"The postoperative nurses who assess the skin condition were unaware of the patient assignment"
Incomplete outcome data addressed? All outcomes	Unclear	No numbers/reasons given for exclusions/ attrition.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"Ninety paired assessments were undertaken for the inter-rater reliability assessment". No statistically significant differences were found
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Day 1, 3 and 5 postoperatively.

Gebhardt 1996

Methods	Trial allocation by hospital number. Two systems: patients were automatically placed on the low-cost mattress within the allocated system. Patients who deteriorated or experienced persisted erythema were transferred to a medium-cost mattress. If deterioration continued they were placed on the highest-cost mattress, or transferred to the alternate group, if appropriate
Participants	Patients in ICU with a Norton score <13, who had been in the unit for < 3 days, with no pressure ulcers

Gebhardt 1996 (*Continued*)

Interventions	1. Alternating-pressure air mattresses (shallow small cell overlays, medium depth large cell overlays, deep mattresses and deep pulsating low-air-loss beds) (n = 23). 2. Constant low-pressure supports (fibre overlays, foam mattresses/overlays, static air overlays, gel overlay, water overlay, bead overlay, low-air-loss mattresses, static air overlay, low-air-loss beds and air-fluidised bead beds) (n = 20)
Outcomes	1. Support provided. 2. Pressure ulcer development: Alternating pressure group (n=0 participants), Constant low-pressure group (n=8 participants of which grade 2 (n=4), grade 3 (n=2), both grade 2 and 3 (n=2)) 3. Cost: Low cost (less than £500) n=22 (n=1shallow small cell overlay, n=5 fibre overlays, n=4 medium-depth large-cell overlays, n=6 foam mattresses/overlays, n=3 static air overlays, n=1 gel overlay, n=1 water overlay, n=1 bead overlay) Medium cost (£500- £5000) n=4 (n=2 deep mattresses, n=1 low-air-loss mattresses, n= 1 static air overlays) High cost (Greater than £5000) n=6 (n=2 deep pulsating low-air-loss beds, n=2 low-air-loss beds, n=2 air fluidised bead beds)
Notes	No ITT analysis. Mechanical unreliability and poor management of alternating-pressure supports was a problem

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	No	Patients allocated "according to the final digit of their hospital number (even to alternating pressure, odd to constant low pressure supports)."
Allocation concealment?	No	Patients allocated "according to the final digit of their hospital number (even to alternating pressure, odd to constant low pressure supports)."
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Yes	Reasons for exclusion/attrition given.
Free of selective reporting?	Unclear	Pre-specified aims not reported. Incidence of pressure ulcers as well as mean cost per type of mattress provided
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	As shown in Table 2.

Gebhardt 1996 (*Continued*)

Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	"Patients were visited four times weekly by the research nurse", however, "patients were taken out of the trial after three months, or if their condition improved so that they were no longer at risk of developing pressure sores, if they were discharged or transferred to another ward or hospital, or if they died".

Gentilello 1988

Methods	RCT, duration of follow up unclear. Trial primarily not a pressure ulcer trial, but of kinetic treatment tables used to prevent chest infection in immobile patients
Participants	Critically ill patients in surgical ICU immobilised because of head injury, spinal injuries or traction. Groups well matched at baseline for demographic and pulmonary risk factors; patients in the conventional bed group had higher incidence of cigarette smoking
Interventions	1. Kinetic Treatment Table (KTT) (n = 27): rotates through an arc of 124^{o} every 7 minutes. Nurses instructed to leave bed rotating except when vital signs were being recorded and treatments being given. If a patient developed a serious complication as result of KTT, they were moved onto a conventional bed. 2. Conventional beds (n = 38): patients turned in conventional fashion every 2 h. Patients who developed a chest infection, where positioning was thought to be a factor, were moved onto a KTT
Outcomes	Primary outcomes were: Incidence of pulmonary complications. Other outcomes measured included Incidence of pressure ulcers: KTT 30%; Conventional beds: 26%.
Notes	1 patient withdrew and was not included in the analysis. No raw data provided for incidence of pressure ulcers

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"Randomization was performed by drawing a randomizing card".
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Only reported that the physician in charge of interpreting X-rays was blinded to treatment allocation

Gentilello 1988 (*Continued*)

Incomplete outcome data addressed? All outcomes	Unclear	No reasons/numbers for attrition/exclusion reported.
Free of selective reporting?	Unclear	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"Patients in the control and experimental groups were similar for most demographic variables"
Free of other bias - was the timing of the outcome assessment similar in all groups?	No	"Patients were evaluated daily. The active study period started with randomisation and ended when the patient was allowed out of bed, died or was discharged from the SICU"

Geyer 2001

Methods	Pilot RCT with 12-month follow-up.
Participants	Recruitment in nursing homes (for the elderly). Eligible patients were wheelchair users aged > 65 y at risk of developing pressure ulcers (Braden score ≤ 18); with a combined Barden activity and mobility sub-scale of ≤ 5; no pressure ulcers on their sitting surface; and tolerant of daily wheelchair sitting for ≥ 6 h in the ETAC twin wheelchair (body weight required to be < 250 lb). Participants well matched at baseline for age, initial Braden score, sex
Interventions	1. Pressure-reducing wheelchair cushion (n = 15). 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. Further details about cushion design were not provided. 2. Standard foam (eggcrate) cushion (Bioclinic Standard, Sunrise Medical) (n = 17)
Outcomes	Number of participants with Incidence pressure ulcer (weekly assessment; blinded outcome assessment): Grade not reported (all grades): 1. Pressure-reducing cushion 40% (6/15); 2. Foam cushion 58.5% (10/17).
Notes	Seating assessments were performed in both groups throughout the study. 1. 1 participant died, 3 lost to follow-up. 2. 1 participant died, 2 lost to follow-up.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"Random treatment assignments with a 1-to-1 scheme were generated prior to the start of the

Geyer 2001 (*Continued*)

		study by a separate research team member who was not involved in executing the trial"
Allocation concealment?	Yes	"Sequentially numbered sealed envelopes containing the treatment assignment were prepared"
Blinding? Pressure ulcer incidence	Yes	"Nursing staff members performing the outcomes measurements were blinded to the treatment group"
Incomplete outcome data addressed? All outcomes	Yes	All reasons/numbers for attrition/exclusion provided.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Table 4 in the study report.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Weekly patient assessments.

Gilcreast 2005

Methods	RCT of heel ulcers: follow-up period unclear.
Participants	Recruitment from military tertiary-care academic medical centres. Eligible patients were at moderate or high risk of pressure ulcer development (Braden score $\leq$ 14). Patients with hip surgery were excluded, as were patients anticipated to be admitted for < 72 h, and those with pre-existing heel pressure ulcers. Limited baseline information presented. There was baseline imbalance in sex
Interventions	1. Bunny Boot (fleece) high cushion heel protector. 2. Egg crate heel lift positioner (holds the foot suspended above the bed surface with heel through a window). 3. Foot waffle air cushion (felt coated plastic inflatable plastic pillow that encircles the foot)
Outcomes	Pressure ulcer incidence (did not stratify by grade; baseline numbers not available and unclear whether the unit was number of ulcers or number of patients): 1. Bunny Boot 4% (3/77); 2. Egg crate 5% (4/87); 3. Foot waffle 7% (5/76).
Notes	69% of participant were in ICU. Of the initial 338 patients, only 240 had follow-up data, given as n in outcomes. Not clear how the 338 were distributed among the three groups. 53 not included, as did not wear the devices for at least 48 h; 45 not included as

Gilcreast 2005 (*Continued*)

	they were non-compliant. No ITT

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Drawing of cards.
Allocation concealment?	No	Inadequate (non-numbered envelopes)
Blinding? Pressure ulcer incidence	No	"The 1 nurse was performing all research tasks and was not blinded to the device to which the participant was assigned"
Incomplete outcome data addressed? All outcomes	Yes	All reasons/numbers for attrition/exclusions reported.
Free of selective reporting?	Unclear	All pre-specified outcomes reported, however, raw numbers of participants unclear
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	Only differences in gender distribution reported.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Daily assessments.

Goldstone 1982

Methods	Patients randomised alternately on arrival in A&E to 1 of 2 alternative surfaces. Follow-up not clear
Participants	Patients (> 60 y) with femur fracture. (Mean Norton score 13). Groups comparable at baseline for age and Norton score
Interventions	1. Beaufort bead bed system (includes 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). 2. Standard supports in A&E, operating theatre, ward (n = 43)
Outcomes	Grading of ulcers not given. Beaufort bead bed system: 16%; Standard surface: 49%. Maximum width of broken skin (mean): Beaufort bead bed system: 6.4 mm; Standard surface: 29.5 mm.

Goldstone 1982 (*Continued*)

Notes	Patients in the Beaufort bead bed group who were incontinent of urine (numbers not given) were catheterised, however, this did not seem to be the same for the control group. Patients who were removed from the Beaufort bed standard surfaces for any reason not included in analysis. Number of withdrawals unclear; no ITT analysis

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	No	"Patients...were assigned alternately (from a random start) either to the Beaufort system or to the existing 'standard' surfaces as encountered on trolleys, beds, surgical tables etc"
Allocation concealment?	Unclear	See above - not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	No	"Patients who were later found to have suffered no fracture, or who requested to be removed from the Beaufort system for any reason, or who died before reaching the post operative ward are excluded from the analysis"
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"The two groups were well matched on a variety of criteria on admission"
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Gray 1994

Methods	RCT with 10-day follow-up. Allocation by sealed envelope.
Participants	Patients from orthopaedic trauma, vascular and medical oncology units without breaks in the skin (Waterlow score > 15). Groups well matched at baseline for age, sex and Waterlow score
Interventions	1. Softfoam mattress (n = 90). 2. Standard 130 mm NHS foam mattress (n = 80).

Outcomes	Incidence of pressure ulcers. Skin condition assessed at 5 and 10 days; presumably assessor not blind to treatment group. Grade 2 or greater ulcer: Softform: 7%; Standard: 34%. Rate of transfer to dynamic support surface: 19% in standard group vs 2% in Softform group
Notes	Impossible to calculate attrition rate, as incidence reported as % only and unclear what the denominator was. Nurses were more positive, and patients gave higher comfort scores to Softform mattress

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	The subjects were then "randomly allocated to one of the two types of mattress using unmarked envelopes".
Allocation concealment?	Unclear	The subjects were then "randomly allocated to one of the two types of mattress using unmarked envelopes".
Blinding? Pressure ulcer incidence	Unclear	No mention of blinding.
Incomplete outcome data addressed? All outcomes	Unclear	Num- bers not reported post-baseline. Might have been issues as the discussion notes that: "A number of patients were excluded from the study because the Waterlow score awarded by the ward staff differed greatly from that of the researcher". Not clear if this exclusion was post-randomisation.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	More patients in orthopaedic and vascular specialities in the treatment arm
Free of other bias - was the timing of the outcome assessment similar in all groups?	No	"...were assessed for deterioration in skin condition at 5 and 10 days respectively...."

Gray 1998

Methods	Trial with follow-up of 10 days.
Participants	Patients admitted to a District General Hospital for bed-rest or surgery, with intact skin, no other skin abnormalities, no terminal illness, weight <160 kg. Mean Waterlow score on admission: Group 1: 14 (3.6); Group 2: 13 (2.5)
Interventions	1. Transfoam mattress (n = 50). 2. Transfoamwave (n = 50) (both foam).
Outcomes	1. 1x grade 4 ulcer. 2. 1x grade 2 ulcer.
Notes	95% follow-up; ITT analysis. Length of stay, pressure ulcer incidence. Comfort not specified (and only in treatment arm)

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	"Subjects were selected from the admissions using serially numbered, sealed opaque envelopes and allocated to either a study mattress... or a non -study mattress.....This form of randomisation ensured that staff were not able to choose which patients be allocated to the study mattress"
Allocation concealment?	Yes	"Subjects were selected from the admissions using serially numbered, sealed opaque envelopes and allocated to either a study mattress... or a non -study mattress.....This form of randomisation ensured that staff were not able to choose which patients be allocated to the study mattress"
Blinding? Pressure ulcer incidence	Yes	"Subjects were reviewed at 5 and 10 days post admission. Observations of the skin were made and any pressure sores documented; these observations were confirmed blindly by the ward link nurse"
Incomplete outcome data addressed? All outcomes	Unclear	Numbers not reported post-baseline.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	Only data for the treatment arm were provided. People were randomised to a non-study treatment, but were not followed-up

Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Subjects were reviewed at 5 and 10 days post admission.

Gunningberg 2000

Methods	RCT with follow-up until discharge, or 14 days postoperatively
Participants	Patients admitted with a suspected hip fracture via an A&E department. Participants were > 65 y and did not have pressure ulcers
Interventions	1. 10 cm visco-elastic foam mattress on arrival in A&E, and visco-elastic foam overlay on standard ward mattress (n = 48). 2. Standard A&E trolley mattress and ward mattress (n = 53).
Outcomes	Grade 2 to 4 incidence:1. 8.3% (4/48); 2. 15% (8/53). Pressure ulcer incidence (all grades):1. 25% (12/48);2. 32% (17/53) Mean comfort rating:1. 4.2;2. 4.0 All results NS.
Notes	Only 44 participants completed the comfort questionnaire.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Only details of process provided state, "On arrival to A and E patients with a suspected hip fracture were randomised to an experimental or control group with concealed allocation"
Allocation concealment?	Unclear	"On arrival to A and E patients with a suspected hip fracture were randomised to an experimental or control group with concealed allocation"
Blinding? Pressure ulcer incidence	Unclear	Main outcome not blinded, but study authors undertook blinded outcome assessment as a 'process check' on a sub-set. "25% Pus....in 13 patients were photographed during the study. The ulcers in these photos were graded by an expert nurse..who was blinded to treatment..."
Incomplete outcome data addressed? All outcomes	Unclear	Difficult to tell if 18 people were excluded before or after randomisation. Outcomes reported for 101 patients: "This study...included 119 patients aged

		over 65 years with a hip fracture....Eighteen were excluded because they died, did not have skin assessment on arrival, were admitted with PUs. Of the remaining 101 patients 48 and 53 were allocated to the experimental and control groups respectively"
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Similar.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	"The pressure ulcer nurse on the ward usually performed the assessments on the 4th day postoperatively and at discharge"

Hampton 1997

Methods	RCT, but method of allocation not described. Duration of follow-up to a maximum of 20 days
Participants	Very little detail; average age 77 y. No data regarding baseline status of patients presented in published paper, therefore, impossible to judge baseline comparability. Only limited information obtained on request: number of patients at high-very high risk Airwave group = 31; number of patients at high-very high risk Cairwave group = 27. Mean age: Airwave group = 79 y; Cairwave group = 75 y
Interventions	1. Alternating-pressure (Cairwave System) (n = 36): 3-cell, 7.5 minute cycle. Manufacturers claim that zero pressure achieved for more than 20% of the cycle. 2. Alternating-pressure (Airwave System) (n = 39): cells arranged in sets of 3 and inflated in waves. 7.5 minute cycle; zero pressure said to be applied for 15% of the time
Outcomes	Incidence of pressure ulcers. No patient in this study developed a pressure ulcer
Notes	Attrition unclear.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Report states, "randomised controlled trial", but no further details given
Allocation concealment?	Unclear	States, "patients were allocated to the Cairwave Therapy System during the randomised controlled trial", but no further information was given

Hampton 1997 (*Continued*)

Blinding? Pressure ulcer incidence	Unclear	No report of blinding.
Incomplete outcome data addressed? All outcomes	Unclear	No information provided.
Free of selective reporting?	Unclear	No access to study protocol.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	No information provided.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	No information provided.

