Support surfaces for pressure ulcer prevention (Review)

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[Intervention Review]

Support surfaces for pressure ulcer prevention

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ABSTRACT

Background

Pressure ulcers (also known as bedsores, pressure sores, decubitus ulcers) are areas of localised damage to the skin and underlying tissue due to pressure, shear or friction. They are common in the elderly and immobile and costly in financial and human terms. Pressure-relieving beds, mattresses and seat cushions are widely used as aids to prevention in both institutional and non-institutional settings.

Objectives

This systematic review seeks to answer the following questions:

(1) to what extent do pressure-relieving cushions, beds, mattress overlays and mattress replacements reduce the incidence of pressure ulcers compared with standard support surfaces?

(2) how effective are different pressure-relieving surfaces in preventing pressure ulcers, compared to one another?

Search strategy

For this second update the Cochrane Wounds Group Specialised Register was searched (28/2/08), The Cochrane Central Register of Controlled Trials (CENTRAL)(2008 Issue 1), Ovid MEDLINE (1950 to February Week 3 2008), Ovid EMBASE (1980 to 2008 Week 08) and Ovid CINAHL (1982 to February Week 3 2008). The reference sections of included studies were searched for further trials.

Selection criteria

Randomised controlled trials (RCTs), published or unpublished, which assessed the effectiveness of beds, mattresses, mattress overlays, and seating cushions for the prevention of pressure ulcers, in any patient group, in any setting. Study selection was undertaken by at least two authors independently with a third author resolving uncertainty. RCTs were eligible for inclusion if they reported an objective, clinical outcome measure such as incidence and severity of new of pressure ulcers developed. Studies which only reported proxy outcome measures such as interface pressure were excluded.

Data collection and analysis

Trial data were extracted by one researcher and checked by a second. The results from each study are presented as relative risk for dichotomous variables. Where deemed appropriate, similar studies were pooled in a meta analysis.

Main results

For this second update 11 trials met the inclusion criteria bringing the total number of RCTs included in the review to 52.

Foam alternatives to the standard hospital foam mattress can reduce the incidence of pressure ulcers in people at risk. The relative merits of alternating and constant low pressure devices are unclear. There is one high quality trial comparing the different alternating pressure devices for pressure ulcer prevention which suggests that alternating pressure mattresses may be more cost effective than alternating pressure overlays.

Pressure-relieving overlays on the operating table have been shown to reduce postoperative pressure ulcer incidence, although two studies indicated that foam overlays resulted in adverse skin changes. Two trials indicated that Australian standard medical sheepskins prevented pressure ulcers. There is insufficient evidence to draw conclusions on the value of seat cushions, limb protectors and various constant low pressure devices as pressure ulcer prevention strategies.

A study of Accident & Emergency trolley overlays did not identify a reduction in pressure ulcer incidence. There are tentative indications that foot waffle heel elevators, a particular low air loss hydrotherapy mattress and two types of operating theatre overlays are harmful.

Authors' conclusions

In people at high risk of pressure ulcer development higher specification foam mattresses rather than standard hospital foam mattresses should be used. The relative merits of higher-tech constant low pressure and alternating pressure for prevention are unclear but alternating pressure mattresses may be more cost effective than alternating pressure overlays. 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. Seat cushions and overlays designed for use in Accident & Emergency settings have not been adequately evaluated.

PLAIN LANGUAGE SUMMARY

Can pressure ulcers be prevented by using different support surfaces?

Pressure ulcers (also called bed 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 pressure relieving surfaces (e.g. beds, mattresses, mattress overlays and cushions) 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 on higher specification foam mattresses. 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 (Allman 1997). They usually occur over bony prominences such as the base of the spine, hips and heels. Pressure ulcers occur in both hospital and community settings, most often in the elderly and immobile (e.g. orthopaedic patients), those with severe acute illness (e.g. patients in intensive care units) and in people with neurological deficits (e.g. with spinal cord injuries).

The development of pressure ulcers is relatively common. A review of epidemiological studies in the UK, Canada and the USA describes reported pressure ulcer prevalence in the UK of between 4.4% in a community unit up to 37% in palliative care (Kaltenhalter 2001). In the USA and Canada prevalence ranged from 4.7% in hospital patients to 33% in spinal cord injured patients in the community. They represent a major burden of sickness and unmeasured effects on quality of life for patients and their carers, and are costly to health care systems. In the UK the cost of preventing and treating pressure ulcers in a 600-bedded large general hospital was estimated at between £600,000 and £3 million per year (Clark 1994). The total cost of pressure ulcers to the NHS has been estimated as £1.4-£2.1 billion annually with most of this cost being due to nurse time (Bennett 2004). The

extent to which pressure ulcers are preventable is not clear.

Description of the intervention

The aim of pressure ulcer prevention strategies is to reduce the magnitude and/or duration of pressure between a patient and their support surface (the "interface pressure"). 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. The cost of these interventions varies widely; from over £30,000 for some bed replacements to less than £100 for some foam overlays. Information on the relative cost-effectiveness of this equipment is clearly needed to aid rational 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 area (constant low pressure devices) (CLP), or mechanically vary the pressure beneath the patient, so 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. 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.
Turning beds, such as turning frames, net beds, and turning/tilting beds move those patients, either manually or automatically, who are unable to turn themselves. Pressure ulcer prevention is often not the reason for using turning and tilting beds; they 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

Health care professionals attempt to reduce the incidence of severe pressure ulcers by the identification of people at high risk and the use of prevention strategies, such as pressure-relieving equipment. It is essential that initiatives are based on the best available evidence of clinical and cost-effectiveness 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 are different pressure-relieving surfaces in preventing pressure ulcers, compared to one another?

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) comparing beds, mattresses and cushions which measured the incidence of new pressure ulcers. Studies which used only subjective measures of outcome (e.g., skin condition "better" or "worse") were excluded, as were studies which reported only proxy measures such as interface pressure. There was no restriction on the basis of the language in which the study reports were written, nor publication status.

Types of participants

Patients receiving health care who were deemed to be at risk of pressure ulcer development, in any setting.

Types of interventions

Studies which evaluated the following interventions for pressure ulcer prevention were included:
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.

High-tech support surfaces:

- Alternating pressure mattresses/overlays: patient lies on air filled sacs which sequentially inflate and deflate and

relieve pressure at different anatomical sites for short periods; may incorporate a pressure sensor (AP).
- Air fluidised beds: warmed air circulated through fine ceramic beads covered by a permeable sheet; allows 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).

Other support surfaces:

- Turning beds/frames: these work by either aiding manual repositioning of the patient, or by motor driven turning and tilting.
- Operating table overlays: as above.
- Wheelchair cushions: may be conforming and therefore reduce contact pressures by increasing surface area in contact, or mechanical 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 have simply measured the pressure on different parts of the body in contact with the support surface (interface pressure). However, interface pressure is an intermediate or surrogate outcome measure which has serious limitations as a proxy for clinical outcome, since the process which leads to the development of a pressure ulcer almost certainly involves the complex interplay of several factors. Unfortunately, because it is relatively simple, quick and inexpensive to measure, most evaluations only compare interface pressure. In this review we have only considered trials which report the clinical outcome measure of pressure ulcer incidence.

Some studies, when reporting outcomes of interventions for prevention, did not differentiate between people developing grade 1 ulcers (in which the skin is unbroken) and those developing more severe ulcers. Studies which 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.

A range of pressure ulcer grading systems is used in pressure ulcer trials. An example of a commonly used grading system is presented below:

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

the following outcomes were also recorded where available:

- Costs of the devices
- Patient comfort
- Durability of the devices
- Reliability of the devices
- Acceptability of the devices

Search methods for identification of studies

Electronic searches

For the second update of this review we searched:
Cochrane Wounds Group Specialised Register (Searched 28/2/08)
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.
See Appendix 1 for the search strategy used for the first update of this review.

Searching other resources

Experts in the field of wound care were originally contacted to enquire about ongoing and recently published trials in the field of wound care. In addition, manufacturers of wound care materials were contacted for details of the trials they are conducting. This process has not been repeated for this update since it was not productive. However citations within obtained reviews and papers were scrutinised 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 by three authors (EMcI, SB-S, JD), full copies of all potentially relevant studies were obtained. Decisions on final inclusion after retrieval of full papers was made by one author (EMcI) and checked by a second author (RL or JD); disagreements were resolved by discussion with a third author (NC or SB-S). Rejected studies were checked by a third author (one of SB-S; NC).

Data extraction and management

Data from included trials were extracted by a single author into pre-prepared data extraction tables and checked by a second author. The following data were extracted from each study:

- patient inclusion/exclusion criteria
- care setting
- key baseline variables by group, for example, age, sex, baseline risk, 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
- outcomes (incidence and severity of new pressure ulcers)
- acceptability and reliability of equipment if reported
- 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)
- clear description of main interventions.

Assessment of risk of bias in included studies

The methodological and reporting quality of each trial were assessed by a single author and checked by a second author. The following quality criteria were used:

- evidence of true randomisation, for example adequate sequence generation is reported using random number tables, computer random number generator, coin tossing, or shuffling.
- evidence of allocation concealment at randomisation, such as central randomisation; serially numbered, opaque, sealed envelopes.
- description of baseline comparability of intervention groups
- outcome assessment stated to be blinded
- evidence of an intention to treat analysis (ITT), for example specifically reported by authors that ITT was undertaken and this was confirmed on study assessment, or not stated in the trial report but evident from study assessment that ITT was undertaken.
- percentage of participants for whom data was complete at defined study end-point

Dealing with missing data

Where study details or data were missing from reports then attempts were made to contact the study authors to complete the information necessary. If studies were published more than once, the most detailed report was used as the basis of the data extraction.

Data synthesis

For each trial, relative risk (RR) was calculated for categorical outcomes such as number of patients developing ulcers. 95% confidence intervals (95% CI) were included when sufficient detail

to allow their calculation was provided. The results from replicated studies were plotted on to graphs and discussed by narrative review. Individual study details are presented in structured tables (Characteristics of included studies). Where there was more than one trial comparing similar devices using the same outcome (though possibly differing lengths of follow up), statistical heterogeneity was tested for by I^2 (Higgins 2003). In the absence of significant statistical heterogeneity, studies with similar comparisons were pooled using a fixed effects model. If heterogeneity was observed both random and fixed effects models were used to pool the data. For the purpose of meta analysis we assumed that relative risk remained constant for different lengths of follow up, hence we pooled studies which followed participants for different lengths of time. All statistical analysis was performed on RevMan 5.

RESULTS

Description of studies

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

Fifty two relevant randomised controlled trials met the inclusion criteria for the review (Characteristics of included studies). Thirty trials involved participants without pre-existing pressure ulcers (intact skin); 4 trials included patients with ulcers greater than stage 1; 5 trials included participants with and without ulcers and in 13 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); eight evaluated different surfaces in intensive care units (ICU) (Cadue 2008; Gentilello 1988; Inman 1993; Laurent 1997; 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 and emergency and ward setting (Gunningberg 2000). The remaining studies looked at a variety of patients, for example those in nursing homes (n=9) and those on care of the elderly, medical and surgical wards.

Interventions

Five trials evaluated cushions, three evaluated the use of sheepskins, and three looked at turning beds/kinetic therapy. The remaining studies evaluated different mattresses, overlays and beds.

Risk of bias in included studies

A summary of the sample size and methodological quality of each trial is shown in Table 1.