Hofman 1994

Methods	RCT with 2-week follow-up. Patients randomised in blocks of 6 but method of randomisation not described
Participants	Patients with a femoral-neck fracture and risk score > 8 (Dutch consensus scale). Excluded patients with pressure ulcers of grade 2 or greater on admission. Groups were similar at baseline for pressure ulcer risk; haemoglobin; total serum protein and serum albumin
Interventions	1. Cubed foam mattress (Comfortex DeCube mattress) (n = 21) - allows removal of small cubes of foam from beneath bony prominences. 2. Standard hospital mattress (n = 23) - standard polypropylene SG40 hospital foam mattress. Both groups were treated according to the Dutch consensus protocol for the prevention of pressure ulcers
Outcomes	Incidence of ulcers of grade 2 or greater at 2 weeks. Outcome assessment not blind to treatment group. Patients were examined 1 and 2 weeks after surgery by 2 independent observers; disagreement resolved by a 3rd observer. Grade 2 or greater ulcers: Comfortex DeCube: 24% (4/17); Standard: 68% (13/19). Maximum pressure ulcer gradings were significantly higher for the standard mattress than the DeCube mattress at 1 and 2 weeks
Notes	78% follow-up. No ITT analysis. DeCube mattress was not always used correctly, and its size was not optimal for all patients. A priori sample size calculation

Risk of bias

Item	**Authors' judgement**	**Description**

Hofman 1994 (*Continued*)

Adequate sequence generation?	Unclear	"Each group of 6 consecutively admitted patients was randomly divided into 3 patients nursed preoperatively and postoperatively on the standard Vredestein polyproleen SG 40 hospital mattress (Vredestein, Netherlands) and 3 nursed on the comfotex DeCube"
Allocation concealment?	Unclear	See above, only description of the randomisation process in paper.
Blinding? Pressure ulcer incidence	No	"The study was not blinded with respect to observer or nurse".
Incomplete outcome data addressed? All outcomes	Unclear	Of the 46 patients randomised, 2 were excluded due to the randomisation not being performed correctly (no further details) both in control group. By week 1, 1 patient had left each group (1 death, 1 discharge). By 2 weeks post randomisation, 4 patients in each group had been discharged or died. It is not totally clear but seems that only those remaining (n = 17 compared with 19) were included in the 2 week analysis.
Free of selective reporting?	Yes	Main outcome of interest was occurrence of pressure ulcers and this was recorded
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Age and length of hospital stay balanced. More medial fractures in control group and 24% male in treatment group compared with 4% in control group. Not sure, though, how these would be linked to outcome and cause bias
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Patients were examined 1 and 2 weeks after surgery.

Inman 1993

Methods	RCT with an average of 17 days' follow-up. Method of allocation unclear
Participants	Patients > 17 y with an Acute Physiology and Chronic Health Evaluation (APACHE II) score > 15 who had an expected ICU stay of > 3 days
Interventions	1. Low-air-loss beds (n = 49). 2. Standard ICU bed (n = 49); patients rotated every 2 h.

Inman 1993 (*Continued*)

Outcomes	Incidence of pressure ulcers reported in the trial both as ulcers per patient and patients with ulcers. We have only extracted the incidence of patients developing ulcers. Grade 2 or greater ulcers: Low-air-loss beds: 12% (6/49); Standard ICU bed: 51% (25/49). Patients with multiple pressure ulcers: Low-air-loss beds: 2% (1/49); Standard ICU bed: 24% (12/49).
Notes	A priori sample size calculation. 98/100 randomised participants completed the study, 1 lost from each group as did not stay in ICU for 3 days; neither developed an ulcer. No ITT analysis.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	"100 consecutive patients were randomly assigned to receive treatment with either the air suspension bed or a standardised ICU bed"
Allocation concealment?	Unclear	See above.
Blinding? Pressure ulcer incidence	Unclear	Blinding not mentioned in the description of outcome assessment. Not explicit that anyone was blinded
Incomplete outcome data addressed? All outcomes	No	100 randomised, 98 analysed. One patient from each group was excluded post-randomisation
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Groups similar at baseline in age and reason for admission. More men in control compared with standard group (59% vs 45%)
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Timing of assessment daily in both groups.

Jolley 2004

Methods	RCT with unclear follow-up period, mean bed days observed/participant Group 1: 7 days, and Group 2: 7.9 days
Participants	Participants recruited from a single hospital, and had to be at low to moderate risk of developing a pressure ulcer and > 18 y. Patients were excluded if they had no risk or high risk (as more complex interventions required), if they had any pre-existing ulcers, had an expected length of stay of < 48 h or had darkly-pigmented skin (justified by authors as making grade 1 ulcers difficult to detect) Participants well matched at baseline for age, sex, mean pressure ulcer risk score
Interventions	1. 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 = 270). 2. 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 = 269)
Outcomes	Number of participants with incidence pressure ulcer (daily assessment; unblinded outcome assessment): All ulcers (grade 1 and 2; no grade 3 or 4 recorded) 1. Sheepskin: 10% (21/218); 2. Usual care: 17% (37/223). Total number of ulcers: 1. Sheepskin: 27; 2. Usual care: 58. Total number of incident grade 2 ulcers: 1. Sheepskin: 12; 2. Usual care: 20.
Notes	Whilst 270 were allocated to the sheepskin and 269 to control; only 218 and 223 received their allocated treatment and are included in the analysis. Not ITT "Any patient whose risk increased to high (Braden score <12) for 48 h was no longer followed up for pressure-ulcer endpoints." Authors did not say why. Of the 218 participants in the sheepskin group 2 died, 7 became high risk (treatment change), 14 requested withdrawal, 6 had ward staff intervention and 11 changed treatment for other reasons. Of the 223 control participants 5 died, 1 became high risk, 8 requested withdrawal, 5 had ward staff intervention and 10 changed treatments for other reasons

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Shuffling cards(?): "Patients were randomly allocated to receive.....using numbered cards in individually sealed opaque envelopes; blocks of 16 envelopes (eight of each group) were shuffled before use"

Jolley 2004 (*Continued*)

Allocation concealment?	Yes	"Patients were randomly allocated to receive.....using numbered cards in individually sealed opaque envelopes; blocks of 16 envelopes (eight of each group) were shuffled before use"
Blinding? Pressure ulcer incidence	No	"As it was logistically impossible to blind patients, ward staff and research nurses to the treatment group this was an open-label, unblinded trial"
Incomplete outcome data addressed? All outcomes	No	"539....were randomly allocated. Of these, 441 received the allocated intervention. All 441 were followed up to the endpoints...". Data for 441 not 539. Is a per protocol analysis.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	Baseline data for 441 participants and not the 539 randomised
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	"Research nurse assessed each participant daily for pressure ulcer risk.....and skin integrity"

Kemp 1993

Methods	RCT with 1-month follow-up. Allocation by random-number table
Participants	Inclusion criteria: > 65 y, inpatients, with a Braden Score of ≤16. Age ranged from 65-98 y, 58 women, 26 men. Recruited from general medicine, acute geriatric medicine and long term care. All patients free from pressure ulcers on admission. Groups similar for important variables at baseline.
Interventions	1. Convoluted foam overlay (CF), 3 or 4 inches thick (n = 45). 2. Solid foam overlay (SF) 4 inches thick, sculptured (n = 39)
Outcomes	Incidence of pressure ulcers assessed by Research Nurse presumably not blinded to intervention. Included grade 1 ulcers: CF: 47%; SF: 31%.
Notes	All patients appear to have completed the study.

Kemp 1993 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"..a random number table was used to assign study participants to...."
Allocation concealment?	Unclear	not clearly reported
Blinding? Pressure ulcer incidence	Unclear	not clearly reported
Incomplete outcome data addressed? All outcomes	No	"..45 patients were assigned to the CF group and 39 to the SF group....." "...33 (39%) patients developed a total of 57 pressure ulcers...."
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	Similar for Braden score, age, mobility, but these figures were not presented for all those randomised. Treatment group were lighter, 118.51 lb vs 129.46 lb when all participants included
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	"Research nurses assessed each patient's skin and completed a Braden scale every Monday, Wednesday and Friday for 1 month or until discharge..."

Keogh 2001

Methods	RCT with follow-up of 5-10 days.
Participants	Patients from 2 surgical and 2 medical wards: > 18 y; Waterlow score of 15-25; tissue damage no greater than grade 1
Interventions	1. Profiling bed with a pressure reducing foam mattress/cushion (n = 50). 2. Flat-based bed with a pressure relieving/redistributing mattress/cushion (n = 50)
Outcomes	Number of pressure ulcers developed: 1. 0/35; 2. 0/35. Healing of existing grade 1 ulcers: 1. 100% (4/4); 2. 20% (2/10).

Keogh 2001 (*Continued*)

Notes	Extent of follow-up difficult to ascertain. No difference between the groups in terms of transferring in and out of bed	

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"The block design randomisation code was computer generated by an independent statistician using blocks of eight"
Allocation concealment?	Yes	"The allocation for each patient was placed in sealed opaque envelopes that were numbered sequentially. The patient and researcher were not aware of allocation until after recruitment"
Blinding? Pressure ulcer incidence	Unclear	Pressure ulcer incidence.
Incomplete outcome data addressed? All outcomes	No	"A total of 100 patients were recruited into the study. Data were incomplete for 30 of these patients. All 100 patients were included in an intention-to-treat analysis in respect of pressure ulcer incidence"
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Imbalance in male to female ratio (M:F 20:30 in control and 35:15 in treatment). Balanced on initial nutritional assessment score BMI, age, mobility score.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	"Waterlow scores were assessed and pressure areas observed daily"

Laurent 1998

Methods	RCT with factorial design. 2 pressure-relieving mattresses used either in ICU (alternating-pressure), or in post-ICU hospitalisation (constant low-pressure), or in combination, and compared in each case with the standard surface. Randomised "by blocks" - method of allocation unclear
Participants	Adults over 15 y of age, admitted for major cardiovascular surgery, hospital stay likely to be at least 5 days, with a period on ICU. Little data provided regarding baseline comparability.

Interventions	2 X 2 factorial design: 1: Standard mattress in ICU; standard mattress postoperatively (n = 80). 2: Nimbus (AP) in ICU; standard mattress postoperatively (n = 80). 3: Standard mattress in ICU; Tempur (CLP) postoperatively (n = 75). 4: Nimbus in ICU; Tempur postoperatively (n = 77).
Outcomes	Incidence of ulcers of grade 2 or above (partial- or full-thickness skin loss and worse): Group 1: 18% (14/80); Group 2: 13% (10/80); Group 3: 15% (11/75); Group 4: 13% (10/77). NS.
Notes	A priori sample size calculation. No reports of withdrawals.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Exact randomisation procedure not reported: "patients were randomised among four groups" and "patients were randomised by blocks".
Allocation concealment?	Unclear	See above - not reported.
Blinding? Pressure ulcer incidence	No	Blinding discussed as follows: "given the kind of material tested, blinding was not possible"
Incomplete outcome data addressed? All outcomes	Yes	Data available for all participants enrolled in study (no attrition)
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"There was no imbalance of characteristics, risk factors, or surgical procedures between the groups"
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Lazzara 1991

Methods	RCT (allocation by random-number tables) in elderly nursing home population with 6-month follow-up
Participants	Nursing home residents at risk of pressure ulcers (Norton score > 15). 9/66 subjects had pressure ulcers on entry to the study
Interventions	1. Air-filled (SofCare) overlay (33 randomised; 2 ulcer on admission; 10/31 developed a new one). 2. Gel mattress (33 randomised; 7 ulcer on admission; 8/26 developed a new one)
Outcomes	Grade 2 or greater ulcers: 1. Air overlay: 16% (5/31); 2. Gel mattress: 15% (4/26).
Notes	Interventions not well described. Of the 74 who entered the study, only those who participated for 4-6 months were included in the analysis (total of 66). 19 patients died and were excluded from the analysis, but these might be at highest risk. It was difficult to maintain inflation of the air overlay; it also punctured easily. During the trial, 110 air overlays were used for 76 patients. Gel mattress was heavy

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random-number table.
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Blinding not reported: "patients in both study groups were assessed by the same researcher for the presence of pressure ulcer development over areas of bony prominence".
Incomplete outcome data addressed? All outcomes	Unclear	Nineteen participants died during the 6-month study; individuals participating for 4-6 months were included in the data analysis, although exact numbers included were not reported.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No important baseline differences.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Lim 1988

Methods	RCT with 5-month follow-up. Patients were "randomly assigned" but method of allocation not described
Participants	62 residents of an extended care facility; aged ≥ 60; free of pressure ulcers but at high risk of developing an ulcer (Norton score ≤ 14); using a wheelchair for ≥3 h/day; without progressive disease or confined to bed. Groups well matched at baseline for sex, age, weight, Norton score, primary diagnosis, sensory status, time spent in wheelchair, and mobility
Interventions	1. Foam slab cushion (2.5 cm medium density foam glued to 5 cm firm chipped foam) (n = 26). 2. Contoured foam cushion (same foam as above; cut into a customised shape to relieve pressure on ischial tuberosities) (n = 26). Both cushions fitted with identical snug fitting covers of knitted polyester
Outcomes	Included grade 1 ulcers: 1. Slab foam: 73% (19/26); 2. Contoured foam: 69% (18/26). Mean severity score was 1.9 in the slab and 1.7 in the contoured (P value > 0.05), and the mean healing duration was 6.2 weeks in the slab and 5.4 weeks in the contoured group (P value > 0.05)
Notes	84% follow-up.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Exact randomisation procedure not described: "qualifying consenting subjects were randomly assigned to one of the two cushions for a period of 5 months"
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	"The incidence, location, severity, and healing time of DU were determined weekly by another occupational therapist, a research assistant, who was from outside of the facility and was not knowledgeable of the Norton's score of the subjects"; assessments taken a half-hour after participants returned to bed
Incomplete outcome data addressed? All outcomes	Yes	10 participants reported as dropouts with reasons given; no ITT analysis conducted, but attrition within 20% limit of total recruited sample.