Table 1. Quality Assessment of Included Studies and sample sizes

Trial	Clear inc & excl	Sample size(arms)	A priori calc	True RCT	Baseline comp	Blind outcome assess	Grade 1 sore exclude	Intervent well docum
Andersen 1982	yes	482(3)	yes	no	yes	no	yes	no
Aronovitch 1999	yes	217(2)	no	no	yes	yes	yes	yes
Bennett 1998	yes	98(2)	no	no	yes	no	yes	no
Cadue 2008	yes	70/69 (2)	no	yes	yes	unclear	no	yes
Cavicchioli 2007	yes	170 (2)	no	unclear	yes	yes	no	yes

Table 1. Quality Assessment of Included Studies and sample sizes (*Continued*)

Cobb 1997	yes	123 (2)	no	yes	no	unclear	no	yes
Collier 1996	no	99(9)	no	yes	no	no	n/a	yes
Conine 1990	yes	187(2)	no	no	yes	yes	yes	no
Conine 1993	yes	288(2)	no	unclear	yes	yes	unclear	yes
Conine 1994	yes	163(2)	no	no	yes	yes	yes	yes
Cooper 1998	yes	100(2)	no	yes	yes	no	yes	yes
Daechsel 1985	yes	32(2)	no	no	yes	no	no	yes
Economides 1995	yes	12(2)	no	yes	yes	no	yes	yes
Ewing 1964	no	30(2)	no	no	no	no	no	yes
Exton-Smith 1982	yes	66(2)	no	on	yes	no	yes	yes
Feuchtinger 2006	yes	175 (2)	yes	Unclear	yes	yes	no	yes
Gebhardt 1994	yes	230(2)	no	no	yes	no	yes	yes
Gentilello 1988	yes	65(2)	no	yes	yes	no	no	yes
Geyer 2001	yes	32 (2)	no	yes	yes	yes	unclear	yes
Gilcreast 2005	yes	338 (2)	yes	yes	no	unclear	no	yes
Goldstone 1982	yes	75(2)	no	no	yes	no	no	yes
Gray 1994b	yes	100(2)	no	yes	yes	yes	yes	no

Table 1. Quality Assessment of Included Studies and sample sizes (*Continued*)

Gray 1994a	yes	170(2)	no	yes	yes	no	yes	yes
Gunningberg 2000	yes	101(2)	yes	yes	yes	yes	yes	yes
Hampton 1997	yes	75(2)	no	no	no	no	no	yes
Hofman 1994	yes	44(2)	yes	no	yes	no	yes	yes
Inman 1993	yes	100(2)	yes	no	yes	no	yes	no
Jolley 2004	yes	539 (2)	Unclear	yes	yes	no	no	yes
Kemp 1993	yes	84(2)	no	yes	yes	yes	no	no
Keogh 2001	yes	100(2)	yes	yes	yes	unclear	unclear	yes
Laurent 1997	yes	312(4)	yes	no	yes	no	yes	yes
Lazzara 1991	yes	74(2)	no	yes	no	no	yes	no
Lim 1988	yes	62(2)	no	no	yes	yes	yes	yes
McGowan 2000	yes	297(2)	yes	no	yes	no	no	yes
Nixon 1998	yes	446(2)	yes	yes	yes	yes	yes	yes
Nixon 2006	yes	1972 (2)	yes	yes	yes	no	yes	yes
Price 1999	yes	80(2)	yes	yes	yes	no	yes	no
Russell 2000	yes	198(2)	no	yes	yes	no	no	yes
Russell 2002	yes	1166(2)	yes	yes	yes	no	no	yes
Sanada 2003	yes	103 (3)	Unclear	yes	yes	no	no	yes
Santy 1994	yes	505(5)	yes	yes	yes	no	no	yes

Table 1. Quality Assessment of Included Studies and sample sizes (*Continued*)

Schultz 1999	yes	413(2)	yes	yes	yes	yes	no	no
Sideranko 1992	yes	57(3)	no	no	yes	no	no	no
Stapleton 1986	yes	100(3)	no	no	no	no	yes	no
Summer 1989	yes	83(2)	no	no	yes	no	no	yes
Takala 1996	yes	40(2)	yes	no	yes	no	yes	yes
Taylor 1999	yes	44(2)	yes	unclear	yes	unclear	no	yes
Theaker 2005	yes	62 (2)	yes	yes	yes	no	Unclear	yes
Tymec 1997	yes	52(2)	yes	no	no	no	yes	yes
Vanderwee 2005	yes	447 (2)	yes	yes	yes	no	yes	yes
Vyhlidal 1997	yes	40(2)	no	no	yes	no	yes	yes
Whitney 1984	no	51(2)	no	no	no	no	no	no

Although the majority of trials discussed the criteria for including patients, only approximately 50% of the reports gave information that indicated that patients were randomly allocated with concealed allocation.

Blinded outcome assessment is rarely used in wound care studies and this was certainly the case in these evaluations of pressure relieving 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 bed 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 assessor blinded to treatment. Of the 52 RCTs in this review, we could be confident that blinded outcome assessment had been used in only 13 trials.

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 described an a priori sample size estimate. High attrition rates and lack of an intention-to-treat analysis were also common. For most comparisons there is a lack of replication.

In studies of pressure ulcer prevention it is extremely important for trialists to report on the baseline comparability of the intervention groups for important variables such as baseline risk. Risk of pressure ulcer development is usually reported as one of various risk scores such as Norton, Waterlow, Gosnell or Braden. 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 of low, medium or at high risk for the development of pressure ulcers. Another shortcoming was being unclear about whether grade 1 pressure ulcers were included in the study sample and/or analysis.

Effects of interventions

HOW THE RESULTS ARE PRESENTED AND WHAT THE TERMS MEAN

Results of dichotomous variables are presented as relative risk (RR)

with 95% confidence intervals (CI). Relative risk has been used rather than odds ratios as event rates are high in these trials and odds ratios would give an inflated impression of the magnitude of effect (Deeks 1998). Relative risk 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 1, then the relative risk reduction associated with using the experimental bed is 1-RR. The relative risk 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 bed 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 7, in other words 7 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 was presented it appears in the Characteristics of included studies, but not incorporated in the analysis.

'Low-tech' constant pressure supports

This section considers comparisons of standard foam hospital mattresses with other low-technology (low-tech), constant low pressure supports (CLP). 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; Silicore-filled supports. 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. We have assumed that standard mattresses are likely to vary less within than between countries and undertaken subgroup analysis by country, however this was not pre-specified.

Standard foam hospital mattress compared with other low-tech CLP.

Eight RCTs compared 'standard' mattresses/surfaces with 'low-tech' supports for the prevention of pressure ulcers (Andersen 1982; Collier 1996; Goldstone 1982; Gray 1994a; Gunningberg 2000; Hofman 1994; Russell 2002; Santy 1994).

When compared with standard hospital mattresses, the incidence and severity of pressure ulcers in 'high risk' patients were reduced when patients were placed on either the Comfortex DeCube mattress (Hofman 1994)(RR 0.34, 95%CI 0.14 to 0.85); the Beaufort bead bed (Goldstone 1982)(RR 0.32, 95%CI 0.14 to 0.76); the Softform mattress (Gray 1994a) (RR 0.2, 95%CI 0.09 to 0.45); or the water-filled mattress (Andersen 1982) (RR 0.35, 95%CI 0.15 to 0.79)(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 as those using one of a number of foam alternatives (Clinifloat, Therarest, Transfoam and Vaperm) (Santy 1994) (RR 0.36, 95%CI 0.22 to 0.59). Another study found a significant decrease in the incidence of grade I pressure ulcers from 26.3% to 19.9% (p=0.0004) and a non-significant decrease in the incidence of pressure ulcers grade II to IV from 10.9% to 8.5% in patients allocated to the high-specification foam mattress/cushion (RR 0.78; 95%CI 0.55 to 1.11) (Russell 2002). No patient developed a pressure ulcer in the Collier 1996 trial. The comparisons were considered too heterogeneous to pool these 7 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 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 (Collier 1996; Gray 1994a; Hofman 1994; Santy 1994; Russell 2002) were pooled using a random effects model (I^2 =77%). 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 2 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 results in comparison groups of unequal size. This analysis yielded a pooled relative risk 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 4 studies which compared alternative foam supports with standard foam mattresses in the UK (Collier 1996; Gray 1994a; Russell 2002; Santy 1994) 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). Therefore foam alternatives to the standard hospital mattress can reduce the incidence of pressure ulcers in at risk patients, including patients with fractured neck of femur.

Comparisons between Alternative foam mattresses

This section covers results of studies which performed head-to-head comparisons of high-specification foam products (i.e. contoured foam, supports comprising foam of different densities). Five RCTs (Collier 1996; Gray 1994a; Kemp 1993; Santy 1994; Vyhlidal 1997) compared different foam alternatives (Analysis 3.1).

Santy 1994 and colleagues compared 5 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; 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 (RR 0.42, 95%CI 0.18 to 0.96) with the mattress replacement, however this trial appeared to have used neither allocation concealment nor blinded outcome assessment.

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, in other words the small sample size may have precluded detection of a significant difference (RR 0.66, 95% CI 0.37 to 1.16). Gray 1994b compared the Transfoam and Transfoamwave foam mattresses however only 1 patient in each group developed a ulcer.

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).

Eleven RCTs have compared different low-tech CLP devices for prevention (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 are underpowered and/or have other methodological flaws.

A trial from Finland (Takala 1996) comparing the Optima (Carital) constant low pressure mattress - which comprises 21 double air bags on a base - with the standard hospital mattress found that significantly more patients (37%) on the standard mattress developed ulcers compared with none on the Optima (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 (Cooper 1998; Lazzara 1991; Sideranko 1992; Stapleton 1986) were all unique comparisons with low power 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, with 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 and the number of people in each group was not clearly reported.

Gilcreast 2005 assessed three heel pressure relief devices: the Bunny Boot (fleece) high cushion heel protector; the egg-crate heel lift positioner and the foot waffle air cushion. There were no statistically significant differences between the devices in terms of pressure ulcer incidence (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.

Sheepskins

Three trials have examined the effects of sheepskins on pressure ulcer incidence. The first (Ewing 1964) comparing the standard hospital mattress with and without sheepskin overlays, was considered too small and poorly designed to detect a difference. The second involving 297 orthopaedic patients (McGowan 2000) 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 conducted a study on a mixed inpatient population of a metropolitan hospital comparing a sheepskin mattress overlay with 'usual care' which 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 states that any patient whose risk increased to high as measured by Braden score <12 for 48 hours was no longer followed up. The rationale for this is not clear. The results for Grade 2 or above pressure ulcers were 12/218 (5.5%) for the sheepskin group and 20/223 (9%) for the 'usual care' group (reported denominators). The participant incidence rate ratio for all ulcer grades was 0.58 (95% CI 0.35 to 0.96). Pooling these two trials using a random effects model (I^2 = 67%) showed there were statistically significantly fewer pressure ulcers in the group using sheepskins (RR 0.42 95% CI 0.22 to 0.81)(Analysis 4.1).

Body support

One trial with 70 intensive care unit participants (Cadue 2008) compared a foam body support and usual care (half-seated position, water mattress and preventative massage 6 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: 0.15 95% CI 0.05 to 0.47) (Analysis 4.1).

'High-tech' pressure supports

Alternating Pressure Supports:

A variety of alternating pressure (AP) supports is used in hospital and community. 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 adequately describe the equipment being evaluated, including the size of the air cells and cell cycle time.

Sixteen RCTs of alternating pressure supports for pressure ulcer prevention were identified: these compared AP and standard hospital mattresses in two studies (Andersen 1982; Sanada 2003); AP and various constant low pressure devices in nine studies such as water (Andersen 1982; Sideranko 1992), static air (Price 1999; Sideranko 1992), Silicore (Conine 1990; Daechsel 1985; Sideranko 1992), foam (Sideranko 1992; Whitney 1984), various (Gebhardt 1994; Laurent 1997); visco-elastic foam (Vanderwee 2005); continuous low pressure (Cavicchioli 2007), and with other alternating pressure supports in five studies (Exton-Smith 1982; Hampton 1997; Nixon 2006; Taylor 1999; Theaker 2005).

Alternating Pressure Compared With Standard Hospital Mattress

Andersen 1982 reported that the use of alternating pressure surfaces significantly reduces the incidence of pressure ulcers compared with standard hospital mattresses (RR 0.32, 95% CI 0.14 to 0.74). This report of this large trial, involving 482 patients 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: the Air Doctor (a single layer air cell overlay); the Tricell (a double-layer cell overlay), (both with 5-minute alternating air pressure) and a Paracare (standard hospital mattress). 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 Paracare 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.