Lim 1988 (*Continued*)

Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No important baseline differences.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

McGowan 2000

Methods	RCT. Discharge from hospital, transfer to a rehabilitation ward
Participants	Orthopaedic patients aged ≥ 60; assessed as being at low or moderate risk of pressure ulcer development by Braden scale; intact skin; anticipated LOS > 48 h
Interventions	1. Standard hospital mattress, sheet and an Australian Medical Sheepskin overlay; sheepskin heel and elbow protectors as required (n = 155). 2. Standard hospital mattress, sheet with or without other low tech constant pressure devices as required (n = 142). Sheepskins were changed as required (at least every 3 days)
Outcomes	1. Sheepskin:9% (4/155) (21 ulcers) 7 participants developed 1 ulcer; 7 developed 2, all grade I. 2. Control: 30% (43/142) (67 ulcers) 25 participants developed 1 ulcer; 7 developed 2; 11 developed 3. 4 ulcers were grade II, 1 grade IV. Comfort rated significantly greater in experimental group. Limb protectors difficult to keep in place
Notes	1 patient from each group withdrew prior to data collection. 6 patients in experimental group withdrew because sheepskin too hot or irritable; 7 in control group withdrew plus 3 in experimental group due to protocol violations (no ITT). Patients in experimental group rated comfort significantly higher than controls (P value < 0.0001)

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Stated, "patients were randomly allocated (using sealed envelopes) by research nurses to receive one of two interventions"
Allocation concealment?	Unclear	Not reported, although sequence generation based on sealed envelopes (see above).
Blinding? Pressure ulcer incidence	No	"Blinded outcome assessments were not possible because the support surfaces could not be disguised and patients could not be moved off the bed for assessment of their

McGowan 2000 (*Continued*)

		pressure ulcers"
Incomplete outcome data addressed? All outcomes	Yes	Withdrawals from study reported with reasons given; and "data collected for patients up until the time of withdrawal has been included in the analysis with the exception of five controls and two patients from the experimental group for whom study participation time was not available".
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No important baseline differences.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Mistiaen 2009

Methods	RCT with 30-day follow-up.
Participants	Patients recruited from aged care facility (predominantly rehabilitation department) and rehabilitation centre. Grade 1 pressure ulcers included in the sample
Interventions	1. Australian medical sheepskin within 48 h of admission on the patient's bed. Application in wheelchair recommended and under heels permitted. (Hi-temp, urine resistant, size XXL mattress) (n = 271). 2. Usual care (n = 272). Cointerventions: usual intervention for prevention of pressure ulcers in study settings
Outcomes	Number and grade of pressure ulcers developed. 1. Grade 1 = 18, Grade 2 = 6, Grade 3 = 0, Grade 4 = 0. 2. Grade 1 = 32, Grade 2 = 6, Grade 3 = 2, Grade 4 = 0.
Notes	ITT analyses performed. Sample size calculation performed, however, not included in this paper (included in published protocol). 33% of intervention group believed the sheepskin to be too warm, and thus the trial was stopped early in these patients

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Truly random methods of randomisation used.
Allocation concealment?	Yes	Adequate methods of allocation concealment used.

Mistiaen 2009 (*Continued*)

Blinding? Pressure ulcer incidence	No	No blinding on patients, clinicians, outcome assessors. Unclear/unstated blinding of data analysts
Incomplete outcome data addressed? All outcomes	Unclear	Not reported.
Free of selective reporting?	Unclear	Not reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Groups were well matched.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Nixon 1998

Methods	RCT with 8-day follow-up. Telephone randomisation (i.e. full allocation concealment) stratified by centre, and age
Participants	Patients aged ≥ 55 y, admitted for elective major general, gynaecological or vascular surgery in supine or lithotomy position and free of preoperative pressure damage greater than grade 1. Groups well matched at baseline for age, sex, Braden score, type of surgery, duration of surgery, length of preoperative stay, proportion of time hypotensive during surgery
Interventions	1. Dry visco-elastic polymer pad on operating table (n = 222). 2. Standard operating theatre table mattress plus Gamgee heel support (n = 224)
Outcomes	Incidence and severity of pressure ulcers: Overall incidence of pressure ulcers of 16% (65/416): 1. Dry visco-elastic polymer pad on operating table: 11% (22/205); 2. Standard mattress: 20% (43/211); P value 0.01, OR = 0.46; 95% CI 0.26-0.82. 56/65 episodes of skin damage were conversions from grade 0 to grade 1 ulcers. 4/65 grade 0 to grade 2A conversions. 5/65 grade 0 to grade 2B conversions. These data were not broken down by group
Notes	A priori sample size calculation. 133 paired assessments by 94 nurses for pre-study inter-rater reliability assessments undertaken. Disagreement in only 2.2% assessments, and only 2 disagreements related to differentiating between grade 1 and grade 2a ulcers (the remainder were grade 0 and grade 1). The majority were associated with heel assessments. For the recovery and ward area assessments, there were discrepant assessments in only 8. 5% cases. Sensitivity analysis assessing the impact of this level of misclassification on the overall result determined that the overall difference between the mattresses remained. Main endpoint data reported for 416 patients; incomplete data for 30 patients (lost forms 3; incomplete postoperative skin assessment 27). The patients with incomplete data were not reported by group

Nixon 1998 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Stratified randomisation by centre and age: "a telephone randomisation schedule was developed within random permuted blocks of 6, with a run-in of 8"; age as 55-69 and 70 or over.
Allocation concealment?	Yes	Randomisation managed by the Northern and Yorkshire Clinical Trials and Research Unit.
Blinding? Pressure ulcer incidence	Yes	The Data Monitoring Committee and statistician were blind to treatment allocation; "the record pertaining to the intra-operative randomised mattress allocation remained separate from the main data collection pro forma to maintain the blind"
Incomplete outcome data addressed? All outcomes	Yes	ITT analyses conducted.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	No	Standard mattress group: longer length of operation, longer pre-operative stay, more time in hypotensive state than dry polymer pad group
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Nixon 2006

Methods	RCT with 30-day follow-up twice weekly, and a further 30-day follow-up once weekly
Participants	Recruited from 11 hospitals. Patients admitted as acute or elective cases. Eligible patients aged ≥ 55, expected to stay for at least 7 days, with either limited activity or mobility (Braden scale activity and mobility score of 1 or 2), or an existing pressure ulcer of grade 2. Elective surgical participants without limited activity or mobility were eligible if the mean LOS for surgery was at least 7 days and they were expected to have Braden scale activity and mobility scores of 1 or 2 for at least 3 days postoperatively. Exclusion criteria: grade 3 or worse pressure ulcer on admission, planned admission to ICU after surgery, admitted to hospital more than 4 days before surgery, slept at night in a chair, weighted > 140 kg or < 45 kg (as per mattress specifications) Participants were well matched at baseline.

Interventions	1. Alternating-pressure overlay (n = 990): alternating cell height minimum 8.5cm, max 12.25cm; cell cycle time 7.5-30 minutes. 2. Alternating-pressure mattress (n = 982): alternating cell height min 19.6cms, max 29. 4cms; cell cycle time 7.5-30 minutes Intervention was allocated within 24 hrs of admission.
Outcomes	Number of participants with incidence pressure ulcer grade 2 and above (unblinded outcome assessment): 1. Overlay: 11% (106/989); 2. Mattress: 10% (101/982). Patient acceptability: requests for mattress change: 1. Overlay: 23% (230/989); 2. Mattress: 19% (186/982). Healing of existing pressure ulcers: 1. Overlay: 34% (20/59); 2. Mattress: 35% (19/54). Cost of treatment (GBP): 1. Overlay: Sterling 6793.33; 2. Mattress: Sterling 6509.73. Mean difference in time to pressure ulcer (grade 2 or higher) development (days). Participants in mattress group took 10.64 days longer to develop pressure ulcer than overlay group
Notes	1 participant was recruited to the trial twice (group 1) and was excluded from analysis. Factors that had a significant effect on the proportion of people developing a new pressure ulcer were admission for an acute condition, the presence of a wound skin trauma or non-blanching erythema on any site at baseline, age, haemoglobin level and diabetes The authors stated that differences in health benefits and total costs for hospital stay between alternating-pressure mattresses and alternating-pressure overlays were not statistically significant. However, a cost effectiveness acceptability curve indicated that on average alternating-pressure mattresses were associated with an 80% probability of cost saving compared with alternating-pressure overlays

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomisation using a computer-generated algorithm.
Allocation concealment?	Yes	"To maintain allocation concealment, the minimisation algorithm and subsequent treatment assignment was provided through an independent, central, secure 24-hour randomisation automated telephone service by the Clinical Trials Research Unit (CTRU), University of Leeds".

Blinding? Pressure ulcer incidence	No	Stated, "owing to the nature of the mattresses under investigation, it was not possible to mask the randomised intervention to the patients participating in the trial, ward nursing staff or the CRNs conducting the skin assessments".
Incomplete outcome data addressed? All outcomes	Yes	ITT analysis conducted.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No important baseline differences.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Price 1999

Methods	RCT with follow-up 14 days postoperatively.
Participants	Patients with fractured neck of femur and Medley score of > 25 (very high risk), aged over 60 y
Interventions	1. Repose system (low-pressure inflatable mattress and cushion in polyurethane material) (n = 40). 2. Nimbus III dynamic flotation plus TransCell cushion (n = 40): all other care standard best practice, including regular repositioning
Outcomes	1. Repose system: at admission 14/40 has pressure ulcers; preoperatively, 7/36; at 7 days: 6/32; at 14 days: 5/24. 2. Nimbus III: at admission had pressure ulcers, 13/40; preoperatively, 8/37; at 7 days: 5/31; at 14 days: 4/26.
Notes	80 patients randomised; 50 featured in final analysis (assessed 14 days post-operatively) i.e. 38% attrition Patients with pressure ulcers recruited. Difficult to ascertain how many of those with existing pressure ulcer included in 7-day and 14-day follow up assessments (see Table 4 of paper)

Risk of bias

Item	**Authors' judgement**	**Description**

Price 1999 (*Continued*)

Adequate sequence generation?	Yes	Stated, "a concealed computer-generated list was used to randomise eligible consecutive consenting patients to one of the support systems".
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	No	"Patients were not assessed blindly as it was considered that displacement for examination would cause excessive discomfort"
Incomplete outcome data addressed? All outcomes	Unclear	"No patient was excluded from the analyses. In many patients the data were incomplete, but they have been included in the analyses for those time points where data are present"; data from 50 (out of 80 patients) only analysed for final assessment.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No statistically significant differences on prognostic indicators at baseline between groups.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Russell 2000

Methods	RCT with 7-day follow-up. Randomisation using sealed opaque envelopes
Participants	Patients aged $\geq$ 18 y; undergoing scheduled cardiothoracic surgery under GA; surgery of at least 4 h duration; free of pressure ulcers. Both groups comparable at baseline for pressure ulcer risk (modified Knoll); history of previous ulceration; disease status; sex; age; weight; height
Interventions	1. MicroPulse system in the OR and postoperatively (n = 98). 2. Conventional care (gel pad in OR, standard mattress postoperatively) (n = 100)
Outcomes	Incidence and severity of pressure ulcers: 1. MicroPulse system: 2%* (2/98); 2. Conventional management: 7% (7/100 patients developed 10 ulcers). Grade of ulcers: 1. MicroPulse system: grade 2 = 22; 2. Conventional management: grade 1 = 2; grade 2 = 5; grade 3 = 3* *1/2 discounted by original authors from their analysis as thought to occur for reasons "not related to the use of the MicroPulse system"!

Russell 2000 (*Continued*)

Notes	No equipment-related adverse events were reported.	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"Randomisation was done blindly by using a sealed opaque envelope that contained the randomisation information (i.e., multi-cell pulsating dynamic mattress system vs. conventional management)."
Allocation concealment?	Unclear	Not reported, although sequence generation based on sealed envelopes (see above).
Blinding? Pressure ulcer incidence	No	Immediate post-surgical assessment described, therefore, patients likely to be using mattresses at time, so blinding of outcome assessors not possible.
Incomplete outcome data addressed? All outcomes	Yes	ITT analysis conducted.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No statistically significant baseline differences.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Russell 2003

Methods	RCT. Median days in study presented by group by hospital (3 hospitals). For the experimental group median days ranged from: 8-14; control group 9-17. Central allocation at trials office/pharmacy, sequentially-numbered or coded vials
Participants	Elderly acute, orthopaedic and rehabilitation wards; > 65 y; Waterlow score of 15-20
Interventions	1. Visco-polymer energy absorbing foam mattress (CONFOR-Med)/cushion combination (n = 562). 2. Standard mattress/cushion combination (n = 604).
Outcomes	Development of non-blanching erythema or worse (including with and without blanching erythema on admission to trial) 1. CONFOR-Med: 19.9% (110/562);

	2. Standard mattress: 26.3% (161/604); P value 0.005. Development of non-blanching erythema or worse: 1. CONFOR-Med: 8.5% (48/562); 2. Standard mattress: 10.9% (66/604). NS. Data for ulcers of grades > 1 not presented separately.
Notes	Patient comfort scores non significant. No adverse events reported

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Different randomisation procedure for sites 1 and 2 from site 3: "equipment allocation at 2 sites was made by converting random numbers...on a 50:50 basis (0-0.5 and 0.5-1.0). At site 3, trial numbers were allocated sequentially and the patient chose from 1 of 2 opaque envelopes. No blocking or stratification was used at any site"
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	No	"Because the data collection team examined participants at bedside and the experimental mattress surface is distinctive, data collection could not be blinded"
Incomplete outcome data addressed? All outcomes	Yes	"Participants who died were included in all statistical analyses"; ITT analysis conducted on all randomised patients (excluding 2 where protocol violations had occurred)
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No statistically significant differences on prognostic indicators at baseline between groups
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Sanada 2003

Methods	RCT: duration of follow-up not reported.
Participants	Recruitment from a single acute care unit. Eligile patients had a Braden score of ≤ 16, were bed bound, free of pressure ulcers before the start of the study, and required head elevation. Exclusion criteria not discussed. Baseline variables were generally balanced
Interventions	1. Double-layer air cell overlay (Tricell) (n = 37): two layers consisting of 24 narrow cylinder air cells. 2. Single-layer air cell overlay (Air doctor) (n = 36): single layer consisting of 20 round air cells. In both overlays the pressure was alternated between cells at 5-minute intervals 3. Standard hospital mattress (Paracare) (n = 35). 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
Outcomes	Number of participants with incidence pressure ulcer (daily assessment). All ulcers were grade 1 or 2. Grade 1 ulcers: 1. Double-layer: 0/26; 2. Single-layer: 3% (1/29); 3. Standard mattress: 15% (4/27). Grade 2 ulcers: 1. Double-layer: 4% (1/26); 2. Single-layer: 14% (4/29); 3. Standard mattress: 22% (6/27).
Notes	Numbers included in study analysis were 26 for the double-layer group (2 discontinued, 2 deaths, 7 head elevation ≤ 30 degrees); 29 for the single-layer group (1 mattress malfunction, 2 deaths, 2 head elevation ≤ 30 degrees); and 27 for the standard mattress group (1 death, 7 head elevation ≤ 30 degrees). No ITT analysis

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"The subjects were randomly allocated to the groups by sequentially-labelled sealed envelopes"
Allocation concealment?	Yes	Following randomisation, "after baseline assessment, the registered nurses opened the envelopes that indicated which surface each subject would be treated on"
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	No	41 patients withdrew from trial; no ITT analysis conducted.