These two trials were pooled using a fixed effects model (I^2 = 0%), there was a statistically significant reduction in pressure ulcer development 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 are of poor quality (Analysis 5.1).

Alternating Pressure Compared With Constant Low Pressure

Ten trials compared AP devices with various constant low pressure devices, however there is conflicting evidence as to their relative effectiveness. One study compared a range of AP supports with a range of CLP supports in a range of specialties in acute care settings (Gebhardt 1994) 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 is difficult to interpret given the wide variety of surfaces used within the study, 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 constant low pressure 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 4 hourly turning and a sitting protocol with a cushion)(Vanderwee 2005), continuous pressure mode of the Hill-Rom Duo mattress (Cavicchioli 2007), individually reported no difference in effectiveness, although many 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 there were statistically significantly more heel pressure ulcers in the control group using the viscoelastic mattress (p = 0.008 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 which 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 3-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 comapred with Silicore or foam overlays (using a fixed effects model; I^2 = 0%) was 0.91, (95% CI 0.71 to 1.17) indicating no statistically significant difference between Silicore or foam overlays and AP (Analysis 6.1).

The studies which compared AP with static water or static air mattresses were similarly considered together (Andersen 1982; Price 1999; Sideranko 1992). The Sideranko trial also had 3 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 all 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 answer the question of 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-square 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) suggesting no statistically significant difference between the rates of pressure ulcer incidence on 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 and alternating pressure 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 1997) (Analysis 7.1).

Comparisons between Different Alternating Pressure Devices

Alternating pressure devices differ somewhat in structure, e.g., the size of the inflatable air cells. One early study of pressure ulcer prevention (Exton-Smith 1982) compared two large-celled alternating pressure devices (Pegasus Airwave and the Large Cell Ripple - similar except the Airwave has two layers of cells). 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 intention-to-treat analysis would not have shown a statistically significant difference in the rate of pressure ulcers (16% vs 34%, P >0.05).

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 in either arm of this study.

Taylor 1999 compared the Pegasus Trinova 3-cell alternating pressure air mattress plus a pressure redistributing cushion (intervention) with a 2-cell alternating pressure air mattress plus a pressure redistributing cushion (control). This study was underpowered to 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 an 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 which uses optional pulsation technology and low air loss to reduce tissue interface pressure and the Hill-Rom Duo mattress (control) which is designed to lay directly onto 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 ulcer 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, high quality trial Nixon 2006 compared an AP overlay with an AP mattress, the primary outcome was pressure ulcer (grade 2 or above) incidence. 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%) people 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 cared for on the overlay requested a change to another device due to dissatisfaction (23.3%) compared to mattress patients (18.9%), a statistically significant difference.

Nixon 2006 also conducted a full cost effectiveness analysis from the perspective of the UK NHS and Personal Social Service. Cost information was calculated based on length of hospital stay and pressure-relieving surface used. Benefits were measured as number of pressure ulcer free days. In the base case analysis the mean per patient cost of the AP mattresses was £6509.73 and the mean patient cost of the AP overlays was £6793.33. The mattress cost on average £283.6 less per patient, (95%CI, £377.59 to £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 or 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 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 Beds

One trial 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) (Inman 1993)(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 (Bennett 1998) (Analysis 9.1). 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 grade 1 ulcers developed on the low air-loss bed (3/62) compared with 1 on the static air overlay (1/61). However, three grade 2 ulcers developed 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). Pooling the two trials which compared low air-loss beds (Cobb 1997; Inman 1993) 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). 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 compared with Dry Flotation

One small trial in patients after plastic surgical repair of pressure ulcers showed no difference between an air-fluidised bed and the Roho dry flotation mattress in post-operative tissue breakdown rates (Economides 1995) (Analysis 10.1).

Other pressure supports

Kinetic Turning Tables

Turning beds contain motors which constantly turn and tilt the patient, and are used in critical care settings primarily to prevent pneumonia and atelectasis. 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). Sample sizes in all the trials was small, and no beneficial effect of kinetic therapy on pressure ulcer incidence was detected (Analysis 11.1).

Profiling Beds

Keogh 2001 recruited 70 participants and found no pressure ulcers developed in either the group assigned the profiling bed with a pressure reducing foam mattress/cushion combination nor the group assigned a flat-based bed with a pressure-relieving/redistributing foam mattress/cushion combination.

Operating Table Overlays

Five RCTs have evaluated different methods of pressure relief on the operating table. The first compared a viscoelastic polymer pad with a standard table and found a relative reduction in the incidence of post-operative 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) (Nixon 1998)(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 skin).

Another trial (Feuchtinger 2006) compared an operating theatre table which included a waterfilled warming mattress, a 4cm thermoactive viscoelastic foam overlay with an operating theatre table with waterfilled warming mattress only. 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 suffered pressure ulcers (all were Grade 1 to 2), with 13/85 (15%) in the experimental group and 9/90 (10%) in the control group. In terms of grade 2 only pressure ulcers there were 2 in the experimental group and 1 in the control group. There was no statistically significant difference between the two groups at the point at which the trial was terminated.

Two further RCTs compared the Micropulse alternating system (applied both during surgery and post-operatively) with a gel pad during surgery and standard mattress post-operatively. We pooled these two trials (I^2= 0%) and derived a pooled relative risk (fixed effects) 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 2 trials whether the effect is due to the intra-operative or the post-operative pressure relief, or both (Analysis 13.1).

Schultz 1999 compared a mattress operating theatre overlay with usual care (which included padding as required, for example 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 more compared with 3 people with ulcers of grade 2 or more in the control group. No attempt was made to gather information on postoperative skin care of the patient. Details regarding stage of ulcer by group and of the unnamed product have been sought from the study authors with no success. In the absence of this information, the clinical importance of the findings is difficult to assess.

Overlay used on Accident & Emergency trolleys

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: ***Standard foam hospital mattress compared with other low-tech CLP*** .

Seat Cushions

There have been four RCTs comparing 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 (Conine 1994) compared the Jay gel and foam wheelchair cushion with a foam cushion in 141 people and found fewer ulcers in the Jay cushion group, though this did not reach statistical significance (RR 0.61, 95% CI 0.37 to 1.00). The third study (Conine 1993) 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 a posterior cut out (Graph: Comparison 14, Outcome 1). The fourth

study was a small pilot trial of 32 wheelchair users which 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. 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 and this difference was not statistically significant (Analysis 14.1).

Summary of Results

Foam alternatives to the standard hospital foam mattress can reduce the incidence of pressure ulcers in people at risk.

The relative merits of alternating and constant low pressure devices, and of the different AP devices for pressure ulcer prevention are unclear. One large, high quality study found no significant differences between an alternating pressure overlay with an AP mattress. However, the AP mattresses were associated with an 80% probability of being cost saving, due to a delay in pressure ulceration and reduced length of stay in hospital.

Pressure-relieving overlays on the operating table and in the postoperative period have been shown to reduce the postoperative pressure ulcer incidence, although there is some evidence that certain OR overlays may result in post-operative skin changes

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

Two trials investigating the effectiveness of a specific sheepskin product in preventing pressure ulcers show that sheepskin overlays are effective in reducing the incidence of pressure ulcers.

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 one can draw is that standard hospital mattresses have been consistently outperformed by a range of foam-based, low pressure mattresses and overlays, and also by 'higher-tech' 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 over time. This factor leads to major difficulties in interpretation of trial results and the importance of 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. Further, the effects of using alternative foam mattresses are noteworthy in their consistency.

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 vary widely. Frequently, it is also often difficult to ascertain whether study participants with Grade 1 ulcers have been accepted into the sample and included in the analyses or not.

The results of 3 of the 5 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 3 trials were of reasonable or good quality; the Nixon 1998 trial particularly 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 post-operatively (the Micropulse system) in the other 2 trials. The Micropulse trials are confounded by their provision of a standard mattress post-operatively in the gel overlay arm, and an alternating pressure overlay post-operatively 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 (Schultz 1999; Feuchtinger 2006) showed that post-operative skin changes occurred as a result of different operating theatre overlays but the clinical importance of these results is difficult to ascertain in the absence of further details on the results and products.

One study suggests that low air-loss beds are more effective than standard foam ICU beds in preventing pressure ulcers for people in ICU beds, however the ICU bed was not described. Another ICU based study found no differences between a low air loss unit and a mattresses that used either continuous or alternative low pressure modes. There are no studies comparing low air-loss therapy with alternating pressure surfaces and other 'high tech' low pressure supports.

Previously the evidence for different alternating pressure devices was unclear due to the poor quality and small size of existing studies. This update includes a large and 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).

Water-filled and bead-filled mattresses were both associated with reductions in the incidence of pressure ulcers compared with standard hospital mattresses, in trials published in the early 1980s. However, the particular products evaluated are no longer available.

There are tentative indications that four interventions may be harmful. Firstly, Foot Waffle heel elevators were associated with a trebling in the incidence of pressure ulcers that did not reach statistical significance due to the small sample size of the study. Secondly low air loss hydrotherapy which was evaluated in a trial in which 19% LAL-hydro patients developed ulcers compared with 7% of standard care patients - again not a statistically significant difference possibly as a result of the small size of the trial (98 patients in total). Thirdly, Schultz 1999 investigated the effectiveness of an alternative foam overlay used in the operating theatre. Results suggest that patients placed on the intervention devices were significantly more likely to experience postoperative skin changes (i.e. mainly grade 1 pressure ulcers). However, it is difficult 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 of an operating theatre table which included a waterfilled warming mattress and a 4cm thermoactive viscoelastic foam overlay compared with an operating theatre table with waterfilled warming mattress only. 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 suffered pressure ulcers (all were Grade 1 to 2).

Few comparisons have been replicated, and as most of the trials undertaken are under-powered there is little information from which to draw firm conclusions. For example, air fluidised therapy as a prevention strategy has only been compared with dry flotation, and low air loss only with standard care, in one trial, as an intervention. There remain gaps in the knowledge base to which a rational research agenda could be developed. 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.

Common methodological flaws 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 participants were pressure ulcer free or not 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.

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

In people at high risk of pressure ulcer development, where possible higher specification foam mattresses rather than standard hospital foam mattresses should be used. 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. Seat cushions have not been adequately evaluated.

Implications for research

Independent, well-designed, multicentre 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 and not others and may vary widely in cost (from less than £1,000 (UK) to more than £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 (Moher 2001) should be used as a guideline for reporting.

Given the high costs associated with the prevention of pressure ulcers generally, and of pressure-relieving surfaces specifically, emphasis should be given to robust economic evaluations 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	Prevention Trial: 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 (161) 2. Alternating air mattress (AP) (166) 3. Water filled mattress (air mattress for camping filled with water) (155)
Outcomes	Incidence of pressure ulcers (skin examined on alternate days). Grade 2 or greater ulcers (broken skin): Alternating mattress: 4.2% (7/166); Water mattress: 4.5% (7/155); Standard mattress: 13.0% (21/161)
Notes	118 out of 600 selected patients dropped out during first 24 hours. 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
Allocation concealment?	Unclear	B - Unclear

Aronovitch 1999

Methods	Prevention Trial: 7 days follow-up
Participants	18 years old; free of pressure ulcers; undergoing elective surgery under GA, of at least 3 hours 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) (112) Micropulse is thin pad with over 2,500 small air cells in rows; 50% cells inflated at any time. 2. Conventional Management (105) Conventional management comprised use of a gel pad in the operating room and a replacement mattress postop

Aronovitch 1999 (*Continued*)

Outcomes	1. MicroPulse system 1% (1/90) however ulcer due to foreign body and considered "not related to the bed" 2. Conventional Management 9% (7/80) (7 patients developed 11 ulcers) Grade 1: 1 Grade 2: 4 Unstageable: 6 P<0.005
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 postop for reasons unrelated to the surface. 2. Conventional Management Group: 6 patients were placed on the MicroPulse postop. Analysis was on an intention-to-treat basis

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - unclear

Bennett 1998

Methods	Prevention Trial: Follow up 60 days. Median length of follow up (days): 1. 4 (1-60) 2. 6 (1-62) P<0.017
Participants	Acute and long term care patients who were incontinent of urine and/or faeces, in bed >16 hours per 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	1. Low Air Loss Hydrotherapy (LAL Hydro) (42) Clensicair (SSI/Hill Rom). Permeable fast drying filter sheet over low air loss cushions (circulating air). Urine collection device integral to bed 2. Standard care (56) Standard care 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: 1.27/42 (64%) 2.10/56 (18%) Number of patients who developed pressure ulcers Grade 2-4: 1.8/42 (19%) 2.4/56 (7%) P=0.11; NS Number of patients with non-blanchable erythema (Grade 1): 1. 6/42 (14%) 2. 0/56 P=0.008 Only 26 ulcers present on enrolment, and only 3 of these were Grade 3 or 4 so no healing data presented

Bennett 1998 (*Continued*)

Notes	The first 68 patients were discounted and a further 26 patients of 116 withdrew. No intention to treat 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 since developed

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - unclear

Cadue 2008

Methods	Prevention RCT with maximum follow-up 30 days.
Participants	Patients in an intensive care setting without exiting a pressure ulcer deemed at high risk (Waterlow Score >10) and aged 18 year 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 a day)(35). 2. Standard pressure ulcer protocol (as above)(35).
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	

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear: Envelope but further details not known

Cavicchioli 2007

Methods	Prevention RCT: 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 one grade 1 pressure ulcer at baseline but were excluded if they had more than one pressure ulcer; or their pressure ulcer was grade 2 or above. Baseline balance for age, sex and Braden score in the randomised groups.

Cavicchioli 2007 (*Continued*)

Interventions	1. High-tech (Duo 2, Hill Rom) mattress on alternating low pressure setting (86). 2. High-tech (Duo 2, Hill Rom) mattress on continuous low pressure setting (84).
Outcomes	Number of participants with Incidence pressure ulcer (blinded outcome assessment at study end): Grade 1 1. Alternating low pressure 1/69 2. Continuous low pressure 0 Grade 2 1. Alternating low pressure 1/69 2. Continuous low pressure 1/71
Notes	This was a three armed study. There was a two armed RCT as described and a controlled group (standard mattress), not formed by randomisation and not included here. Blinded outcome assessment ws conducted for the randomised groups. Follow up figures were: 1. 69 (four deaths, 8 participants discharged before final assessment, and five classed as not having completed the study due to non-concordance); 2. 71 (5 deaths, four discharged and 4 classed as non-concordant). Not ITT.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear no details provided

Cobb 1997

Methods	Prevention RCT: 40 days follow-up
Participants	Recruitment took place in hospital wards and intensive care units. Participant had to be over 18 years of age, weigh 290 pounds or less, not have a pre-existing pressure ulcer, an expected length of stay of one to two weeks and be at "high risk" based on the Braden Scale. Patients were allocated through the selection of a treatment card by an independent nurse. There was some baseline imbalance observed with older participants and more participants with co-morbidities in the KinAir group.
Interventions	1. Low loss air bed (KinAir Bed) (62) 2. Static air mattress overlay (EHOB waffle) (61)
Outcomes	Number of participants with Incidence pressure ulcer (ICU participants assessed daily, ward patients assessed every 48 hours): Grade 1 1. KinAir Bed 3/62 2. EHOB waffle 1/61

Cobb 1997 (*Continued*)

	Grade 2. 1. KinAir Bed 3/62 2. EHOB waffle 11/61 Eschar 1. KinAir Bed 2/62 2. EHOB waffle 0/61
Notes	No higher grades reported. Not loss to follow up reported.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - The use of an independent nurse picking a treatment card.

Collier 1996

Methods	Prevention Trial: 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 detail given
Interventions	Comparison of 8 foam mattresses: 1. New Standard Hospital Mattress (Relyon) (130 mm) (9) 2. Clinifloat (11) 3. Omnifoam (11) 4. Softform (12) 5. STM5 (10) 6. Therarest (13) 7. Transfoam (10) 8. Vapourlux (14)
Outcomes	Incidence of pressure ulcers. Patients were assessed at least weekly throughout the hospital stay. No patient developed a pressure ulcer of any grade during whole study
Notes	9 patients were 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 the centre of the foam base in Standard and Omnifoam mattress on completion of study (detected using a "fist test" of unknown reliability). All mattress covers remained intact and inner foam protected

Collier 1996 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	No	C - Inadequate

Conine 1990

Methods	Prevention Trial: Sequential RCT with 3 month follow up. Method of allocation unclear
Participants	Patients with chronic neurological diseases aged 18-55 years 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
Interventions	1. Alternating pressure overlay (72) 10 cm air cells. Cycle time not stated, nor the make of overlay 2. Silicore (Spenco) overlay (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), not statistically significant
Notes	Alternating air overlay needed frequent monitoring and expensive prolonged repairs. It was reported that the patients sank into the Silicore overlay and found it difficult to move. Patients complained of bad odour build-up, instability (especially Silicore), and noise of the alternating pressure motor. High dropout rate due to discomfort

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Conine 1993

Methods	Prevention trial with 3 month follow up
Participants	Extended care patients > 60 years; 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 hours; free of any progressive disease which could lead to bed confinement
Interventions	1. Slab cushion bevelled at base to prevent seat sling (144) 2. Contoured foam cushion with a posterior cut out in the area of ischial tuberosities and an anterior ischial bar (144)
Outcomes	1. Slab cushion 85/125 (68%) 2. Contoured foam cushion 84/123 (68%)
Notes	No intention to treat analysis

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - unclear

Conine 1994

Methods	Prevention Trial: RCT of two 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 yrs) in an extended care hospital deemed at high risk of pressure ulcers (Norton Score of 14 or less); sitting in a wheelchair daily for minimum of 4 consecutive hours; free of progressive disease likely to confine them to bed. Excluded if diabetic, had peripheral vascular disease; confined to bed for more than 120 consecutive hours (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 (68) The Jay cushion is a contoured urethane foam base over gel pad 2. Foam cushion (73) 30kg per cubic metre density foam bevelled at the bottom to prevent sling effect Both cushions fitted with identical Jay air-exchange covers of knitted polyester. Patients were assigned to their specific wheelchairs by a seating specialist as per a local policy unaffected by the trial
Outcomes	1. Jay Cushion 17/68 (25%) 2. Foam Cushion 30/73 (41%) Pressure ulcer incidence data is 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

Conine 1994 (*Continued*)

	patient). Therefore it is impossible to present the incidence data as number of patients affected by ulcers of Grade 2 or above
Notes	13% attrition; not analysed by intention to treat

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Cooper 1998

Methods	Prevention Trial: RCT with 7 day follow up. Allocation by consecutively numbered, sealed, opaque envelopes
Participants	100 patients aged over 65 years, with no pressure ulcers, from three 24 bedded mixed emergency orthopaedic trauma wards. All patients at risk of pressure ulcers with Waterlow Risk scores of 15 and above. Baseline variables similar for each group (age, sex, mobility, Waterlow scores).
Interventions	1. Dry flotation mattress (Roho) (49) [Data supplied for only 43] 2. Dry flotation mattress (Sofflex) (51) [Data supplied for only 41]
Outcomes	Grade 2 and above: 1. Roho mattress: 2. Sofflex mattress: 1/51 (2%) Grade 1 ulcers: 1. Roho mattress: 5/43 (12%) 2. Sofflex mattress 2/41 (5%)
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 intention to treat analysis.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Daechsel 1985

Methods	Prevention Trial: 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 between 19 and 60 years, free from skin breakdown on entry, considered at high risk of pressure ulcers

Daechsel 1985 (*Continued*)

Interventions	1. Alternating pressure mattress (Gaymar Inc)(16) 2. Silicore overlay (JW Westman Inc)(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 two 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
Allocation concealment?	Unclear	B - Unclear

Economides 1995

Methods	Prevention Trial: RCT with 2 week follow up. Allocation by sealed envelope
Participants	12 patients who had stage 4 pressure sores needing myocutaneous flap closure. 10 out of 12 participants were paraplegic or quadriplegic. Groups appear 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 (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 (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 so distributing body weight away from bony prominences
Outcomes	Wound breakdown: 2/6 on Roho vs 2/5 on Clinitron. No significant difference between two support surfaces in the prevention of flap breakdown in the immediate post-operative period
Notes	Do not appear to have had any withdrawals

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Ewing 1964

Methods	Prevention and Treatment Trial: RCT with 6 months follow up. Mode of allocation unclear - stated as random selection
Participants	Elderly patients, average age 72.5 years, confined to bed, with reduced mobility in the legs due to neurological disorder, or fixed joints, peripheral vascular disease. No baseline data given and baseline comparability not described. Setting is the geriatric unit of a convalescent hospital
Interventions	1. The sheepskins were adjusted so that both legs were supported on the woolly fleece (18) 2. Control, without sheepskins (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
Notes	

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Exton-Smith 1982

Methods	Prevention Trial: RCT with 2 week follow up. Allocation by alternation and where the surface of choice was not available the patient was given an available surface
Participants	Newly-admitted geriatric patients, with fractured neck of femur, and long-stay patients; without pressure sores 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 (31) 2 layers of air cells; pressure alternated by deflating every 3rd cell in a 7.5 minute cycle. The mattress is ventilated with pinholes through which air passes to keep the patient's skin dry 2. Large Cell Ripple Mattress (31) Large cell ripple not described
Outcomes	Grade 2 ulcer or greater 1. Airwave (AWS): 16% (5/31) 2. Large Cell Ripple (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

Exton-Smith 1982 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Feuchtinger 2006

Methods	Prevention RCT: 5-day follow-up (post-operative)
Participants	Recruitment took place in a Department of Cardionvascular Surgery. Eligible patients were aged 18 years or over, schduled for cardiac surgery with extracorporal circulation. They did not have to be pressure ulcer free and four patients had grade 1 pressure ulcers as they went into surgery. Participants were well matched at baseline.
Interventions	1. Operating table with waterfilled warming mattress and a 4cm thermoactive viscoelastic foam overlay. (85) 2. Standard OR table configuration (OR table with waterfilled warming mattress). (90)
Outcomes	Number of participants with incidence pressure ulcer (assessed day 1, 3 and 5 post-operatively; blinded outcome assessment): Grade 1; Post op day 0-5 1. Thermo 15.3% (13/85) 2. Standard 10% (9/90) Grade 2; Post-op day 0-5 1. Thermo 2.4% (2/85) 2. Standard 1% (1/90)
Notes	No higher grades reported. No participant loss reported. The study was stopped after interim analysis due to the 11.1% total incidence in the standard group vs. 17.6% in the treatment group.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear no details provided

Gebhardt 1994

Methods	Prevention Trial: Allocation by case sheet number Follow up mean 16 days
Participants	Newly admitted patients aged over 18 years with Norton score <14 and without existing ulcers. Patients in ICU, oncology, medical, care of the elderly, orthopaedic wards. Groups well matched at baseline for age, Norton score, sex

Gebhardt 1994 (*Continued*)

Interventions	1. Alternating pressure air mattresses [various] (115) 2. Constant low pressure (foam, fibrefill, air, water, gel) supports [various] (115) Patients with deteriorated ulcers were transferred to more sophisticated medium cost support in the same group (e.g., Pegasus, Nimbus, Orthoderm, Convertible, Roho)
Outcomes	Grade 2 or greater ulcer: 1. Alternating pressure: 16% (18/115) 2. Constant low pressure: 55% (63/115)
Notes	Analysis by intention to treat. Mechanical unreliability and poor management of alternating pressure supports was a problem

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Gentilello 1988

Methods	Prevention Trial: RCT though method of allocation unclear. Duration of follow up unclear. Trial primarily not a pressure sore trial; 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 (27) Rotates through an arc of 124 degrees every 7 minutes. Nurses were instructed to leave the bed rotating except when vital signs being recorded and treatments given. If a patient developed a serious complication as result of KTT, they were moved onto conventional bed 2. Conventional beds (38) Patients turned in conventional fashion every 2 hours. If a patient in this group developed a chest infection and positioning thought to be a factor the patient was moved onto a KTT
Outcomes	Primary outcomes were: Incidence of pulmonary complications Other outcomes measured included Incidence of pressure ulcers Kinetic Treatment Table 30% Conventional: 26%
Notes	1 patient withdrew and was not included in the analysis

Risk of bias

Gentilello 1988 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Geyer 2001

Methods	Pilot Prevention RCT: 12 months follow-up
Participants	Recruitment of wheel chair users in (elderly) nursing homes. Eligible patients were users aged 65 years and over at risk of PU development (Braden score of less than or equal to 18). They also had to have a combined Barden activity and mobility sub-scale of less than or equal to 5, no pressure ulcers on their sitting surface and be tolerant of daily wheelchair sitting for 6 hours or more, in the ETAC twin wheelchair (this required a body weight below 250lbs). Participants were well matched at baseline for age, inital Braden score, sex.
Interventions	1. Pressure-reducing wheel chair cushion. (15) No single make of cushion was specificed, rather this could be selected by the nurse from a group of cushions based on the participants clinical status. Further details about cushion design not provided. 2. Standard foam (eggerate) cushion (Bioclinic Standard, Sunrise Medical) (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 through-out the study. 1. One participant died, three lost to follow-up. 2. One participant died two lost to follow-up.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate (Sequentially numbered envelopes)

Gilcreast 2005

Methods	Prevention RCT of heel ulcers: follow-up period unclear
Participants	Recruitment was from military tertiary care academic medical centres. Eligilbe patients were at moderate or high risk of pressure ulcer development (Braden score equal to or less than 14). Patients with hip surgery were excluded as were patients anticipated to be admitted for less than 72 hours and those with pre-existing heel pressure ulcers. Limited baseline information presented. There was baseline imbalance in sex.