Sanada 2003 (*Continued*)

Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No statistically significant differences on prognostic indicators at baseline between groups
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Santy 1994

Methods	RCT with 14-day follow-up. Allocation by random-number tables; degree of allocation concealment unclear
Participants	Patients aged > 55 y with hip fracture, with or without pressure ulcers. Excluded: those with a pressure ulcer of grade 3 or 4 at entry. Patients in each group were well matched for age and Waterlow score at baseline
Interventions	Results for Group 2 (NHS contract surface - standard foam): 17/64 Results for Groups 1, 3, 4 and 5, alternating foam combined) 42/441
Outcomes	Rates of removal from study due to skin deterioration: 1. Clinifloat: 9%; 2. NHS contract: 27%; 3. Transfoam: 10%; 4. Therarest: 11%; 5. Vaperm: 8%.
Notes	9% attrition. At interim analysis, Clinifloat and NHS contract mattresses were removed from the study; Clinifloat due to superior performance, and the NHS mattress due to high rates of pressure ulcer development. This explains why there were fewer patients on these surfaces. Omnifoam mattress showed foam collapse after 6 weeks and were withdrawn from use and replaced with Vaperm mattresses. Problems with mattress cover found on 2 Therarest mattresses, 3 Transfoam mattress covers, and 3 times with the Clinifloat mattress

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random-number tables used.
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Skin assessments undertaken by research nurse; patient unlikely to be removed from mattress for assessment, although not ex-

Santy 1994 (*Continued*)

		plicitly reported
Incomplete outcome data addressed? All outcomes	Unclear	Patient removal numbers reported; attrition within reasonable limits (20% of total participants recruited at baseline)
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Mean age and Waterlow scores reported as well-matched across different mattress groups
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Schultz 1999

Methods	RCT with 6-day follow-up.
Participants	Patients admitted for surgery lasting at least 2 h in lithotomy position, aged ≥18; admitted with intact skin
Interventions	1. 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). 2. Usual care (padding as required, including gel pads, foam mattresses, ring cushions (donuts) etc) (n = 207)
Outcomes	1. Experimental operating room mattress overlay: 27% (55/206); 6 people had ulcers of grade 2 or more. 2. Usual care: 16% (34/207); 3 people had ulcers of grade 2 or more
Notes	Experimental product caused postoperative skin changes. Authors contacted for more information relating to grade of ulcer by group

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Random-numbers tables used.
Allocation concealment?	No	Patients randomly assigned for consideration in study from operating room schedule, then screened by nurses or primary investigator against inclusion/exclusion criteria before randomisation to experimental or control group.
Blinding? Pressure ulcer incidence	Yes	"Beginning on the day after surgery an continuing for 6 days, 2 research assistants, blinded to the study group of the patient, examined the skin over the bony prominences

Schultz 1999 (*Continued*)

		of each patient for any evidence of skin changes".
Incomplete outcome data addressed? All outcomes	Yes	No attrition.
Free of selective reporting?	Yes	All pre-specified outcomes reported.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No important baseline differences.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	No other concerns.

Sideranko 1992

Methods	RCT with mean follow-up of 9.4 days. Method of randomisation not reported though said to be "random"
Participants	Adult, surgical ICU patients: Surgical ICU stay > 48 h, without existing skin breakdown on admission. Groups broadly similar at baseline, although water mattress group appeared to be heavier and had fewer days in ICU (significance of these differences unclear)
Interventions	1. Alternating air mattress: 1.5-inch thick Lapidus Airfloat System (n = 20). 2. Static air mattress: 4-inch thick Gay Mar Sof Care (n = 20). 3. Water mattress: 4-inch thick Lotus PXM 3666 (n = 17).
Outcomes	Grade of ulcers not reported. 1. Alternating air mattress: 25% (5/20); 2. Static air mattress: 5% (1/20); 3. Water mattress: 12% (2/17).
Notes	The trial was primarily about interface pressure and patient position, therefore, there was relatively little detail about the incidence part of the study, and no description of co-interventions. No withdrawals reported.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Not explicitly reported, "...randomly assigned...".
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported. Patients and carers would note have been blinded

Sideranko 1992 (*Continued*)

Incomplete outcome data addressed? All outcomes	Unclear	No withdrawals reported. 57 patients were enrolled in the study but no numbers were provided in the results text or tables, except to say that 8 subjects (14% of the total sample) developed pressure ulcers
Free of selective reporting?	Yes	Pressure measurement and development of pressure ulcers were described as the outcomes of interest (with interface pressure and patient position being the main outcomes of interest) and these were both reported in the results section
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	"Demographic information from patients' charts describing patient age, sex, height, and weight upon admission were records" but the data were not provided in the results section
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Stapleton 1986

Methods	Quasi RCT: allocation by means of alternation. Duration of follow-up unclear
Participants	Female elderly patients with fractured neck of femur, without existing pressure ulcers, Norton score 14 or less. Baseline data presented and groups well matched for age and Norton score
Interventions	1. Large Cell Ripple (Talley) (n = 32). 2. Polyether foam pad 2 feet x 2 feet x 3-inch thickness (n = 34). 3. Spenco pad (n = 34).
Outcomes	Ulcers of grade 2 or greater: 1. Large Cell Ripple: 34% (11/32); 2. Polyether foam pad: 41% (14/34); 3. Spenco pad: 35% (12/34). Grade 3 and greater: 1. Large Cell Ripple: 0% (0/32); 2. Foam pad: 24% (8/34); 3. Spenco pad: 6% (2/34).
Notes	45 Large Cell Ripple mattresses required 50 motor repairs and 90 material repairs during 12- month study. Patients did not like the feel of the ripples. No mention of withdrawals
Risk of bias	

Stapleton 1986 (*Continued*)

Item	Authors' judgement	Description
Adequate sequence generation?	Unclear	Randomisation for first 2 groups, but not for subsequent groups: "patients for the first two groups were selected by lottery, and thereafter patients were allocated to each group systematically, in rotation"; total numbers for the first 2 groups were not reported
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	Not reported.
Incomplete outcome data addressed? All outcomes	Yes	Out of 100 patients recruited, "two patients allocated to the Ripple pad were lost to ward transfer"
Free of selective reporting?	Unclear	Outcomes not pre-specified.
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	No baseline differences on mean age and Norton scores (the presence of existing pressure ulcers was an exclusion criterion for the study)
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Inclusion criteria stated female patients only.

Summer 1989

Methods	RCT: duration of follow-up unclear. Randomisation by random sequences of letters corresponding to treatment groups, however, level of concealment unclear
Participants	Patients admitted to the ICU in diagnostic groups, namely: sepsis-sepsis syndrome/ pneumonia; respiratory failure; drug overdose; metabolic coma; stroke/neuromuscular disease; adult respiratory distress syndrome. Groups comparable at baseline for APACHE score; condition of pressure area at baseline not discussed
Interventions	1. Kinetic Treatment Table (n = 43) 7 feet x 3 feet padded, vinyl-covered platform on central rotating pivot which turns through an arc every 1.7 seconds. Reported to be of value in respiratory failure. 2. Routine 2-hourly turning on conventional beds (n = 43).
Outcomes	1 patient developed small facial ulcer on Kinetic Treatment Table; none on conventional beds

Summer 1989 (*Continued*)

Notes	3/86 (3%) patients lost to follow-up	
Risk of bias		
Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"Random sequences of 30 letters (K for KTT and C for control) were supplied using standard tables of random numbers for each of the six groups..."
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	The study nurse collecting APACHE score data was not involved in patient management or triage decisions, but there is no indication that outcome assessors were blinded
Incomplete outcome data addressed? All outcomes	Yes	83 patients were analysed as 5 separate groups, but later in results 11/86 were diagnosed independently by infection control surveillance. It would appear that 3/86 were not analysed, but this was only 3.5% so well within conventional limits. Reasons for drop-outs not given
Free of selective reporting?	Yes	"...(9) development of new decubitus ulcers". Results section: "No patient developed a classic decubitus ulcer during the entire period." And later "...one patient developed a small facial ulcer related to pressure from a padded support of the kinetic table..."
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	There was no significant difference in the initial mean APACHE-II score between all individuals placed on KTT...and the manually turned subjects... but it is not clear if this is at baseline or throughout the study. No other baseline data provided and no Table of characteristics shown
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Takala 1996

Methods	RCT with 14-day follow-up. Randomisation influenced by mattress availability, therefore, not concealed
Participants	Non-trauma patients admitted to ICU expected to stay > 5 days. Treatment groups similar at baseline, however, not compared for degree of pressure ulcer risk
Interventions	1. Carital Optima (n = 21): constant low pressure mattress comprising 21 double air bags on a base. 2. Standard hospital foam mattress (n = 19): 10 cm thick foam density 35 kg/m^3.
Outcomes	1. No ulcers. 2. 37% (7/19) patients developed a total of 13 ulcers. P value < 0.005. 9 ulcers were grade 1A (erythema), 4 were grade 1B (superficial and limited to the dermis)
Notes	40% withdrawals; ITT analysis undertaken.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Not explicitly reported, "...randomly assigned..." Later the authors talk about "...each block of four patients that completed treatment". This may refer to block randomisation but it is not clear
Allocation concealment?	No	Randomisation influenced by mattress availability, therefore, allocation not concealed
Blinding? Pressure ulcer incidence	Unclear	This study was not blinded, since the severity of illness of the patients precluded their transfer for evaluation of the skin condition by a blinded reviewer, and the type of mattress in the bed could not be blinded but further on note that ...all sore areas were measured and photographed for independent verification of severity... It would appear that perhaps some outcome assessment was perhaps blinded but this is still unclear
Incomplete outcome data addressed? All outcomes	Yes	An ITT was performed but there were significant losses - "Ten patients were randomised but not treated due to either early discharge or death..." and, "Six patients randomised on the pressure-relieving mattress were included only in the intention-

Takala 1996 (*Continued*)

		to-treat analysis, since the start of treatment was delayed due to mattress non-availability..." No discussion of how the trialists handled the missing data
Free of selective reporting?	Yes	Methods: ...primary outcome variable (pressure sore formation)... All outcomes reported related to pressure ulcer formation
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Table 1 (from study report) indicates that patient characteristics were well balanced, e.g. age, clinically infected and APACHE score
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Taylor 1999

Methods	RCT - length of follow up - discharge from hospital or death
Participants	Hospital inpatients aged 16 or over, with intact skin, requiring a pressure-relieving support
Interventions	1. Alternating-pressure mattress with pressure-redistributing cushion (Pegasus Trinova) (n = 22). 2. Alternative alternating-pressure system (unnamed) with pressure-redistributing cushion (control) (n = 22)
Outcomes	1. TriNova: 0/22; 2. Control: 9% (2/22) (both ulcers superficial).
Notes	Study underpowered. Data relating to comfort were not reported for control group. Nurse rating of acceptability: 1. TriNova: good to very good n = 15; acceptable n = 1; 2. Control: good to very good n = 9; acceptable n = 11.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Abstract states "...randomised controlled trial". No further details reported
Allocation concealment?	Yes	"Upon recruitment, the data collector opened the next opaque envelope in sequence..."

Taylor 1999 (*Continued*)

Blinding? Pressure ulcer incidence	Unclear	Not reported. Patients and nurses would not have been blinded
Incomplete outcome data addressed? All outcomes	Unclear	No statement regarding drop-outs/withdrawals. "Forty-four subjects were recruited to the study over a 5-month period, with equal numbers of subjects allocated to the two mattress groups". "...eighteen (81.8%) of the 22 patients allocated to the Trinova completed the comfort questionnaire..." but comfort data were not reported for the control group, so losses in that group, and the way in which they compared to the intervention group, remain unknown. This is a loss of 20% overall which is acceptable but there is no indication that there was an ITT analysis
Free of selective reporting?	No	"..the primary end point rests with measuring differences in comfort and acceptance, while the secondary objective of the study is to measure clinical outcomes of a group of patients vulnerable to pressure sore development." Although comfort data were not reported for the control group, but only for the intervention group
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Table 2 (from study report) indicates that patient characteristics were well balanced, e.g. age, weight and Waterlow score
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Theaker 2005

Methods	RCT: follow-up for 2 weeks after discharge from ICU.
Participants	Recruitment from an ICU. Eligible participants were deemed at high risk of pressure ulcer development (from a set of 5 predetermined factors; details not provided, but reference given), and aged ≥18 y. Patients with pressure ulcers on admission were excluded. Baseline data presented by outcome, so difficult to assess
Interventions	1. KCI TheraPulse bed (n = 30). 2. Hill-Rom Duo mattress (n = 32). No further details provided about the devices.

Outcomes	Number of participants with incidence pressure ulcer (assessed every 8 h; blinded outcome assessment*); all grades (not given by group, reported that most were grade 2 with one grade 3): 1. TheraPulse: 10% (3/30); 2. Duo:19% (6/32). 8/9 ulcers were heel ulcers.
Notes	Participant lost not mentioned. * Trial is described as unblinded, but the methods described blinded outcome assessment with photographs

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	Patients "...were randomly assigned..." "Selection of an unmarked envelope from a pile of envelopes by staff unconnected with the study formed the randomisation process". Describes an adequate concealment of allocation sequence, but not how the sequence was generated
Allocation concealment?	Yes	"Selection of an unmarked envelope from a pile of envelopes by staff unconnected with the study formed the randomisation process"
Blinding? Pressure ulcer incidence	Yes	This was an unblinded, randomised prospective trial, but it appears that outcome assessment was blinded for the primary outcome: For the study purposes, the digital photographs were anonymised and analysed subsequently by two independent Tissue Viability Nurses for confirmation of the existence of a pressure ulcer and assessment of severity
Incomplete outcome data addressed? All outcomes	Unclear	No statement made regarding withdrawals.
Free of selective reporting?	Yes	The only outcome mentioned in the methods section was pressure ulcer development : "Patients were assessed once every 8 h for pressure sore development".

Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	"There were no significant differences in age, sex, Apache score or length of stay..."
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Tymec 1997

Methods	RCT.
Participants	52 patients admitted to selected nursing units of a large hospital with a Braden score of <16 (risk); intact skin on heels. 23 women and 29 men aged 27-90 y, mean age 66.6 ± 16.5 y. Mean Braden score on admission 11.8; 21 patients with respiratory conditions; 6 with cancer; 5 with stroke
Interventions	Factorial design evaluating effect of heel elevation device plus positioning and order of positioning. 1. Foot Waffle (FDA approved, non-abrasive vinyl boot with built-in foot cradle and inflated air chamber). 2. Hospital pillow under both legs from below knee to the Achilles tendon Unclear how many patients in each group.
Outcomes	Number of pressure ulcers developed: 1. Foot Waffle: 6. 2. Hospital pillow: 2. Denominators unclear.
Notes	There did not appear to be any losses.