Gilcreast 2005 (*Continued*)

Interventions	1. Bunny Boot (fleece) high cushion heel protector 2. Egg crate (holds the foot suspended above the bed surface with heel through a window) heel lift positioner 3. Foot waffle (felt coated plastic inflatable plastic pillow which encircles the foot) air cushion
Outcomes	Pressure ulcer incidence (Does not stratify by grade; baseline numbers not available and not clear if the unit is number of ulcers or number of patients): 1. Bunny Boot (fleece) 3/77 2. Egg crate 4/87 3. Foot waffle 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 was distributed among the three groups. 53 not included as did not wear the devices for at least 48 hours; 45 not included as they were non-compliant. Not ITT.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	No	C- Inadequate (non-numbered envelopes)

Goldstone 1982

Methods	Prevention Trial: Patients allocated alternately to one of 2 alternative surfaces. Follow up not clear
Participants	Patients (>60 years) with femur fracture. (Mean Norton score 13) Groups comparable at baseline for age, Norton Score
Interventions	1. Beaufort bead bed system which includes bead-filled mattress on A&E trolley; bead-filled operating table overlay; bead-filled sacral cushion of operating table; bead-filled boots to protect heels on operating table (32) 2. Standard supports in A&E, operating theatre, ward (43)
Outcomes	Grading of ulcers was not given. Beaufort bed: 16% Standard surface: 49% Maximum width of broken skin (mean): 6.4 mm on Beaufort beds vs 29.5 mm on Standard
Notes	Patients who were found to be incontinent of urine (numbers not given) and in the Beaufort bead bed group were catheterised however it does not seem to be the same for the control group. Patients were removed from Beaufort bed standard surfaces due to unknown reasons. Number of withdrawals unclear; no intention to treat analysis

Risk of bias

Goldstone 1982 (*Continued*)

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Gray 1994a

Methods	Prevention Trial: 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, Waterlow score
Interventions	1. Softfoam mattress (90) 2. Standard 130 mm NHS foam mattress (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 is. Nurses were more positive and patients gave higher comfort scores to Softform mattress

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Gray 1994b

Methods	Follow up 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: 1. 14 (3.6) 2. 13 (2.5)
Interventions	1. Transfoam mattress (50) 2. Transfoamwave (50) (both foam)

Gray 1994b (*Continued*)

Outcomes	1. 1 Grade IV ulcer 2. 1 Grade II ulcer	
Notes	95% follow up; intention to treat analysis	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - unclear

Gunningberg 2000

Methods	Follow up until discharge or 14 days post-op	
Participants	Patients admitted with a suspected hip fracture via an A&E department who were >65 years 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 (48) 2. Standard A&E trolley mattress and ward mattress (53)	
Outcomes	Grade II-IV incidence: 1. 4/48 (8.3%); 2. 8/53 (15%) Pressure ulcer incidence (all grades) 1. 12/48 (25%); 2.17/53 (32%) Mean comfort rating 1. 4.2; 2.4.0 All results non-significant	
Notes	Only 44 participants completed the comfort questionnaire	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - unclear

Hampton 1997

Methods	Prevention Trial: RCT but method of allocation not described. Duration of follow up to a maximum of 20 days
Participants	Very little detail; average age 77 years. No data regarding baseline status of patients presented in the published paper therefore impossible to judge baseline comparability. Only limited information obtained

Hampton 1997 (*Continued*)

	on request: Number patients at high-very high risk Airwave Group = 31; Number patients at high-very high risk Cairwave Group = 27. Mean age A=79 Mean Age C=75
Interventions	1. Alternating pressure (Cairwave System) (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) (39) Cells arranged in sets of 3 and are 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**
Allocation concealment?	Unclear	B - Unclear

Hofman 1994

Methods	Prevention Trial: 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) (21) Allows removal of small cubes of foam from beneath bony prominences 2. Standard hospital mattress (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 two 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

Hofman 1994 (*Continued*)

Notes	78% follow up. No intention to treat analysis. DeCube mattress was not always used correctly and its size was not optimum for all patients. A priori sample size calculation

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Inman 1993

Methods	Prevention Trial: RCT with an average of 17 days follow up. Method of allocation unclear
Participants	Patients aged over 17 years with an Acute Physiology and Chronic Health Evaluation (APACHE II) score greater than 15 who had an expected intensive care unit stay of >3 days
Interventions	1. Low-air-loss beds (49) 2. Standard ICU bed (49); patients rotated every 2 hours
Outcomes	Incidence of pressure ulcers reported in the trial as both 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%; Standard ICU bed: 51% Patients with multiple pressure ulcers: 2% on Low-air-loss beds and 24% on standard ICU bed
Notes	A priori sample size calculation. 98/100 patients randomised completed the study (1 lost from each group) as did not stay in ICU for 3 days; neither developed a sore. No ITT analysis

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Jolley 2004

Methods	Prevention RCT: Unclear follow-up period, mean bed days observed/participant 1. 7 days and 2. 7.9 days
Participants	Participants were recruited from a single hospital, and had to be at low to moderate risk of developing a pressure ulcer and over 18 years of age. Patients were excluded if they had no risk or high risk (more complex interventions required), if they had any pre-existing ulcers, had an expected length of stay of less than 48 hours or had darkly pigmented skin (justified by authors as making grade 1 ulcer difficult to detect).

Jolley 2004 (*Continued*)

	Participants well matched at baseline for age, sex, mean pressure ulcer risk score.
Interventions	1. Sheepskin mattress overlay. This is leather-backed with a dense, uniform 25 mm wool pile. Used as a partial mattress overlay. Pressure points not covered by sheepskin were protected by a second sheepskin or specific sheepskin elbow and heel protectors. Overlays were changed three times a week (unless required). Received usual care including repositioning. (270) 2.Usual care as determined by ward staff. Includes repositioning and any other PRD or prevention strategy with/without low-tech constant pressure relieving devices. (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 21/218 2. Usual care 37/223 Total number of incidence ulcers 1. Sheepskin 27 2. Usual care 58 Total number of incident stage 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 hours was no longer followed up for pressure-ulcer endpoints. Authors do not say why. Of the 218 included participants in the sheepskin group there were 2 deaths, 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 there were 5 deaths, 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
Allocation concealment?	Yes	A - Adequate (numbered cards in opaque envelopes)

Kemp 1993

Methods	Prevention Trial: RCT with 1 month follow up. Allocation by random number table
Participants	Inclusion criteria were: aged over 65 years, inpatients, with a Braden Score of 16 or less. Age ranged from 65-98, 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

Kemp 1993 (*Continued*)

Interventions	1. Convoluted foam overlay, 3 or 4 inches thick (45) 2. Solid foam overlay 4 inches thick, sculptured (39)
Outcomes	Incidence of pressure ulcers assessed by Research Nurse presumably not blind to intervention. Included grade 1 ulcers: Convoluted foam overlay: 47%; Solid foam overlay: 31%
Notes	All patients appear to have completed the study

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Keogh 2001

Methods	Follow up 5-10 days
Participants	Patients from two surgical and two medical wards who were: >18 years; Waterlow score of 15-25; tissue damage no greater than grade 1
Interventions	1. Profiling bed with a pressure reducing foam mattress/cushion (50) 2. Flat-based bed with a pressure relieving/redistributing mattress/cushion (50)
Outcomes	1. 0/35 2. 0/35 Healing of existing grade 1 ulcers 1.4/4 2.2/10
Notes	The 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
Allocation concealment?	Unclear	B - unclear

Laurent 1997

Methods	Prevention Trial: RCT with factorial design. Two 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 years 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 ICU; Standard Mattress Postop (80) 2: Nimbus (AP) ICU; Standard Mattress Postop (80) 3: Standard Mattress ICU; Tempur (CLP) Postop (75) 4: Nimbus ICU; Tempur Postop (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
Allocation concealment?	Unclear	B - Unclear

Lazzara 1991

Methods	Prevention and Treatment Trial: RCT (allocation by random number tables) in elderly nursing home population with 6 month follow up
Participants	Nursing home residents at risk (Norton score greater than 15) of pressure ulcers. 9 out of the total 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)

Lazzara 1991 (*Continued*)

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
Allocation concealment?	No	C - Inadequate

Lim 1988

Methods	Prevention Trial: 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 or over; free of pressure ulcers; at high risk of developing a sore (Norton score 14 or less); using a wheelchair for 3 or more hours per 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, mobility
Interventions	1. Foam slab cushion (2.5 cm medium density foam glued to 5 cm firm chipped foam) (26) 2. Contoured foam cushion (same foam as above; cut into a customised shape to relieve pressure on ischial tuberosities) (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>0.05), and the mean healing duration was 6.2 weeks in the slab and 5.4 weeks in the contoured group (P>0.05)
Notes	84% follow up.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

McGowan 2000

Methods	Prevention Trial: Discharge from hospital, transfer to a rehab ward
Participants	Orthopaedic patients aged 60 or over; assessed at low or moderate risk of pressure ulcer development by Braden scale; intact skin; anticipated LOS greater than 48 hours
Interventions	1. Standard hospital mattress, sheet and an Australian Medical Sheepskin overlay; sheepskin heel and elbow protectors as required (155) 2. Standard hospital mattress, sheet with or without other low tech constant pressure devices as required (142) Sheepskins were changed as required (at least every 3 days)
Outcomes	1. Sheepskin Group 14/155 (9%) (21 ulcers) 7 developed 1 ulcer; 7 developed 2. None more severe than stage I. 2. Control Group 43/142 (30%) (67 ulcers) 25 developed 1 ulcer; 7 developed 2; 11 three. 4 ulcers were stage II, 1 stage IV. Comfort was rated significantly greater in experimental group. Limb protectors difficult to keep in place
Notes	One patient from each group withdrew prior to data collection. 6 patients in experimental group withdrew because sheepskin to hot or irritable; 7 in the control group withdrew plus 3 in experimental group due to protocol violations (no intention to treat). Patients in experimental group rated comfort significantly higher than controls (P=<0.0001)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - unclear

Nixon 1998

Methods	Prevention Trial: RCT with 8 day follow up. Telephone randomisation (i.e. full allocation concealment) stratified by centre, and age
Participants	Patients aged 55 years and over, admitted for elective major general, gynaecological or vascular surgery in supine or lithotomy position and free of pre-op pressure damage greater than Grade 1. Groups well matched at baseline for age, sex, Braden score, type of surgery, duration of surgery, length of preop stay, proportion of time hypotensive during surgery
Interventions	1. Dry visco-elastic polymer pad on operating table (222) 2. Standard operating theatre table mattress plus Gamgee heel support (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=0.01 OR=0.46, 95% CI 0.26-0.82.