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	Assignment to either pillow or Foot Waffle was undertaken "... using a block randomised list and the patient's position order ". ..was determined by a coin toss"
Allocation concealment?	Unclear	Not reported.
Blinding? Pressure ulcer incidence	Unclear	The blinding of outcome assessment was not reported.
Incomplete outcome data addressed? All outcomes	Unclear	52 patients (23 women and 29 men) in the study, but nowhere was the number/group reported. 8/52 patients developed grade 1 pressure ulcers and were removed from the study, so it would appear that the 52 participants were followed-up

Tymec 1997 (*Continued*)

Free of selective reporting?	Yes	Occurrence of a pressure ulcer, mean survival time (i.e. time until one occurred), and mean interface pressures were reported. These are all meaningful outcomes
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	No table of characteristics provided. Methods section gives characteristics for the sample overall, but not by group
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Vanderwee 2005

Methods	RCT.
Participants	Recruitment from 19 surgical, internal medicine or geriatric hospital wards. Eligible patients at risk of developing pressure ulcer (Braden score < 17); or had at least 1 grade 1 ulcer; aged ≥18 y, with expected hospital stay of > 3 days; not contraindicated for turning. Particpants excluded if had a grade 2 or worse pressure ulcer, or weighed > 140 kg. Participants well balanced at baseline
Interventions	1. APAM (Alpha X-cell, Huntleigh Healthcare): generates alternating high and low interface pressure between the body and support by alternating inflation and deflation. Sitting protocol with air cushion (Airtech, Huntleigh), with no turning protocol (n = 222). 2. Visco-elastic foam mattress (Tempur, Tempur-World). Sitting protocol with air cushion (Airtech, Huntleigh). Turning every 4 h (n = 225)
Outcomes	Number of participants with incidence pressure ulcer (assessed daily by ward nurse; grade 1 excluded): Grade 2 to 4 pressure ulcers (NS): 1. APAM: 15.3% (34/222); 26 grade 2; 8 grade 3 or 4. 2. Visco: 15.6% (35/225); 33 grade 2; 2 grade 3 or 4.
Notes	No significant difference in incidence of pressure ulcers (grades 2-4) between the groups. There were significantly more heel pressure ulcers in the control group (P value 0.006) . However, authors noted that patients nursed on an APAM seemed to develop more severe pressure ulcers

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Yes	"...randomisation tables generated with the SPSS 10 software package..."

Vanderwee 2005 (*Continued*)

Allocation concealment?	Yes	"Serially numbered closed envelopes were made for each participating ward"
Blinding? Pressure ulcer incidence	Unclear	A random sample of patients was observed at unexpected moments by both the researcher and the data nurse. In addition a data nurse was responsible for the follow-up of the study on each ward. So the researchers and data nurse were probably not blinded to allocation because they were at the patients' bedsides
Incomplete outcome data addressed? All outcomes	Unclear	Drop-outs/withdrawals not reported. Flow chart showed 447 patients enrolled in total, 297 assessed by Braden and 150 by non-blanchable erythema (NBE). Numbers in Table 2 (from study report) match these
Free of selective reporting?	Unclear	Assessment were designed to detect skin changes; used NBE and Braden scale
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Yes	Patients well balanced at baseline, e.g. Braden score and age. Since the groups were similar in all characteristics except medical specialty, this variable was adjusted for in the analysis
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Vyhlidal 1997

Methods	RCT with 10-21 day follow-up. Allocation to surfaces achieved by investigator drawing assignment out of a hat, therefore, extent of concealment inadequate
Participants	Patients newly admitted to a skilled nursing facility; estimated stay $\geq$ 10 days; free of pressure ulcers but at risk (Braden score <18 with sub-scale score of < 3 in sensory perception, mobility or activity levels). Diagnoses: musculoskeletal 45%; cardiovascular 27.5%; neurological 12.4%; others 15%. Patients in the MAXIFLOAT group were younger, though not significantly so. Braden Scale scores (risk of pressure ulcer development) similar between groups at baseline. Patients in the MAXIFLOAT group were significantly heavier and stayed on the mattress longer than the IRIS group
Interventions	1. IRIS 3000: 4-inch thick foam overlay with dimpled surface (n = 20). 2. MAXIFLOAT: mattress replacement in 5 sections (n = 20). The mattress has a water/bacteria repellent top cover; is made of 1.5-inch thick antimicrobial foam with a centre core of cut foam; has a non-removable polyester fibre heel pillow and a water/bacteria-proof bottom cover. Subjects in both groups received standards of care according to the protocols of the organisation

Outcomes	All grades of ulcer: 1. IRIS 3000: 60% (12/20); Grade 1: 25% (4/20); Grade 2: 40% (8/20). 2. MAXIFLOAT: 25% (5/20); Grade 1: 10% (2/20); Grade 2: 15% (3/20). P value 0.025. Time to ulcer: 1. IRIS 3000: 6.5 days; 2. MAXIFLOAT: 9.2 days (NS).
Notes	No record of any withdrawals. The IRIS 3000 is an overlay which goes on an existing mattress resulting (in the trial) in a bed height of 29 inches. 1 participant refused the IRIS because of the height of the bed. IRIS is lighter at 6.9 lb than the MAXIFLOAT (25 lb) and easier to manipulate, however, the latter is still lighter than standard hospital mattress (48 lb). IRIS can be sent home with patient. IRIS costs USD 38 compared to USD 260 for MAXIFLOAT

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	"...subjects were randomly assigned by research interviewer by drawing assignment out of a hat". "...randomly assigned by lot by the investigator...".
Allocation concealment?	Unclear	No information about what was drawn out of the hat (as above)
Blinding? Pressure ulcer incidence	Unclear	"....skin assessments and vital signs were performed...by a research team member". Probably not the research interviewer but it was not clear
Incomplete outcome data addressed? All outcomes	Yes	No statement regarding withdrawals. There were 20 patients per group and it was reported that, " ...17 subjects developed pressure ulcers, 12 of the 20 in the Iris 3000 group and 5 of the 20 in the MAXIFLOAT group."
Free of selective reporting?	Yes	"purpose of this study was to compare the incidence of pressure ulcers in 40 newly admitted...". Outcomes discussed were number of par-

Vyhlidal 1997 (*Continued*)

		ticipants developing pressure ulcers, and average number of days to pressure ulcer development, but there was no mention in the methods of what the trialists intended to measure, only that "...skin assessments and vital signs were performed..."
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	No	"Subjects in the MAXIFLOAT group were significantly heavier..." "the MAXIFLOAT group also stayed on the mattress longer.." Text states both differences were statistically significant.
Free of other bias - was the timing of the outcome assessment similar in all groups?	Unclear	Not reported.

Whitney 1984

Methods	RCT with 8-day follow-up. Method of allocation not reported; patients were "selected at random" for each group
Participants	Patients on medical-surgical units who were in bed for 20 h/day. Most patients had relatively little skin breakdown. Ages ranged from 19-91 y; mean 63.2 y. Majority of patients were confused, lethargic, stuporous. Only 39% classed as mentally alert. Baseline data were not presented.
Interventions	1. Alternating-pressure mattress (n = 25): consisted of 134 3-inch diameter air cells. 3-minute cycle. 2. Convoluted foam pad (Eggcrate) (n = 26). Patients in both groups were turned every 2 h.
Outcomes	Changes in skin condition did not differ significantly between patients using the alternating-pressure air mattress and the foam mattress (better: 20% vs 19%; same: 60% vs 58%; worse 20% vs 23%)
Notes	4 patients died. Analysis by ITT. Alternating-pressure mattress: pump maintenance was costly, patients objected to the movement. The alternating mattress was more easily cleaned and retained its original properties over several weeks compared to the foam, which compressed and flattened

Risk of bias

Item	**Authors' judgement**	**Description**
Adequate sequence generation?	Unclear	"26 were selected at random and placed in the foam mattress group, 25 in the AP mattress group..."

Whitney 1984 (*Continued*)

Allocation concealment?	Yes	"Upon recruitment, the data collector opened the next opaque envelope in sequence..."
Blinding? Pressure ulcer incidence	Unclear	Not reported. Patients and nurses would not have been blinded
Incomplete outcome data addressed? All outcomes	Yes	No statement regarding drop-outs/withdrawals, but there were 51 patients in the study and Table 3 (from study report) indicates that data for all of these were included (25 +26 = 51)
Free of selective reporting?	Yes	The study was conducted to determine ".. .which mattress is the best choice for pressure sore prevention and under which circumstances".
Free of other bias - were groups similar at baseline regarding the most important prognostic indicators?	Unclear	Not reported. Patient characteristics described for the group as a whole, not by mattress group
Free of other bias - was the timing of the outcome assessment similar in all groups?	Yes	Description of outcome assessment seems to indicate all patients were treated the same, "Risk factors and skin assessment scores were recorded three times each week". It is noted that, "In most cases patients were assessed by two investigators as a team and occasionally by only one...", but that would not impact on timing of assessment

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Allen 1993	No clinical outcomes, only interface pressure recorded.
Andrews 1989	Did not fulfil study design criteria.
Ballard 1997	Data recorded were comfort data; no pressure ulcer outcomes.
Barhyte 1995	Did not fulfil study design criteria. No data presented.
Bliss 1967	Did not fulfil study design criteria. Patients were recruited to the trial on the basis of their risk score

(*Continued*)

Bliss 1995	Whilst 8 surfaces were evaluated in this prospective trial, not all surfaces were in the trial at the same time, therefore, the surfaces were not truly compared with one another contemporaneously. Furthermore, it was possible for patients to be re-randomised back into the study, which occurred frequently, with a total of 457 mattress trials reported for only 238 patients. The data were not presented by patient; only by mattress trial. *Duplicate citation of Bliss 1994 (Conference abstract).*
Braniff-Matthews 1997	Healing and prevention outcome data were not separated.
Brienza 2001	Study of pressure measurement.
Büchner 1995	Did not fulfil study design criteria. Criteria for anti-decubitus management not reported and decided by nurses. Number of pillows provided to third arm of the study was limited and not given to all participants
Chaloner 2000	Did not fulfil study design criteria, randomisation corrupted, authors reported that randomisation was compromised on the basis of bed availability
Colin 1996	No clinical outcomes recorded; only measurements taken were for transcutaneous oxygen tension
Conine 1991	Did not fulfil study design criteria.
deBoisblanc 1993	Outcome incidence of pneumonia, no pressure ulcer outcomes.
Defloor 1997	Compared turning.
Defloor 2000	Did not compare surfaces.
Defloor 2004	Compared turning.
Della Valle 2001	Outcome of interface pressure.
Flam 1995	Outcome skin temperature and skin moisture level, no pressure ulcer outcomes
Fleischer 1997	Did not fulfil study design criteria.
Geelkerken 1994	Did not fulfil study design criteria. No data presented.
Gil Agudo 2009	Outcome measure of interface pressure.
Gray 2008	Not an RCT, but a clinical audit.
Grindley 1996	Patients were crossed over between intervention groups at 3 days. Outcome used was the assessment of patient comfort
Grisell 2008	Outcome measure of interface pressure.
Gunningberg 1998	Did not fulfil study design criteria. Study of risk calculation rather than prevention

(*Continued*)

Haalboom 1994	Did not fulfil study design criteria.
Hampton 1998	Did not fulfil study design criteria.
Hawkins 1997	Did not fulfil study design criteria.
Heyneman 2009	Meta-analysis of 2 previously published RCTs (Vanderwee 2005; Vanderwee 2007). Vanderwee 2005 already included in this review. Vanderwee 2007 excluded as it is a turning trial.
Holzgreve 1993	Full paper unavailable. Insufficient information to assess.
Huang 2009	Evaluated dressings.
Inman 1999	Comparison of a bed rental versus a bed purchase strategy, not a comparison of surfaces
Jacksich 1997	Did not fulfil study design criteria.
Jesurum 1996	Did not fulfil study design criteria.
Koo 1995	Did not fulfil study design criteria, study of interface pressure in healthy volunteers
Marchand 1993	Did not fulfil study design criteria, was a retrospective chart audit
McMichael 2008	Outcome measure of interface pressure.
Neander 1996	Paper in German - translator stated it was not an RCT. There were no data on how the decision to include patients in the control and intervention groups was made
Ooka 1995	Did not fulfil study design criteria, convenience sample used
Phillips 1999	N of 1 trial design, only one participant in the trial
Regan 1995	This study reported an audit of pressure ulcer incidence after implementation of a comprehensive pressure ulcer policy; it is not a prospective RCT
Reynolds 1994	Did not fulfil study design criteria.
Rosenthal 1996	Did not fulfil study design criteria. Outcome measure of interface pressure
Scott 1995	Insufficient information available to make a decision.
Scott 1999	No clinical outcomes, healthy volunteer study of interface pressures
Scott 2000	Not an RCT of beds and mattresses.
Stoneberg 1986	Historical control group.

(*Continued*)

Suarez 1995	Controlled clinical trial which recorded only pressure measurements
Takala 1994	Not an RCT, outcome measure of interface pressure.
Thomas 1994	Did not fulfil study design criteria.
Timmons 2008	Did not fulfil study design criteria. Review of a product not a trial
Torra i Bou 2002	Evaluated dressings.
Turnage-Carrier 2008	Outcome measure of interface pressure.
Vanderwee 2007	Compared turning.
Vanderwee 2008	Literature review of previously conducted studies.
Wells 1984	Only recorded interface pressure measurements.
Wild 1991	Interface pressure measurements.
Zernike 1997	Incidence of pressure ulcers not reported
Zernike 1994	Unable to assess due to information in research paper. Email address provided was no longer valid and we were unable to find other contact details

Characteristics of studies awaiting assessment *[ordered by study ID]*

Allegretti 2008

Methods	
Participants	
Interventions	
Outcomes	
Notes	Dissertation. Author contacted and advised us to wait for publication

Berthe 2007

Methods	
Participants	
Interventions	
Outcomes	
Notes	Further details required for appraisal. Awaiting email reply from author

Demarré 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting full text retrieval

Mastrangelo 2010

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting full text retrieval

Mayer 2008

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting full text retrieval

Taccone 2009

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting full text retrieval

van Leen 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	Awaiting full text retrieval

Abbreviations

> = more than
≥ = greater than or equal to
< = less than
≤ = less than or equal to
A&E = Accident and Emergency department
AP = alternating pressure
AWS = airwave system
BMI = body mass index
CF = convoluted foam
CRN = clinical research nurse
FDA = Food and Drug Administration
GA = general anaesthetic
h = hour(s)
ICU = intensive care unit
ITT = intention-to-treat analysis
LAL = low air loss
LCR = large cell ripple
LOS = length of stay
n = number in sample/group
NBE = non-blanchable erythema
NS = not statistically significant
OR = odds ratio
PRD = pressure reducing device
SF = solid foam
vs = versus

y = year(s)

DATA AND ANALYSES

Comparison 1. Constant low-pressure supports (CLP) vs standard foam mattresses (SFM)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	7		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
1.1 Cubed foam mattress	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.2 Bead-filled mattress	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.3 Softform mattress	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.4 Water-filled mattress	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.5 Alternative foam	2		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.6 Hi-spec foam mattress/cushion	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable

Comparison 2. Alternative foam mattress vs standard foam mattress

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	5	2016	Risk Ratio (M-H, Random, 95% CI)	0.40 [0.21, 0.74]
1.1 Various alternatives (pooled)	5	2016	Risk Ratio (M-H, Random, 95% CI)	0.40 [0.21, 0.74]
2 Pressure ulcer incidence UK studies only	4	1980	Risk Ratio (M-H, Random, 95% CI)	0.41 [0.19, 0.87]

Comparison 3. Comparisons between alternative foam supports

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	4		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Alternative foam vs standard foam	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Maxifloat foam mattress vs Iris foam overlay	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Solid foam vs convoluted foam	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 Transfoam mattress vs Transfoamwave mattress	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 4. Comparisons between CLP supports