Nixon 1998 (*Continued*)

	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. This data is not broken down by group
Notes	A priori sample size calculation. 133 paired assessments by 94 nurses for pre-study interrater reliability assessments were undertaken. There was 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. In the recovery and ward area assessments, there were discrepant assessments in only 8.5% cases and sensitivity analysis assessing the impact of this level of misclassification on the overall result determined that the overall difference between the mattresses remains. Main endpoint data reported for 416 patients; incomplete data for 30 patients (lost forms 3; incomplete postop skin assessment 27). The patients with incomplete data were not reported by group

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Nixon 2006

Methods	Prevention RCT: 30 day follow up twice weekly and a further 30 day follow up once weekly.
Participants	Recruitment took place in 11 hosiptals. Patients admitted as acute or elective cases. Eligible patients were aged 55 or over, had expected length of stay of at least 7 days and either limitation of activity and mobility (Braden scale activity and mobility score of 1 or 2) or an existing pressure ulcer of grade 2. Elective surgical without limited avitivty or mobilty were eligible if the mean length of stay for their 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 post-operatively. Patients were not eligible if they had a grade 3 or worse pressure ulcer on admission, had a planned admission to ICU after surgery, were admitted to hospital more than 4 days before surgery, slept at night in a chair, weighted more than 140kgs or less than 45 kgs (as per mattress specifications). Participants were well matched at baseline
Interventions	1. Alternating pressure overlay (990) Alternating cell height min 8.5, max 12.25; cell cycle time 7.5-30, cell cycle 1 in 2, 1 in 3 or 1 in 4. 2. Alternating pressure mattress (982) Alternating cell height min 19.6, max 29.4; cell cycle time 7.5-30, cell cycle 1 in 2, 1 in 3 or 1 in 4. Alternating pressure mattress within 24 hrs of admission (larger cells than for overlay)
Outcomes	Number of participants with incidence pressure ulcer grade 2 and above (unblinded outcome assessment) 1. Overlay 10.7% 106/989 2. Mattress 10.3% 101/982 Patient acceptability: requests for mattress change

Nixon 2006 (*Continued*)

	1. Overlay 23.3% 230/989 2. Mattress 18.9% 186/982 Healing of existing pressure ulcers 1. Overlay 34% 20/59 2. Mattress 35% 19/54 Cost of treatment (£ sterling) 1. Overlay 6793.33 2. Mattress 6509.73 Mean difference in time to pressure ulcer (grade 2 or higher) developement (days) Participants in mattress group took 10.64 days longer to develop pressure ulcer than overaly group.
Notes	1 participant was recruited to the trial twice (group 1) and was excluced from analysis. Factors that has 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 state 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 compared with alternating pressure overlays were associated with an 80% probability of being cost saving

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Price 1999

Methods	Follow up 14 days postoperatively
Participants	Patients with fractured neck of femur and Medley score of greater than 25 (very high risk), aged over 60 years
Interventions	1. Repose system (low pressure inflatable mattress and cushion in polyurethane material) (40) 2. Nimbus III dynamic flotation plus TransCell cushion (40) All other care standard best practice including regular repositioning
Outcomes	Blister + Grade II: 1. At admission 1 + 1/40; preoperatively, 1 + 0/36; at 7 days, 2 + 1/32; at 14 days, 0 + 3/24 2. At admission, 0 + 2/40; preoperatively, 1 + 3/37; at 7 days 1 + 0/31,

Price 1999 (*Continued*)

	at 14 days, 1 + 1/26
Notes	80 patients were randomised; 50 in the final analysis i.e.. 38% attrition

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - unclear

Russell 2000

Methods	Prevention Trial: RCT with 7 day follow up. Randomisation using sealed opaque envelope
Participants	Patients aged at least 18 years; undergoing scheduled cardiothoracic surgery under GA; surgery of at least 4 hours 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 post op (98) 2. Conventional care (gel pad in OR, standard mattress post op) (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: Grade 2: 22. Conventional: 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"!
Notes	No equipment-related adverse events were reported

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Russell 2002

Methods	Median days in study presented by group by hospital. For the expt 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 years; Waterlow of 15-20
Interventions	1. Visco-polymer energy absorbing foam mattress (CONFOR-Med)/cushion combination (562) 2. Standard mattress/cushion combination (604)
Outcomes	Development of non-blanching erythema or worse (including with and without blanching erythema on admission to trial) 1. 110/562 (19.9%) 2. 161/604 (26.3%) P=0.005 Development of non-blanching erythema or worse 1. 48/562 (8.5%) 2. 66/604 (10.9%) Non-significant Data for ulcers of Grade >1 not presented separately
Notes	Patient comfort scores non significant. NO adverse events reported

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate

Sanada 2003

Methods	Prevention RCT: duration of follow-up not stated
Participants	Recruitment was from a single acute care unit. Eligile patients had a Braden score of less than or equal to 16, were bed bound, were pressure free 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) (37) 2. Single-layer air cell overlay (Air doctor) (36) Both consisted of multiple air cells where the pressure was alternated between cells at 5 minute intervals. The two cell overlay has two layers consisting of 24 narrow cylinder air cells. The one cell overlay is one layer and has 20 round air cells. 3. Standard hospital mattress (Paracare) (35) All groups had change of body position every 2 hours and special skin care to guard against friction and sheer. Nutritional intervention was given where required.

Sanada 2003 (*Continued*)

Outcomes	Number of participants with incidence pressure ulcer (daily assessment). All ulcers were grade 1 or 2: Grade 1 1. Double 0/26 2. Single 1/29 3. Standard 4/27 Grade 2 1. Double 1/26 2. Single 4/29 3. Standard 6/27
Notes	Number included in study analysis were 1. 26 (2 discontinued, 2 deaths, 7 head elevation equal to or less than 30 degrees); 29 (1 mattress malfunction, 2 deaths, 2 head elevation equal to or less than 30 degrees) 3. 27 (1 death, 7 head elevation equal to or less than 30 degrees). Not ITT.

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Yes	A - Adequate (sequentially numbered envelopes)

Santy 1994

Methods	Prevention Trial: RCT with 14 day follow up. Allocation by random number tables; degree of allocation concealment unclear
Participants	Patients aged over 55 years 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 well matched for age and Waterlow Score at baseline
Interventions	1. Clinifloat (87) Deep cut foam cubes in 3 sections with loose fitting cover 2. NHS contract (150 mm) (64) Single block of high resilience foam. Zipped cover of PVC nylon 3. Vaperm (116) Made from 4 layers of foam of varying density with holes for ventilation. Profiled heel and head sections and 2 part cover 4. Therarest (136) 3 layers of foam; extra soft top layer; middle layer claimed to absorb and disperse pressure; bottom layer prevents bottoming out 5. Transfoam (102) 150 mm thick layered foam with zipped cover of vapour permeable 2-way stretch material. Very high density foam used with firm central core and firmed edge.

Santy 1994 (*Continued*)

Outcomes	Rates of removal from study due to skin deterioration: Clinifloat 9% NHS contract 27% Transfoam 10% Therarest 11% 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 sore development. This explains why fewer patients on these surfaces. Omnifoam mattress showed foam collapse after six weeks and were withdrawn from use and replaced with Vaperm mattresses. Problems with mattress cover found on two Therarest mattresses, three Transfoam mattress covers, and three times with the Clinifloat mattress

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Schultz 1999

Methods	Follow up 6 days
Participants	Patients admitted for surgery lasting at least 2 hours in lithotomy position, aged 18 or over; admitted with intact skin
Interventions	1. Experimental mattress overlay in OR made of foam with a 25% ILD of 30 pounds and density of 1.3 (206) 2. Usual care (padding as required, including gel pads, foam mattresses, donuts etc) (207)
Outcomes	1. Experimental OR mattress overlay 55/206 (27%) 6 people had ulcers of Stage II or more 2. Usual care 34/207 (16%) 3 people had ulcers of Stage II or more. Total number of ulcers = 13915/139 ulcers Grade II or more severe (11%) p=0.0111
Notes	Experimental product caused post-operative skin changes. Authors contacted for more information relating to grade of ulcer by group

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - unclear

Sideranko 1992

Methods	Prevention Trial: RCT with mean follow up of 9.4 days. Method of randomisation not stated though said to be "random"
Participants	Adult, surgical intensive care unit patients: SICU stay >48 hr, without existing skin breakdown on admission. Groups broadly similar at baseline although water mattress group appear to be heavier and with shorter number of days in ICU (significance of these differences unclear)
Interventions	1. Alternating air overlay - 1.5" thick Lapidus Airfloat System (20) 2. Static air mattress - 4" thick Gay Mar Sof Care (20) 3. Water mattress - 4" thick Lotus PXM 3666 (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 is primarily about interface pressure and patient position, therefore there is 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
Allocation concealment?	Unclear	B - Unclear

Stapleton 1986

Methods	Prevention Trial: Method of allocation - 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) (32) 2. Polyether foam pad 2 ft x ft x 3 inch thickness (34) 3. Spenco pad (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%; 2. Foam pad: 24%; 3. Spenco pad: 6%

Stapleton 1986 (*Continued*)

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

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Summer 1989

Methods	Prevention Trial: 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 Intensive Care Unit in diagnostic groups: 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 (43) 7 ft x 3 ft 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 (43)
Outcomes	1 patient developed small facial ulcer on Kinetic Treatment Table; none on conventional beds
Notes	3/86 (3%) patients lost to follow up

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Takala 1996

Methods	Prevention Trial: RCT with 14 day follow up. Randomisation influenced by mattress availability therefore not concealed
Participants	Non trauma patients admitted to Intensive Care Unit who were expected to stay >5 days. Treatment groups similar at baseline however not compared for degree of pressure sore risk

Takala 1996 (*Continued*)

Interventions	1. Carital Optima (21): constant low pressure mattress comprising 21 double air bags on a base. 2. Standard hospital foam mattress (19): 10 cm thick foam density 35 kg/m3
Outcomes	1. No ulcers 2. 7/19 patients (37%) developed a total of 13 sores P<0.005. 9 ulcers were Grade 1A (erythema), 4 were Grade 1B (superficial and limited to the dermis)
Notes	40% withdrawals; intention to treat analysis undertaken

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Taylor 1999

Methods	Prevention Trial: 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) (22) 2. Alternative alternating pressure system (unnamed) with pressure redistributing cushion (22)
Outcomes	1. TriNova 0/22 2. Control 2/22 (both ulcers superficial)
Notes	Study underpowered. Comfort data was not reported for control group. Nurse acceptability - Intervention: good to very good n=15; acceptable n=1; Controls: good to very good n=9; acceptable n=11

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - unclear

Theaker 2005

Methods	Prevention RCT: follow up until two weeks after discharge from ICU
Participants	Recruitment was from an IC unit. Eligible participants were deemed at high risk of pressure ulcer development (from a set of five predetermined factors; details not provided but reference given) and aged 18 yeras or over. Patients with pressure sores on admission were excluded. Baseline data presented by outcome so difficult to assess.
Interventions	1. KCI TheraPulse bed (30) 2. Hill-Rom Duo mattress (32) No further details about the devices given
Outcomes	Number of participants with incidence pressure ulcer (assessed every 8 hours; blinded outcome assessment*). All grades (not given by group, stated that most were grade 2 with one grade 3): 1. TheraPulse 3/30 2. Duo 6/32 8 of the 9 ulcers were heel ulcers.
Notes	Participant lost not mentioned. * Trial is described as unblinded, but the methods tdescribe blinded outcome assessment with photographs.

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - adequate envelopes opened by independent person.