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	9		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Optima vs SFM	1	40	Risk Ratio (M-H, Random, 95% CI)	0.06 [0.00, 0.99]
1.2 Sofflex vs ROHO	1	84	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.16, 2.47]
1.3 Gel mattress vs air-filled overlay	1	66	Risk Ratio (M-H, Random, 95% CI)	0.8 [0.24, 2.72]
1.4 Static air mattress vs water mattress	1	37	Risk Ratio (M-H, Random, 95% CI)	0.43 [0.04, 4.29]
1.5 Foam overlay vs Silicore overlay	1	68	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.64, 2.14]
1.6 Sheepskin vs no sheepskin (Including all pressure ulcers regardless of Grade)	3	1281	Risk Ratio (M-H, Random, 95% CI)	0.48 [0.31, 0.74]
1.7 Foam support surface vs no support	1	70	Risk Ratio (M-H, Random, 95% CI)	0.16 [0.05, 0.49]
2 Pressure ulcer incidence	3	1281	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.32, 0.97]
2.1 Sheepskin vs no sheepskin (grade 2 + pressure ulcers only)	3	1281	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.32, 0.97]

Comparison 5. Alternating-pressure vs standard foam mattress

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	2	409	Risk Ratio (M-H, Fixed, 95% CI)	0.31 [0.17, 0.58]

Comparison 6. Alternating-pressure (AP) vs constant low-pressure

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	10	1606	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.64, 1.13]
1.1 AP (various) vs CLP (various)	1	230	Risk Ratio (M-H, Random, 95% CI)	0.38 [0.22, 0.66]
1.2 AP vs Silicore or foam overlay	4	331	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.72, 1.16]
1.3 AP vs water or static air mattress	3	458	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.51, 3.35]
1.4 AP vs continuous low pressure mattress	1	140	Risk Ratio (M-H, Random, 95% CI)	2.06 [0.19, 22.18]

1.5 AP vs visco-elastic foam mattress	1	447	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.64, 1.52]

Comparison 7. AP and CLP in ICU/post ICU (factorial design)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Standard ICU/SFM post-ICU vs Nimbus AP ICU/SFM post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Standard ICU/SFM post-ICU vs standard ICU/Tempur CLP post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Nimbus AP ICU/SFM post-ICU vs standard ICU/Tempur CLP post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 Standard ICU/SFM post-ICU vs Nimbus AP ICU/Tempur CLP post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.5 Nimbus AP ICU/SFM post-ICU vs Nimbus ICU/Tempur post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.6 Standard ICU/Tempur post-ICU vs Nimbus ICU/Tempur post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 8. Comparisons between alternating-pressure devices

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	5		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Airwave vs Large Cell Ripple	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Airwave vs Pegasus Carewave	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Trinova vs control	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 AP overlay vs AP mattress	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.5 TheraPulse vs Duo	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 9. Low Air Loss vs standard bed

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	3		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
2 Pressure incidence pooled	2	221	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.16, 0.67]
3 Incidence of patients developing multiple ulcers	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 10. Air-Fluidised therapy vs dry flotation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Rate of wound breakdown	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 11. Kinetic treatment table vs standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	2	151	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [0.57, 2.65]

Comparison 12. Operating table overlay vs no overlay

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Viscoelastic polymer pad vs no overlay	1	416	Risk Ratio (M-H, Random, 95% CI)	0.53 [0.33, 0.85]
1.2 Viscoelastic foam overlay vs no overlay	1	175	Risk Ratio (M-H, Random, 95% CI)	1.53 [0.69, 3.39]

Comparison 13. Micropulse System for surgical patients

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	2	368	Risk Ratio (M-H, Fixed, 95% CI)	0.21 [0.06, 0.70]

Comparison 14. Seat cushions

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	4		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 Slab foam v Bespoke contoured foam	2		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Jay Gel Cushion v Foam	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Pressure reducing cushion v Standard foam cushion	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Analysis 1.1. Comparison 1 Constant low-pressure supports (CLP) vs standard foam mattresses (SFM), Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 1 Constant low-pressure supports (CLP) vs standard foam mattresses (SFM)

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Favours CLP n/N	SFM n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
1 Cubed foam mattress				
Hofman 1994	4/17	13/19		0.34 [0.14, 0.85]
2 Bead-filled mattress				
Goldstone 1982	5/32	21/43		0.32 [0.14, 0.76]
3 Softform mattress				
Gray 1994	6/90	27/80		0.20 [0.09, 0.45]
4 Water-filled mattress				
Andersen 1982	7/155	21/161		0.35 [0.15, 0.79]
5 Alternative foam				
Collier 1996	0/130	0/9		Not estimable
Santy 1994	42/441	17/64		0.36 [0.22, 0.59]
6 Hi-spec foam mattress/cushion				
Russell 2003	48/562	66/604		0.78 [0.55, 1.11]

Analysis 2.1. Comparison 2 Alternative foam mattress vs standard foam mattress, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 2 Alternative foam mattress vs standard foam mattress

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Alternative Foam n/N	Std Foam n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Various alternatives (pooled)					
Collier 1996	0/130	0/9			Not estimable
Gray 1994	6/90	27/80		21.3 %	0.20 [0.09, 0.45]
Hofman 1994	4/17	13/19		19.8 %	0.34 [0.14, 0.85]
Russell 2003	48/562	66/604		30.8 %	0.78 [0.55, 1.11]
Santy 1994	42/441	17/64		28.1 %	0.36 [0.22, 0.59]
Total (95% CI)	**1240**	**776**		**100.0 %**	**0.40 [0.21, 0.74]**

Total events: 100 (Alternative Foam), 123 (Std Foam)

Heterogeneity: $Tau^2 = 0.30$; $Chi^2 = 13.24$, df = 3 (P = 0.004); $I^2 = 77\%$

Test for overall effect: Z = 2.89 (P = 0.0039)

Analysis 2.2. Comparison 2 Alternative foam mattress vs standard foam mattress, Outcome 2 Pressure ulcer incidence UK studies only.

Review: Support surfaces for pressure ulcer prevention

Comparison: 2 Alternative foam mattress vs standard foam mattress

Outcome: 2 Pressure ulcer incidence UK studies only

Study or subgroup	Alternative foam n/N	Std Foam n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Collier 1996	0/130	0/9			Not estimable
Gray 1994	6/90	27/80		27.5 %	0.20 [0.09, 0.45]
Russell 2003	48/562	66/604		37.6 %	0.78 [0.55, 1.11]
Santy 1994	42/441	17/64		34.8 %	0.36 [0.22, 0.59]
Total (95% CI)	**1223**	**757**		**100.0 %**	**0.41 [0.19, 0.87]**
Total events: 96 (Alternative foam), 110 (Std Foam)					
Heterogeneity: Tau^2 = 0.37; Chi^2 = 12.41, df = 2 (P = 0.002); I^2 =84%					
Test for overall effect: Z = 2.31 (P = 0.021)					

Analysis 3.1. Comparison 3 Comparisons between alternative foam supports, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 3 Comparisons between alternative foam supports

Outcome: 1 Pressure ulcer incidence

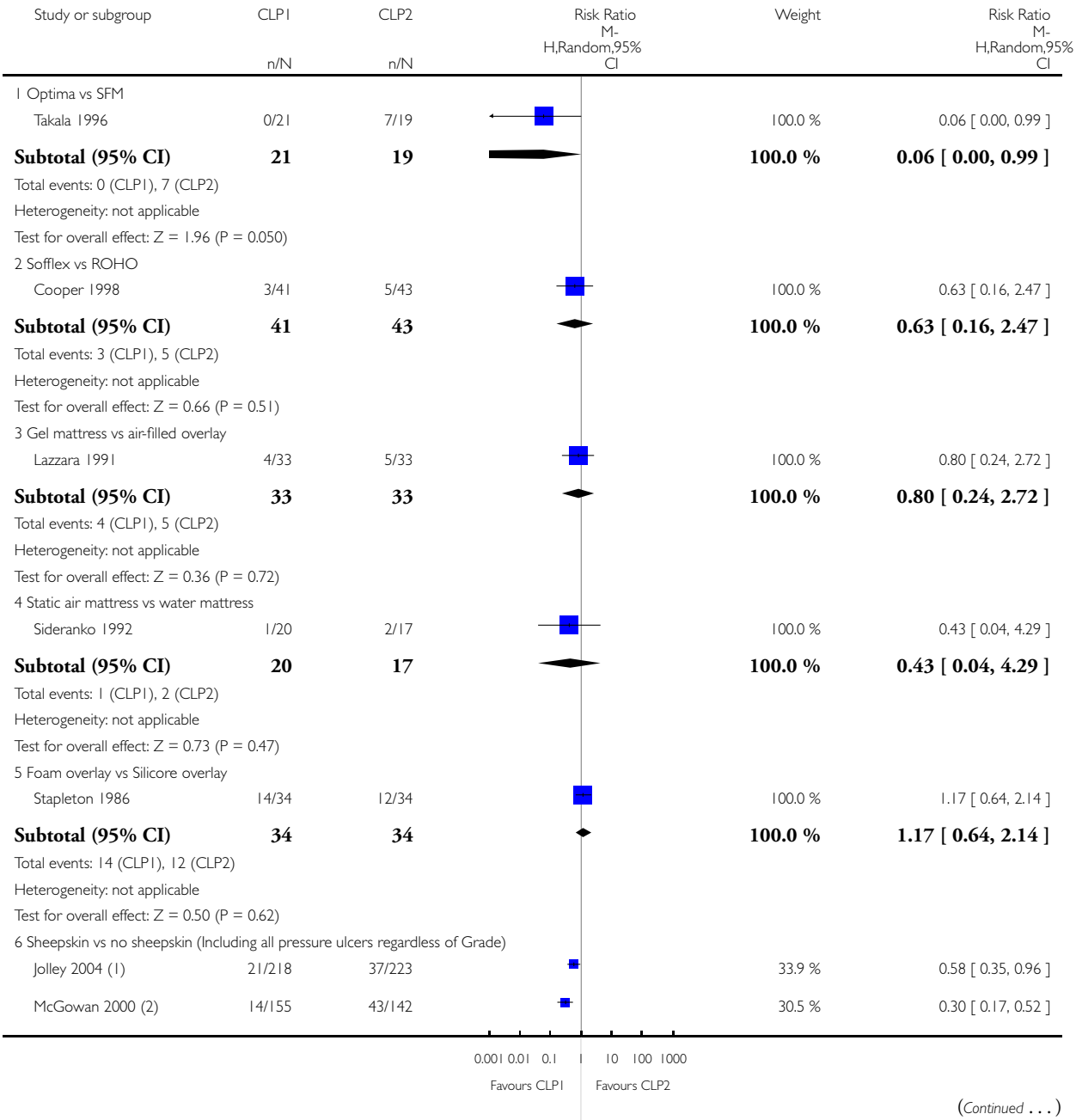
Study or subgroup	Foam 1 n/N	Foam 2 n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Alternative foam vs standard foam				
Santy 1994	42/441	17/64		0.36 [0.22, 0.59]
2 Maxifloat foam mattress vs Iris foam overlay				
Vyhlidal 1997	5/20	12/20		0.42 [0.18, 0.96]
3 Solid foam vs convoluted foam				
Kemp 1993	12/39	21/45		0.66 [0.37, 1.16]
4 Transfoam mattress vs Transfoamwave mattress				
Gray 1998	1/50	1/50		1.00 [0.06, 15.55]

Analysis 4.1. Comparison 4 Comparisons between CLP supports, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 4 Comparisons between CLP supports

Outcome: 1 Pressure ulcer incidence



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Study or subgroup	CLP1 n/N	CLP2 n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Mistiaen 2009 (3)	24/271	40/272		35.5 %	0.60 [0.37, 0.97]
Subtotal (95% CI)	**644**	**637**		**100.0 %**	**0.48 [0.31, 0.74]**
Total events: 59 (CLP1), 120 (CLP2)					
Heterogeneity: $Tau^2 = 0.07$; $Chi^2 = 4.20$, df = 2 (P = 0.12); $I^2 = 52\%$					
Test for overall effect: Z = 3.36 (P = 0.00077)					
7 Foam support surface vs no support					
Cadue 2008	3/35	19/35		100.0 %	0.16 [0.05, 0.49]
Subtotal (95% CI)	**35**	**35**		**100.0 %**	**0.16 [0.05, 0.49]**
Total events: 3 (CLP1), 19 (CLP2)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.22 (P = 0.0013)					

(1) This study evaluates all patients with pressure ulcers regardless of grade

(2) This study evaluates all patients with pressure ulcers regardless of grade

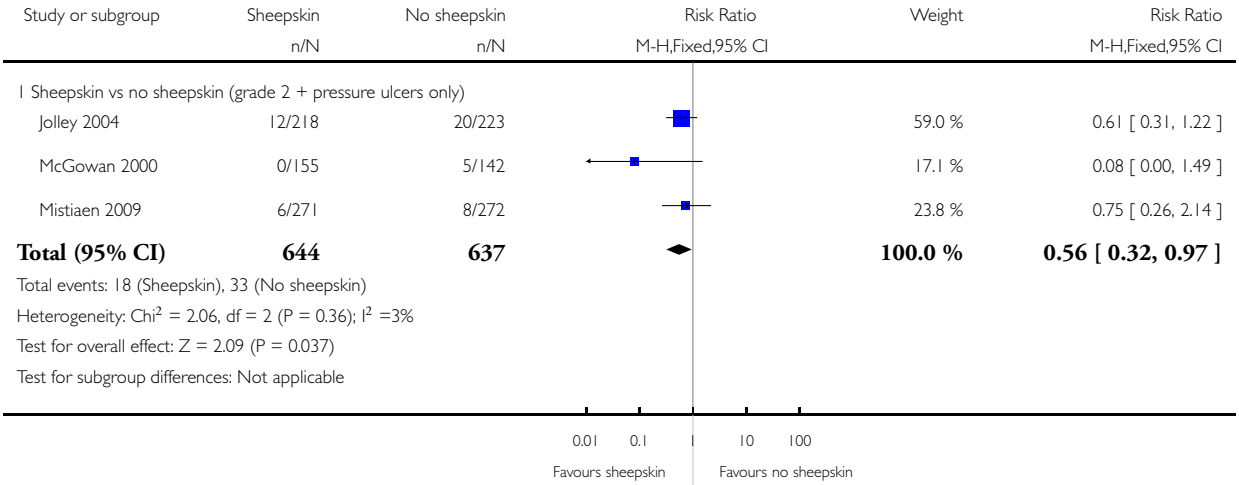
(3) This study evaluates all patients with pressure ulcers regardless of grade

Analysis 4.2. Comparison 4 Comparisons between CLP supports, Outcome 2 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 4 Comparisons between CLP supports

Outcome: 2 Pressure ulcer incidence



Analysis 5.1. Comparison 5 Alternating-pressure vs standard foam mattress, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 5 Alternating-pressure vs standard foam mattress

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Alternating Pressure n/N	SFM n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Andersen 1982	7/166	21/161		61.4 %	0.32 [0.14, 0.74]
Sanada 2003	6/55	10/27		38.6 %	0.29 [0.12, 0.73]
Total (95% CI)	**221**	**188**		**100.0 %**	**0.31 [0.17, 0.58]**

Total events: 13 (Alternating Pressure), 31 (SFM)