Tymec 1997

Methods	Prevention Trial
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 years, mean age 66.6±16.5 yrs. Mean Braden score on admission 11.8. 21 patients with respiratory conditions, 6 with cancer, 5 with CVA
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	Do not appear to be any losses

Tymec 1997 (*Continued*)

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - unclear

Vanderwee 2005

Methods	Prevention RCT:
Participants	Recruitment was from 19 surgical, internal medicine or geriatric hospital wards. Eligible patients were deemed at risk of pressure ulcers (Braden score less than 17) or had at least one grade 1 ulcer, aged 18 years or over and had an expected hospital stay of at least 3 days and were not contrindicated fro turning. Particpants were exlcuded if they had a grade 2 or above pressure ulcer, weighted more than 140 kgs. 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). No turning protocol. (222) 2. Visco-elastic foam mattress (Tempur, Tempur-World). Sitting protocol with air cushion (Airtech, Huntleigh). Turning every 4 hrs (225)
Outcomes	Number of participants with incidence pressure ulcer (assessed daily by ward nurse; grade 1 exlcuded): 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 (grade 2-4) between the groups. There were significantly more heel pressure ulcers in the control group (p=0.006). However, authors note that patients nursed on an APAM seemed to develop more sever pressure ulcers.

Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Yes	A - Adequate (sequentially numbered envelopes)

Vyhlidal 1997

Methods	Prevention Trial: RCT with 10-21 day follow up. Allocation to surfaces achieved by investigator drawing assignment out of a hat therefore extent of concealment inadequate

Vyhlidal 1997 (*Continued*)

Participants	Patients newly admitted to a skilled nursing facility; estimated stay at least 10 days; free of pressure ulcers but at risk (Braden score <18 with subscale 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. 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" thick foam overlay with dimpled surface (20) 2. MAXIFLOAT; mattress replacement in 5 sections (20). The mattress has a water/bacteria repellent top cover; is made of 1.5" thick antimicrobial foam with a centre core of cut foam; has a nonremovable 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=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. One subject 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 $38 cf. $260 for MAXIFLOAT

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	No	C - Inadequate

Whitney 1984

Methods	Prevention Trial: RCT with 8 day follow up. Method of allocation not stated - patients were "selected at random" for each group
Participants	Patients on medical-surgical units who were in bed for 20 hours daily. Most patients had relatively little skin breakdown. Ages ranged from 19 - 91 years; mean 63.2 years. Majority of patients were confused, lethargic, stuporous. Only 39% classed as mentally alert Baseline data not presented
Interventions	1. Alternating pressure mattress (25) Consisted of 134 3" diameter air cells. 3 minute cycle 2. Convoluted foam pad (Eggcrate) (26) Patients in both groups were turned every two hours
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 intention to treat. 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
Allocation concealment?	Unclear	B - Unclear

Allocation concealment rated as:
A Adequate
B Unclear
C Inadequate
D Not used

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

Allen 1993	No clinical outcomes, interface pressure only recorded
Andrews 1989	Not an RCT
Ballard 1997	Data recorded was comfort data no pressure sore outcomes

(*Continued*)

Barhyte1995	Not an RCT
Bliss 1967	Not an RCT. Patients were recruited to the trial based on their risk score
Bliss 1995	Whilst 8 surfaces were evaluated in this prospective trial, not all surfaces were in the trial at any 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, and this occurred frequently; there were a total of 457 mattress trials reported in only 238 patients. The data are not presented by patient; only by mattress trial. Duplicate citation of Bliss 1994
Braniff 1997	Healing and prevention outcome data not separated
Brienza 2001	Study of pressure measurement
Chaloner 1999	Not an RCT, Controlled clinical trial. Duplicate citation with Chaloner D 2000
Chaloner 2000	Not an RCT, randomisation corrupted, authors report that randomisation compromised on the basis of bed availability
Colin 1996	No clinical outcomes recorded, only transcutaneous oxygen tension measurements were taken
Conine 1991	Not an RCT
deBoisblanc 1993	Outcome incidence of pneumonia, no pressure sore outcomes
Defloor 2000	Does not compare surfaces
Defloor 2004	Compares turning
Flam 1995	Outcome skin temperature and skin moiture level, no pressure sore outcomes
Fleischer 1997	Not an RCT
Grindley 1996	Patients were crossed over between intervention groups at 3 days. Outcome used was the assessment of patient comfort
Gunningberg 1998	Not an RCT. Study of risk calculation rather than prevention
Hampton 1998	Not an RCT
Hawkins 1997	Not an RCT.
Inman 1999	Comparison of a bed rental versus a bed purchase strategy not a comparison of surfaces

(*Continued*)

Jacksich 1997	Not an RCT
Jesurum 1996	Not an RCT
Koo 1995	Not an RCT, study of interface pressure in healthy volunteers
Marchand 1993	Not an RCT
Ooka 1995	Quasi randomised trial design
Phillips 1999	N of 1 trial design
Regan 1995	This study reports an audit of pressure sore incidence after implementation of a comprehensive pressure sore policy; it is not a prospective RCT
Reynolds 1994	Not an RCT
Rosenthal 1996	Not an RCT
Scott 1995	Ongoing study
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
Suarez 1995	Controlled clinical trial which records only pressure measurements
Takala 94	Not an RCT, outcome measure of interface pressure
Thomas 1994	Not an RCT
Torra i Bou 2002	Evaluates dressings
Wells 1984	Interface pressure measurements only recorded
Wild 1991	Interface pressure measurements
Zernike 1997	Use of eggcrate foam as a heel pressure relieving device, intervention not a bed or mattress. Incidence of pressure sores not reported

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

Berthe 2007

Methods	
Participants	
Interventions	
Outcomes	
Notes	under assessment

Büchner 1995

Methods	
Participants	
Interventions	
Outcomes	
Notes	awaiting translation

Defloor 1997

Methods	
Participants	
Interventions	
Outcomes	
Notes	abstract only - awaiting further information

Geelkerken 1994

Methods	
Participants	
Interventions	
Outcomes	

Geelkerken 1994 (*Continued*)

Notes	awaiting translation

Haalboom 1994

Methods	
Participants	
Interventions	
Outcomes	
Notes	awaiting translation

Holzgreve 1993

Methods	
Participants	
Interventions	
Outcomes	
Notes	awaiting translation

Neander 1996

Methods	
Participants	
Interventions	
Outcomes	
Notes	awaiting translation

Zernike 1994

Methods	
Participants	
Interventions	
Outcomes	
Notes	under assessment

DATA AND ANALYSES

Comparison 1. Constant low pressure supports v 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 Water	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.2 Bead Bed	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.3 Comfortex DeCube mattress	1		Risk Ratio (M-H, Random, 95% CI)	Not estimable
1.4 Softform 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 v 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	3		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected
1.1 alternative foam v standard foam	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Maxifloat Foam Mattress v Iris Foam Overlay	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Solid Foam v Convoluted Foam	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	8		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Sofflex v ROHO	1	84	Risk Ratio (M-H, Random, 95% CI)	0.63 [0.16, 2.47]
1.2 Optima v SFM	1	40	Risk Ratio (M-H, Random, 95% CI)	0.06 [0.00, 0.99]
1.3 Gel Mattress v Air-filled Overlay	1	66	Risk Ratio (M-H, Random, 95% CI)	0.8 [0.24, 2.72]
1.4 Static Air Mattress v Water Mattress	1	37	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.04, 4.29]
1.5 Foam Overlay v Silicore Overlay	1	68	Risk Ratio (M-H, Random, 95% CI)	1.17 [0.64, 2.14]
1.6 Sheepskin v no sheepskin	2	738	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.22, 0.81]
1.7 Foam support surface v no support	1	69	Risk Ratio (M-H, Random, 95% CI)	0.15 [0.05, 0.47]

Comparison 5. Alternating Pressure v 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 v 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) v CLP (various)	1	230	Risk Ratio (M-H, Random, 95% CI)	0.38 [0.22, 0.66]
1.2 AP v Silicore or Foam Overlay	4	331	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.72, 1.16]
1.3 AP v Water or Static Air Mattress	3	458	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.51, 3.35]
1.4 AP v continuous low pressure mattress	1	140	Risk Ratio (M-H, Random, 95% CI)	2.06 [0.19, 22.18]
1.5 AP v Visco-elastic foam mattress	1	447	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.64, 1.52]
2 AP devices versus silicore or foam overlay	4	331	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.71, 1.17]
3 AP devices versus water or static air mattress	3	458	Risk Ratio (M-H, Random, 95% CI)	1.31 [0.51, 3.35]

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 Std ICU/SFM post-ICU v Nimbus AP ICU/SFM post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Std ICU/SFM post-ICU v Std ICU/Tempur CLP post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Nimbus AP ICU/SFM post-ICU v Std ICU/Tempur CLP post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 Std ICU/SFM post-ICU v 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 v Nimbus ICU/ Tempur post-ICU	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.6 Std ICU/Tempur post-ICU v 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 v Large Cell Ripple	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 Airwave v Pegasus Carewave	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.3 Trinova v control	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.4 AP Overlay v AP Mattress	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.5 TheraPulse v Duo	1		Risk Ratio (M-H, Fixed, 95% CI)	Not estimable

Comparison 9. Low Air Loss v 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 sores	1		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 10. Air-Fluidised Therapy v Dry Flotation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Rate of wound breakdown	1	12	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.20, 4.95]

Comparison 11. Kinetic Treatment Table v Standard

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pressure ulcer incidence	2		Risk Ratio (M-H, Fixed, 95% CI)	Totals not selected

Comparison 12. Operating Table Overlay v 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 v No overlay	1	416	Risk Ratio (M-H, Random, 95% CI)	0.53 [0.33, 0.85]
1.2 Viscoelastic foam overlay v 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 v Standard foam mattresses (SFM), Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 1 Constant low pressure supports v Standard foam mattresses (SFM)

Outcome: 1 Pressure ulcer incidence

Study or subgroup	CLP n/N	SFM n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
1 Water				
Andersen 1982	7/155	21/161		0.35 [0.15, 0.79]
2 Bead Bed				
Goldstone 1982	5/32	21/43		0.32 [0.14, 0.76]
3 Comfortex DeCube mattress				
Hofman 1994	4/17	13/19		0.34 [0.14, 0.85]
4 Softform mattress				
Gray 1994a	6/90	27/80		0.20 [0.09, 0.45]
5 Alternative foam				

(*Continued* . . .)

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Study or subgroup	CLP n/N	SFM n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
Collier 1996	0/130	0/9		0.0 [0.0, 0.0]
Santy 1994	42/441	17/64		0.36 [0.22, 0.59]
6 Hi spec foam mattress/cushion				
Russell 2002	48/562	66/604		0.78 [0.55, 1.11]

Analysis 2.1. Comparison 2 Alternative Foam Mattress v Standard Foam Mattress, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 2 Alternative Foam Mattress v 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	Risk Ratio M-H,Random,95% CI
1 Various alternatives (pooled)				
Collier 1996	0/130	0/9		0.0 [0.0, 0.0]
Gray 1994a	6/90	27/80		0.20 [0.09, 0.45]
Hofman 1994	4/17	13/19		0.34 [0.14, 0.85]
Russell 2002	48/562	66/604		0.78 [0.55, 1.11]
Santy 1994	42/441	17/64		0.36 [0.22, 0.59]
Total (95% CI)	**1240**	**776**		**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 v Standard Foam Mattress, Outcome 2 Pressure ulcer incidence UK studies only.