Heterogeneity: $Chi^2 = 0.02$, df = 1 (P = 0.88); $I^2 = 0.0\%$

Test for overall effect: Z = 3.69 (P = 0.00022)

Test for subgroup differences: Not applicable

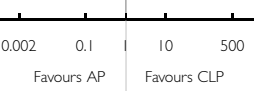
Analysis 6.1. Comparison 6 Alternating-pressure (AP) vs constant low-pressure, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 6 Alternating-pressure (AP) vs constant low-pressure

Outcome: 1 Pressure ulcer incidence

Study or subgroup	AP n/N	CLP n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 AP (various) vs CLP (various)					
Gebhardt 1996	15/115	39/115		15.7 %	0.38 [0.22, 0.66]
Subtotal (95% CI)	**115**	**115**		**15.7 %**	**0.38 [0.22, 0.66]**
Total events: 15 (AP), 39 (CLP)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.49 (P = 0.00048)					
2 AP vs Silicore or foam overlay					
Conine 1990	39/72	45/76		26.1 %	0.91 [0.69, 1.21]
Daechsel 1985	4/16	4/16		4.9 %	1.00 [0.30, 3.32]
Stapleton 1986	11/32	26/68		14.7 %	0.90 [0.51, 1.58]
Whitney 1984	5/25	6/26		6.1 %	0.87 [0.30, 2.48]
Subtotal (95% CI)	**145**	**186**		**51.8 %**	**0.91 [0.72, 1.16]**
Total events: 59 (AP), 81 (CLP)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.03, df = 3 (P = 1.00); I^2 =0.0%					
Test for overall effect: Z = 0.74 (P = 0.46)					
3 AP vs water or static air mattress					
Andersen 1982	7/166	7/155		6.3 %	0.93 [0.34, 2.60]
Price 1999	1/40	2/40		1.4 %	0.50 [0.05, 5.30]
Sideranko 1992	5/20	3/37		4.1 %	3.08 [0.82, 11.59]
Subtotal (95% CI)	**226**	**232**		**11.8 %**	**1.31 [0.51, 3.35]**
Total events: 13 (AP), 12 (CLP)					
Heterogeneity: Tau^2 = 0.18; Chi^2 = 2.67, df = 2 (P = 0.26); I^2 =25%					
Test for overall effect: Z = 0.57 (P = 0.57)					
4 AP vs continuous low pressure mattress					
Cavicchioli 2007	2/69	1/71		1.4 %	2.06 [0.19, 22.18]
Subtotal (95% CI)	**69**	**71**		**1.4 %**	**2.06 [0.19, 22.18]**
Total events: 2 (AP), 1 (CLP)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.59 (P = 0.55)					
5 AP vs visco-elastic foam mattress					
Vanderwee 2005	34/222	35/225		19.4 %	0.98 [0.64, 1.52]



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Study or subgroup	AP n/N	CLP n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Subtotal (95% CI)	**222**	**225**		**19.4 %**	**0.98 [0.64, 1.52]**
Total events: 34 (AP), 35 (CLP)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.07 (P = 0.94)					
Total (95% CI)	**777**	**829**		**100.0 %**	**0.85 [0.64, 1.13]**
Total events: 123 (AP), 168 (CLP)					
Heterogeneity: Tau^2 = 0.06; Chi^2 = 13.69, df = 9 (P = 0.13); I^2 =34%					
Test for overall effect: Z = 1.09 (P = 0.28)					

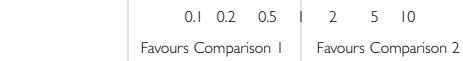
Analysis 7.1. Comparison 7 AP and CLP in ICU/post ICU (factorial design), Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 7 AP and CLP in ICU/post ICU (factorial design)

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Comparison 1 n/N	Comparison 2 n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Standard ICU/SFM post-ICU vs Nimbus AP ICU/SFM post-ICU				
Laurent 1998	4/80	10/80		0.40 [0.13, 1.22]
2 Standard ICU/SFM post-ICU vs standard ICU/Tempur CLP post-ICU				
Laurent 1998	14/80	11/75		1.19 [0.58, 2.46]
3 Nimbus AP ICU/SFM post-ICU vs standard ICU/Tempur CLP post-ICU				
Laurent 1998	10/80	11/75		0.85 [0.38, 1.89]
4 Standard ICU/SFM post-ICU vs Nimbus AP ICU/Tempur CLP post-ICU				
Laurent 1998	14/80	10/77		1.35 [0.64, 2.85]
5 Nimbus AP ICU/SFM post-ICU vs Nimbus ICU/Tempur post-ICU				
Laurent 1998	10/80	10/77		0.96 [0.42, 2.18]
6 Standard ICU/Tempur post-ICU vs Nimbus ICU/Tempur post-ICU				
Laurent 1998	11/75	10/77		1.13 [0.51, 2.50]



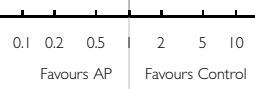
Analysis 8.1. Comparison 8 Comparisons between alternating-pressure devices, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 8 Comparisons between alternating-pressure devices

Outcome: 1 Pressure ulcer incidence

Study or subgroup	AP device n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Airwave vs Large Cell Ripple				
Exton-Smith 1982	5/31	12/31		0.42 [0.17, 1.04]
2 Airwave vs Pegasus Carewave				
Hampton 1997	0/36	0/39		Not estimable
3 Trinova vs control				
Taylor 1999	0/22	2/22		0.20 [0.01, 3.94]
4 AP overlay vs AP mattress				
Nixon 2006	106/989	101/982		1.04 [0.81, 1.35]
5 TheraPulse vs Duo				
Theaker 2005	3/30	6/32		0.53 [0.15, 1.94]



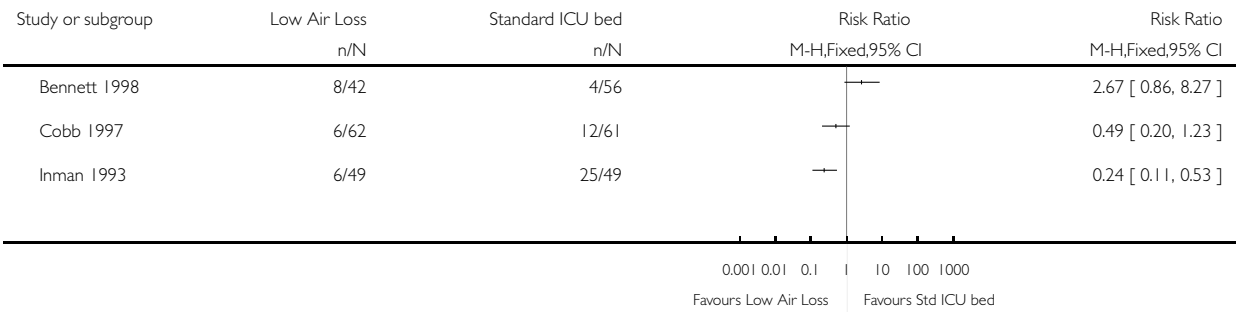
Analysis 9.1. Comparison 9 Low Air Loss vs standard bed, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 9 Low Air Loss vs standard bed

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Low Air Loss n/N	Standard ICU bed n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Bennett 1998	8/42	4/56		2.67 [0.86, 8.27]
Cobb 1997	6/62	12/61		0.49 [0.20, 1.23]
Inman 1993	6/49	25/49		0.24 [0.11, 0.53]



Analysis 9.2. Comparison 9 Low Air Loss vs standard bed, Outcome 2 Pressure incidence pooled.

Review: Support surfaces for pressure ulcer prevention

Comparison: 9 Low Air Loss vs standard bed

Outcome: 2 Pressure incidence pooled

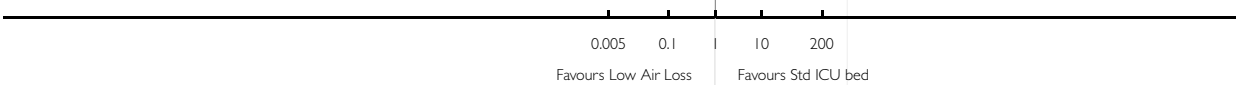
Study or subgroup	Low Air Loss n/N	Standard ICU bed n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Cobb 1997	6/62	12/61		45.0 %	0.49 [0.20, 1.23]
Inman 1993	6/49	25/49		55.0 %	0.24 [0.11, 0.53]
Total (95% CI)	**111**	**110**		**100.0 %**	**0.33 [0.16, 0.67]**

Total events: 12 (Low Air Loss), 37 (Standard ICU bed)

Heterogeneity: $Tau^2 = 0.07$; $Chi^2 = 1.35$, df = 1 (P = 0.25); $I^2 = 26\%$

Test for overall effect: Z = 3.09 (P = 0.0020)

Test for subgroup differences: Not applicable



Analysis 9.3. Comparison 9 Low Air Loss vs standard bed, Outcome 3 Incidence of patients developing multiple ulcers.

Review: Support surfaces for pressure ulcer prevention

Comparison: 9 Low Air Loss vs standard bed

Outcome: 3 Incidence of patients developing multiple ulcers

Study or subgroup	Low Air Loss n/N	Standard ICU n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Inman 1993	1/49	12/49		0.08 [0.01, 0.62]

Analysis 10.1. Comparison 10 Air-Fluidised therapy vs dry flotation, Outcome 1 Rate of wound breakdown.

Review: Support surfaces for pressure ulcer prevention

Comparison: 10 Air-Fluidised therapy vs dry flotation

Outcome: 1 Rate of wound breakdown

Study or subgroup	Air fluidised bed n/N	Dry flotation mattress n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Economides 1995	2/6	2/6		1.00 [0.20, 4.95]

Analysis 11.1. Comparison 11 Kinetic treatment table vs standard care, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 11 Kinetic treatment table vs standard care

Outcome: 1 Pressure ulcer incidence

Study or subgroup	KTT n/N	Standard n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Gentilello 1988	8/27	10/38		94.3 %	1.13 [0.51, 2.48]
Summer 1989	1/43	0/43		5.7 %	3.00 [0.13, 71.65]
Total (95% CI)	**70**	**81**		**100.0 %**	**1.23 [0.57, 2.65]**

Total events: 9 (KTT), 10 (Standard)

Heterogeneity: $Chi^2 = 0.35$, df = 1 (P = 0.55); $I^2 = 0.0\%$

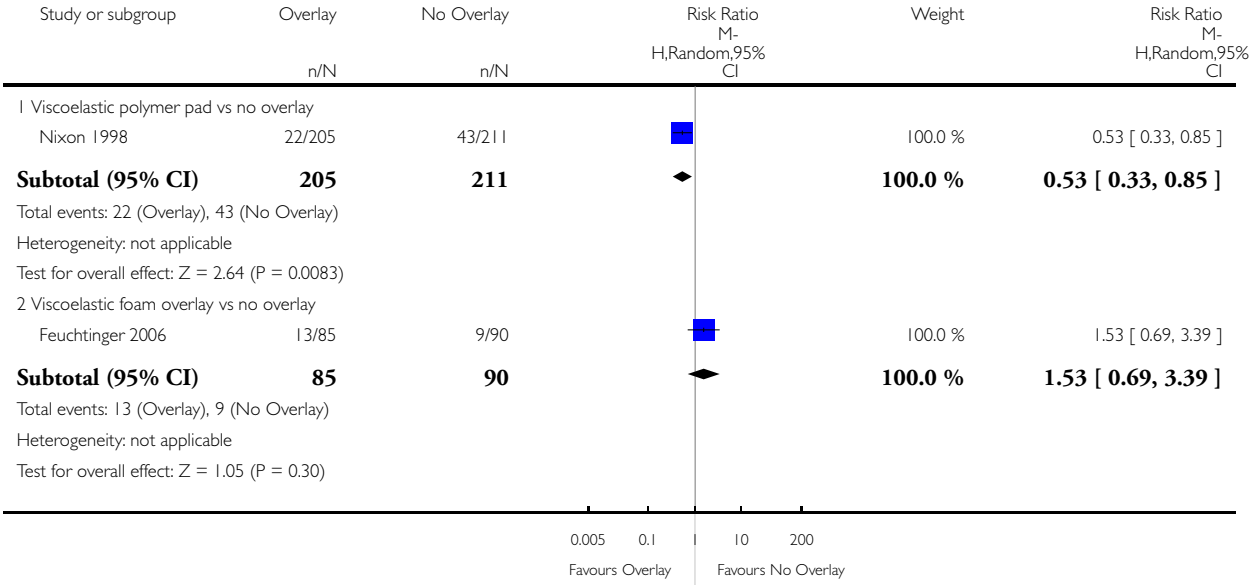
Test for overall effect: Z = 0.54 (P = 0.59)

Analysis 12.1. Comparison 12 Operating table overlay vs no overlay, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 12 Operating table overlay vs no overlay

Outcome: 1 Pressure ulcer incidence



Analysis 13.1. Comparison 13 Micropulse System for surgical patients, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 13 Micropulse System for surgical patients

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Micropulse System n/N	Std Care n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Aronovitch 1999	1/90	7/80		51.7 %	0.13 [0.02, 1.01]
Russell 2000	2/98	7/100		48.3 %	0.29 [0.06, 1.37]
Total (95% CI)	**188**	**180**		**100.0 %**	**0.21 [0.06, 0.70]**

Total events: 3 (Micropulse System), 14 (Std Care)

Heterogeneity: Chi² = 0.40, df = 1 (P = 0.53); I² =0.0%

Test for overall effect: Z = 2.53 (P = 0.011)

Analysis 14.1. Comparison 14 Seat cushions, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 14 Seat cushions

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
1 Slab foam v Bespoke contoured foam				
Conine 1993	85/125	84/123		1.00 [0.84, 1.18]
Lim 1988	19/26	18/26		1.06 [0.75, 1.49]
2 Jay Gel Cushion v Foam				
Conine 1994	17/68	30/73		0.61 [0.37, 1.00]
3 Pressure reducing cushion v Standard foam cushion				
Geyer 2001	6/15	10/17		0.68 [0.33, 1.42]

ADDITIONAL TABLES

Table 1. Additional information on included studies

Trial	Clear inclusion & exclusion criteria	Sample size (arms)	A priori calculation	Grade 1 ulcer excluded	Intervention well documented
Andersen 1982	Yes	482 (3)	Yes	Yes	No
Aronovitch 1999	Yes	217 (2)	No	Yes	Yes
Bennett 1998	Yes	98 (2)	No	Yes	No
Cadue 2008	Yes	70/69 (2)	No	No	Yes
Cavicchioli 2007	Yes	170 (2)	No	No	Yes
Cobb 1997	Yes	123 (2)	No	No	Yes
Collier 1996	No	99 (9)	No	Not applicable	Yes
Conine 1990	Yes	187 (2)	No	Yes	No
Conine 1993	Yes	288 (2)	No	Unclear/No	Yes
Conine 1994	Yes	163 (2)	No	Yes	Yes
Cooper 1998	Yes	100 (2)	No	Yes	Yes
Daechsel 1985	Yes	32 (2)	No	No	Yes
Economides 1995	Yes	12 (2)	No	Yes	Yes
Ewing 1964	No	30 (2)	No	No	Yes
Exton-Smith 1982	Yes	66 (2)	No	Yes	Yes
Feuchtinger 2006	Yes	175 (2)	Yes	No	Yes
Gebhardt 1996	Yes	43 (2)	No	Unclear/No	Yes
Gentilello 1988	Yes	65 (2)	No	No	Yes
Geyer 2001	Yes	32 (2)	No	Unclear/No	Yes
Gilcreast 2005	Yes	338 (2)	Yes	No	Yes
Goldstone 1982	Yes	75 (2)	No	No	Yes
Gray 1998	Yes	100 (2)	No	Yes	No

Table 1. Additional information on included studies *(Continued)*

Gray 1994	Yes	170 (2)	No	Yes	Yes
Gunningberg 2000	Yes	101 (2)	Yes	Yes	Yes
Hampton 1997	Yes	75 (2)	No	No	Yes
Hofman 1994	Yes	44 (2)	Yes	Yes	Yes
Inman 1993	Yes	100 (2)	Yes	Yes	No
Jolley 2004	Yes	539 (2)	Unclear/No	No	Yes
Kemp 1993	Yes	84 (2)	No	No	No
Keogh 2001	Yes	100 (2)	Yes	Unclear/No	Yes
Laurent 1998	Yes	312 (4)	Yes	Yes	Yes
Lazzara 1991	Yes	74 (2)	No	Yes	No
Lim 1988	Yes	62 (2)	No	Yes	Yes
McGowan 2000	Yes	297 (2)	Yes	No	Yes
Mistiaen 2009	Yes	5434 (2)	Yes	No	Yes
Nixon 1998	Yes	446 (2)	Yes	Yes	Yes
Nixon 2006	Yes	1972 (2)	Yes	Yes	Yes
Price 1999	Yes	80 (2)	Yes	Yes	No
Russell 2000	Yes	198 (2)	No	No	Yes
Russell 2003	Yes	1166 (2)	Yes	No	Yes
Sanada 2003	Yes	103 (3)	Unclear/No	No	Yes
Santy 1994	Yes	505 (5)	Yes	No	Yes
Schultz 1999	Yes	413 (2)	Yes	No	No
Sideranko 1992	Yes	57 (3)	No	No	No
Stapleton 1986	Yes	100 (3)	No	Yes	No
Summer 1989	Yes	83 (2)	No	No	Yes

Table 1. Additional information on included studies *(Continued)*

Takala 1996	Yes	40 (2)	Yes	Yes	Yes
Taylor 1999	Yes	44 (2)	Yes	No	Yes
Theaker 2005	Yes	62 (2)	Yes	Unclear/No	Yes
Tymec 1997	Yes	52 (2)	Yes	Yes	Yes
Vanderwee 2005	Yes	447 (2)	Yes	Yes	Yes
Vyhlidal 1997	Yes	40 (2)	No	Yes	Yes
Whitney 1984	No	51 (2)	No	No	No

APPENDICES

Appendix 1. Search strategy for the second update of this review - 2008

Electronic searches

For the second update of this review we searched:

- Cochrane Wounds Group Specialised Register (Searched 28 February 2008);
- The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2008, Issue 1);
- Ovid MEDLINE (1950 to February Week 3 2008);
- Ovid EMBASE (1980 to 2008 Week 08);
- Ovid CINAHL (1982 to February Week 3 2008).

The following search strategy was used for CENTRAL, and modified, where appropriate, for other databases:
#1 MeSH descriptor Beds explode all trees
#2 mattress*
#3 cushion*
#4 “foam” or transfoam
#5 overlay*
#6 “pad” or “pads”
#7 “gel”
#8 pressure NEXT relie*
#9 pressure NEXT reduc*
#10 pressure NEXT alleviat*
#11 “low pressure” NEAR/2 device*
#12 “low pressure” NEAR/2 support
#13 constant NEAR/2 pressure
#14 “static air”
#15 alternat* NEXT pressure
#16 air NEXT suspension*

#17 air NEXT bag*
#18 water NEXT suspension*
#19 elevation NEAR/2 device*
#20 clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or “foot waffle” or silicore or pegasus or cairwave
#21 (turn* or tilt*) NEXT (bed* or frame*)
#22 kinetic NEXT (therapy or table*)
#23 net NEXT bed*
#24 “positioning” or “repositioning”
#25 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24)
#26 MeSH descriptor Pressure Ulcer explode all trees
#27 pressure NEXT (ulcer* or sore*)
#28 decubitus NEXT (ulcer* or sore*)
#29 (bed NEXT sore*) or bedsore*
#30 (#26 OR #27 OR #28 OR #29)
#31 (#25 AND #30)
The MEDLINE search was combined with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximizing version (2008 revision); Ovid format (Lefebvre 2008). The EMBASE and CINAHL searches were combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN 2008). There was no restriction on the basis of the language in which the study reports were written, nor publication status.

Appendix 2. Ovid MEDLINE Search Strategy

1 exp Beds/
2 mattress$.mp.
3 cushion$.mp.
4 (foam or transfoam).mp.
5 overlay$.mp.
6 (pad or pads).ti,ab.
7 gel.ti,ab.
8 pressure relie$.mp.
9 pressure reduc$.mp.
10 pressure alleviat$.mp.
11 (low pressure adj2 device$).mp.
12 (low pressure adj2 support).mp.
13 (constant adj2 pressure).mp.
14 static air.mp.
15 (alternat$ adj pressure).mp.
16 air suspension$.mp.
17 air bag$.mp.
18 water suspension$.mp.
19 (elevation adj2 device$).mp.
20 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).mp.
21 ((turn$ or tilt$) adj (bed$ or frame$)).mp.
22 (kinetic adj (therapy or table$)).mp.
23 net bed$.mp.
24 (positioning or repositioning).mp.
25 or/1-24
26 exp Pressure Ulcer/
27 (pressure adj (ulcer$ or sore$)).mp.
28 (decubitus adj (ulcer$ or sore$)).mp.
29 (bed adj (ulcer$ or sore$)).mp.

30 or/26-29
31 25 and 30

Appendix 3. Ovid EMBASE Search Strategy

1 exp Bed/
2 mattress$.mp.
3 cushion$.mp.
4 (foam or transfoam).mp.
5 overlay$.mp.
6 (pad or pads).ti,ab.
7 gel.ti,ab.
8 pressure relie$.mp.
9 pressure reduc$.mp.
10 pressure alleviat$.mp.
11 (low pressure adj2 device$).mp.
12 (low pressure adj2 support).mp.
13 (constant adj2 pressure).mp.
14 static air.mp.
15 (alternat$ adj pressure).mp.
16 air suspension$.mp.
17 air bag$.mp.
18 water suspension$.mp.
19 (elevation adj2 device$).mp.
20 (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave).mp.
21 ((turn$ or tilt$) adj (bed$ or frame$)).mp.
22 (kinetic adj (therapy or table$)).mp.
23 net bed$.mp.
24 (positioning or repositioning).mp.
25 or/1-24
26 exp Decubitus/
27 (pressure adj (ulcer$ or sore$)).mp.
28 (decubitus adj (ulcer$ or sore$)).mp.
29 (bed adj (ulcer$ or sore$)).mp.
30 or/26-29
31 25 and 30

Appendix 4. EBSCO CINAHL Search Strategy

S29 S23 and S28
S28 S24 or S25 or S26 or S27
S27 TI decubitus or AB decubitus
S26 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)
S25 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)
S24 (MH "Pressure Ulcer")
S23 S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11 or S12 or S13 or S14 or S15 or S16 or S17 or S18 or S19 or S20 or S21 or S22
S22 TI (positioning or repositioning) or AB (positioning or repositioning)
S21 TI net bed* or AB net bed*
S20 TI (kinetic therapy or kinetic table*) or AB (kinetic therapy or kinetic table*)
S19 TI (turn* bed* or tilt* bed*) or AB (turn* frame* or tilt* frame*)

S18 TI (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave) or AB (clinifloat or maxifloat or vaperm or therarest or sheepskin or hammock or foot waffle or silicore or pegasus or cairwave)
S17 TI elevation N2 device* or AB elevation N2 device*
S16 TI water suspension or AB water suspension
S15 TI air bag* or AB air bag*
S14 TI air suspension or AB air suspension
S13 TI alternat* pressure or AB alternat* pressure
S12 TI static air or AB static air
S11 TI constant N2 pressure or AB constant N2 pressure
S10 TI low pressure N2 support or AB low pressure N2 support
S9 TI low pressure N2 device* or AB low pressure N2 device*
S8 TI pressure alleviat* or AB pressure alleviat*
S7 TI pressure reduc* or AB pressure reduc*
S6 TI pressure relie* or AB pressure relie*
S5 TI (overlay* or pad or pads or gel) or AB (overlay* or pad or pads or gel)
S4 TI (foam or transfoam) or AB (foam or transfoam)
S3 TI (mattress* or cushion*) or AB (mattress* or cushion*)
S2 (MH "Pillows and Cushions")
S1 (MH "Beds and Mattresses+")

Appendix 5. Criteria for judgments for the sources of bias

1. Was the allocation sequence randomly generated?

Yes, low risk of bias

The investigators describe a random component in the sequence generation process such as: referring to a random number table; using a computer random number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots.

No, high risk of bias

The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example: sequence generated by odd or even date of birth; sequence generated by some rule based on date (or day) of admission; sequence generated by some rule based on hospital or clinic record number.

Unclear

Insufficient information about the sequence generation process to permit judgement of either Yes or No (as above) to be made.

2. Was the treatment allocation adequately concealed?

Yes, low risk of bias

Participants and investigators enrolling participants could not foresee assignment either because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, web-based and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes.

No, high risk of bias

Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, i.e. when allocation used: an open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure.

Unclear

Insufficient information to permit judgement of either Yes or No to be made. This is usually the case if the method of concealment is not described, or is not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding was knowledge of the allocated interventions adequately prevented during the study?

Yes, low risk of bias

Any one of the following:

- No blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, but outcome assessment was blinded and the non-blinding of others unlikely to introduce bias.

No, high risk of bias

Any one of the following:

- No blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by lack of blinding.
- Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken.
- Either participants or some key study personnel were not blinded, and the non-blinding of others likely to introduce bias.

Unclear

Any one of the following:

- Insufficient information to permit judgement of Yes or No to be made.
- The study did not address this outcome.

4. Were incomplete outcome data adequately addressed?

Yes, low risk of bias

Any one of the following:

- No missing outcome data.
- Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias).
- Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size.
- Missing data have been imputed using appropriate methods.

No, high risk of bias

Any one of the following:

- Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups.
- For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate.
- For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size.
- As-treated analysis done with substantial departure of the intervention received from that assigned at randomisation.
- Potentially inappropriate application of simple imputation.

Unclear

Any one of the following:

- Insufficient reporting of attrition/exclusions to permit judgement of Yes or No (e.g. number randomised not stated, no reasons for missing data provided).
- The study did not address this outcome.

5. Are reports of the study free of suggestion of selective outcome reporting?

Yes, low risk of bias

Any of the following:

- The study protocol is available and all of the pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way.
- The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).

No, high risk of bias

Any one of the following:

- Not all of the study's pre-specified primary outcomes reported.
- One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified.
- One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect).
- One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis.
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study.

Unclear

Insufficient information to permit judgement of Yes or No to be made. It is likely that the majority of studies will fall into this category.

6. Other sources of potential bias:

Yes, low risk of bias

The study appears to be free of other sources of bias.

No, high risk of bias

There is at least one important risk of bias. For example, the study:

- Had a potential source of bias related to the specific study design used; or
- Stopped early due to some data-dependent process (including a formal-stopping rule); or
- Had extreme baseline imbalance; or
- Has been claimed to have been fraudulent; or
- Had some other problem.

Unclear

There may be a risk of bias, but there is either:

- Insufficient information to assess whether an important risk of bias exists; or
- Insufficient rationale or evidence that an identified problem will introduce bias

WHAT'S NEW

Last assessed as up-to-date: 7 December 2010.

Date	Event	Description
20 December 2010	New search has been performed	Third update of review, new searches undertaken. One new trial included; excluded list, pending assessment list and reference list updated. Risk of bias assessment completed
20 December 2010	New citation required but conclusions have not changed	New author added to the review team.

HISTORY

Protocol first published: Issue 3, 1998

Review first published: Issue 2, 2000

Date	Event	Description
18 July 2008	New search has been performed	Second update of review.
18 July 2008	New citation required and conclusions have changed	Second update with the inclusion of 11 additional trials.
23 April 2008	Amended	Converted to new review format.
20 May 2004	New citation required and conclusions have changed	First update (substantive amendment) published Issue 3, 2004. This review includes only trials which consider interventions which aim to prevent pressure ulcers. The title of

(*Continued*)

		the review has been changed to more accurately reflect the scope of the review The original review: Beds, mattresses and cushions for preventing and treating pressure ulcers. Cullum N, Deeks J, Sheldon TA, Song F, Fletcher AW, has been substantially updated and now forms the basis of a prevention review and a separate treatment review

CONTRIBUTIONS OF AUTHORS

NC conceived the original idea, wrote the protocol, extracted and analysed the data and drafted the original review, contributed to both updates and is responsible for the final edit.

EMcI made inclusion decisions, extracted data, assessed study quality, undertook analyses and contributed to the text for all updates.

SBS undertook searching, inclusion decisions, analysis, contributed text for all updates, addressed the copy editor feedback and co-ordinated the editorial process for the updates.

JD made inclusion decisions, extracted data, assessed study quality, undertook analyses and contributed to the text for the second and third updates.

AJ-B made inclusion decisions, extracted data, updated the pending assessment of studies list, updated the background section, undertook analyses and contributed to the text for the third update.

DECLARATIONS OF INTEREST

Nicky Cullum was the Principal Investigator in the PRESSURE Trial, one of the trials included in this review (Nixon 2006), however, she was not involved in the data extraction or analysis for this trial.

No interests declared for E McInnes, A Jammali-Blasi, SEM Bell-Syer and JC Dumville.

SOURCES OF SUPPORT

Internal sources

- Department of Health Sciences, University of York, UK.

External sources

- NIHR/Depatment of Health (England), (Cochrane Wounds Group) (all versions), UK.
- NHS Health Technology Assessment Programme (original review), UK.
- National Institute of Clinical Excellence Guidelines Programme (first update), UK.
- Nursing Research Institute SV&MHS and Australian Catholic University, Sydney (third update), Australia.

NOTES

The original review: Beds, mattresses and cushions for preventing and treating pressure ulcers. Cullum N, Deeks J, Sheldon TA, Song F, Fletcher AW, has been substantially updated and now forms the basis of a prevention review and a separate treatment review. The review: Support surfaces for treating pressure ulcers is currently being updated.

This review along with the updates: Support surfaces for pressure ulcer prevention has been prepared by McInnes E, Jammali-Blasi A, Bell-Syer SEM, Dumville JC, and Cullum NA and includes only trials which consider interventions which aim to prevent pressure ulcers. The title of the review has been changed to reflect the scope of the review more accurately.

INDEX TERMS

Medical Subject Headings (MeSH)

*Beds [standards]; Pressure Ulcer [*prevention & control; therapy]; Randomized Controlled Trials as Topic

MeSH check words

Humans