Review: Support surfaces for pressure ulcer prevention

Comparison: 2 Alternative Foam Mattress v Standard Foam Mattress

Outcome: 2 Pressure ulcer incidence UK studies only

Study or subgroup	Treatment n/N	Control n/N	Risk Ratio M-H,Random,95% CI	Risk Ratio M-H,Random,95% CI
Collier 1996	0/130	0/9		0.0 [0.0, 0.0]
Gray 1994a	6/90	27/80		0.20 [0.09, 0.45]
Russell 2002	48/562	66/604		0.78 [0.55, 1.11]
Santy 1994	42/441	17/64		0.36 [0.22, 0.59]
Total (95% CI)	**1223**	**757**		**0.41 [0.19, 0.87]**

Total events: 96 (Treatment), 110 (Control)

Heterogeneity: Tau² = 0.37; Chi² = 12.41, df = 2 (P = 0.002); I² =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 v standard foam				
Santy 1994	42/441	17/64		0.36 [0.22, 0.59]
2 Maxifloat Foam Mattress v Iris Foam Overlay				
Vyhlidal 1997	5/20	12/20		0.42 [0.18, 0.96]
3 Solid Foam v Convoluted Foam				
Kemp 1993	12/39	21/45		0.66 [0.37, 1.16]

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

Study or subgroup	CLP1 n/N	CLP2 n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Sofflex v ROHO					
Cooper 1998	3/41	5/43		100.0 %	0.63 [0.16, 2.47]
Subtotal (95% CI)	**41**	**43**		**100.0 %**	**0.63 [0.16, 2.47]**
Total events: 3 (CLP1), 5 (CLP2)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.66 (P = 0.51)					
2 Optima v SFM					
Takala 1996	0/21	7/19		100.0 %	0.06 [0.00, 0.99]
Subtotal (95% CI)	**21**	**19**		**100.0 %**	**0.06 [0.00, 0.99]**
Total events: 0 (CLP1), 7 (CLP2)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.96 (P = 0.050)					
3 Gel Mattress v Air-filled Overlay					
Lazzara 1991	4/33	5/33		100.0 %	0.80 [0.24, 2.72]
Subtotal (95% CI)	**33**	**33**		**100.0 %**	**0.80 [0.24, 2.72]**
Total events: 4 (CLP1), 5 (CLP2)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.36 (P = 0.72)					
4 Static Air Mattress v Water Mattress					
Sideranko 1992	1/20	2/17		100.0 %	0.43 [0.04, 4.29]
Subtotal (95% CI)	**20**	**17**		**100.0 %**	**0.42 [0.04, 4.29]**
Total events: 1 (CLP1), 2 (CLP2)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.73 (P = 0.47)					
5 Foam Overlay v Silicore Overlay					
Stapleton 1986	14/34	12/34		100.0 %	1.17 [0.64, 2.14]
Subtotal (95% CI)	**34**	**34**		**100.0 %**	**1.17 [0.64, 2.14]**
Total events: 14 (CLP1), 12 (CLP2)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.50 (P = 0.62)					
6 Sheepskin v no sheepskin					
Jolley 2004	21/218	37/223		51.0 %	0.58 [0.35, 0.96]
McGowan 2000	14/155	43/142		49.0 %	0.30 [0.17, 0.52]

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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
Subtotal (95% CI)	**373**	**365**		**100.0 %**	**0.42 [0.22, 0.81]**
Total events: 35 (CLP1), 80 (CLP2)					
Heterogeneity: $Tau^2 = 0.15$; $Chi^2 = 3.03$, df = 1 (P = 0.08); $I^2 = 67\%$					
Test for overall effect: Z = 2.60 (P = 0.0094)					
7 Foam support surface v no support					
Cadue 2008	3/35	19/34		100.0 %	0.15 [0.05, 0.47]
Subtotal (95% CI)	**35**	**34**		**100.0 %**	**0.15 [0.05, 0.47]**
Total events: 3 (CLP1), 19 (CLP2)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.27 (P = 0.0011)					

Analysis 5.1. Comparison 5 Alternating Pressure v Standard Foam Mattress, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 5 Alternating Pressure v 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)					

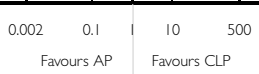
Analysis 6.1. Comparison 6 Alternating Pressure v Constant Low Pressure, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 6 Alternating Pressure v 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) v CLP (various)					
Gebhardt 1994	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 v 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 v 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 v 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 v 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 6.2. Comparison 6 Alternating Pressure v Constant Low Pressure, Outcome 2 AP devices versus silicore or foam overlay.

Review: Support surfaces for pressure ulcer prevention

Comparison: 6 Alternating Pressure v Constant Low Pressure

Outcome: 2 AP devices versus silicore or foam overlay

Study or subgroup	AP device n/N	CLP device n/N	Risk Ratio M-H,Fixed,95% CI	Weight	Risk Ratio M-H,Fixed,95% CI
Conine 1990	39/72	45/76		62.3 %	0.91 [0.69, 1.21]
Daechsel 1985	4/16	4/16		5.7 %	1.00 [0.30, 3.32]
Stapleton 1986	11/32	26/68		23.7 %	0.90 [0.51, 1.58]
Whitney 1984	5/25	6/26		8.4 %	0.87 [0.30, 2.48]
Total (95% CI)	**145**	**186**		**100.0 %**	**0.91 [0.71, 1.17]**
Total events: 59 (AP device), 81 (CLP device)					
Heterogeneity: Chi^2 = 0.03, df = 3 (P = 1.00); I^2 =0.0%					
Test for overall effect: Z = 0.73 (P = 0.47)					

Analysis 6.3. Comparison 6 Alternating Pressure v Constant Low Pressure, Outcome 3 AP devices versus water or static air mattress.

Review: Support surfaces for pressure ulcer prevention

Comparison: 6 Alternating Pressure v Constant Low Pressure

Outcome: 3 AP devices versus water or static air mattress

Study or subgroup	AP device n/N	CLP device n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
Andersen 1982	7/166	7/155		50.2 %	0.93 [0.34, 2.60]
Price 1999	1/40	2/40		14.0 %	0.50 [0.05, 5.30]
Sideranko 1992	5/20	3/37		35.8 %	3.08 [0.82, 11.59]
Total (95% CI)	**226**	**232**		**100.0 %**	**1.31 [0.51, 3.35]**

Total events: 13 (AP device), 12 (CLP device)

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)

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 Std ICU/SFM post-ICU v Nimbus AP ICU/SFM post-ICU				
Laurent 1997	4/80	10/80		0.40 [0.13, 1.22]
2 Std ICU/SFM post-ICU v Std ICU/Tempur CLP post-ICU				
Laurent 1997	14/80	11/75		1.19 [0.58, 2.46]
3 Nimbus AP ICU/SFM post-ICU v Std ICU/Tempur CLP post-ICU				
Laurent 1997	10/80	11/75		0.85 [0.38, 1.89]
4 Std ICU/SFM post-ICU v Nimbus AP ICU/Tempur CLP post-ICU				
Laurent 1997	14/80	10/77		1.35 [0.64, 2.85]
5 Nimbus AP ICU/SFM post-ICU v Nimbus ICU/Tempur post-ICU				

(*Continued . . .*)

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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
Laurent 1997	10/80	10/77		0.96 [0.42, 2.18]
6 Std ICU/Tempur post-ICU v Nimbus ICU/Tempur post-ICU				
Laurent 1997	11/75	10/77		1.13 [0.51, 2.50]

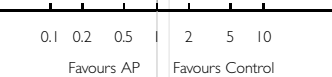
Analysis 8.1. Comparison 8 Comparisons Between Alternating Pressure Devices, Outcome 1 Pressure ulcer incidence.

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 v Large Cell Ripple				
Exton-Smith 1982	5/31	12/31		0.42 [0.17, 1.04]
2 Airwave v Pegasus Carewave				
Hampton 1997	0/36	0/39		0.0 [0.0, 0.0]
3 Trinova v control				
Taylor 1999	0/22	2/22		0.20 [0.01, 3.94]
4 AP Overlay v AP Mattress				
Nixon 2006	106/989	101/982		1.04 [0.81, 1.35]
5 TheraPulse v Duo				
Theaker 2005	3/30	6/32		0.53 [0.15, 1.94]

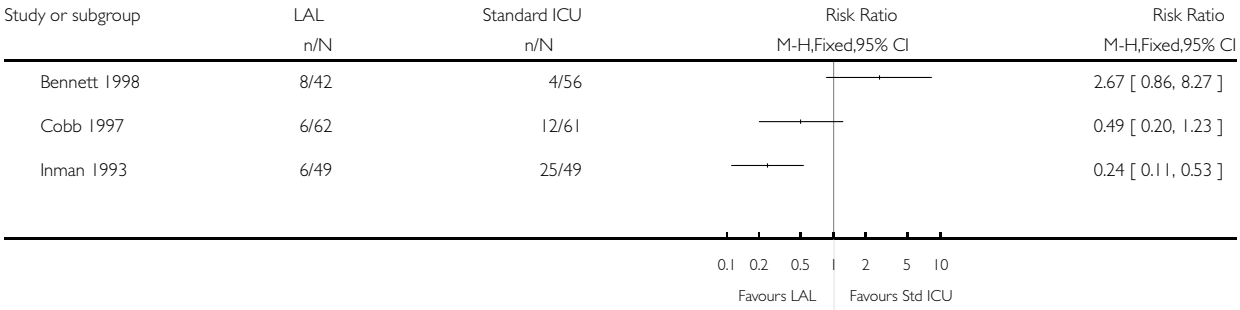


Analysis 9.1. Comparison 9 Low Air Loss v Standard Bed, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 9 Low Air Loss v Standard Bed

Outcome: 1 Pressure ulcer incidence

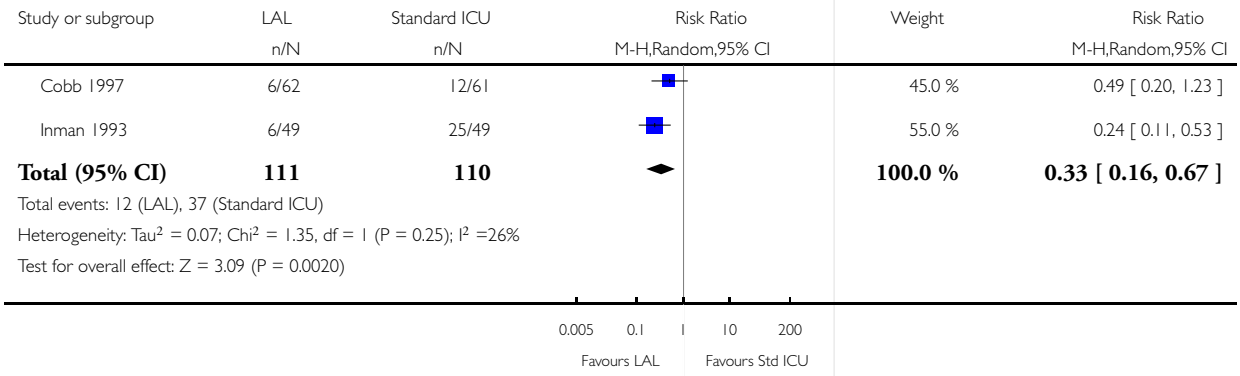


Analysis 9.2. Comparison 9 Low Air Loss v Standard Bed, Outcome 2 Pressure incidence pooled.

Review: Support surfaces for pressure ulcer prevention

Comparison: 9 Low Air Loss v Standard Bed

Outcome: 2 Pressure incidence pooled

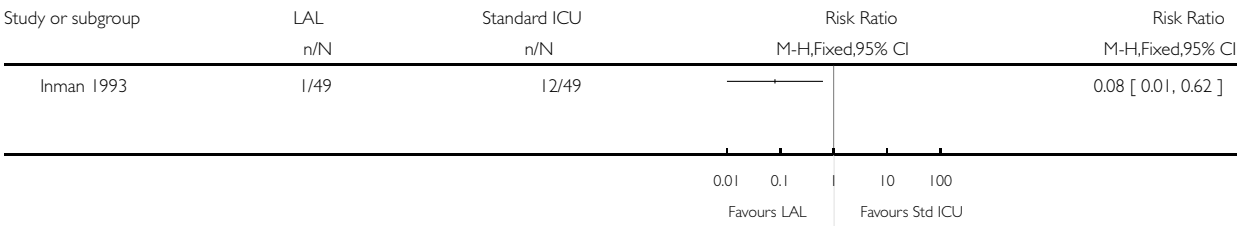


Analysis 9.3. Comparison 9 Low Air Loss v Standard Bed, Outcome 3 Incidence of patients developing multiple sores.

Review: Support surfaces for pressure ulcer prevention

Comparison: 9 Low Air Loss v Standard Bed

Outcome: 3 Incidence of patients developing multiple sores

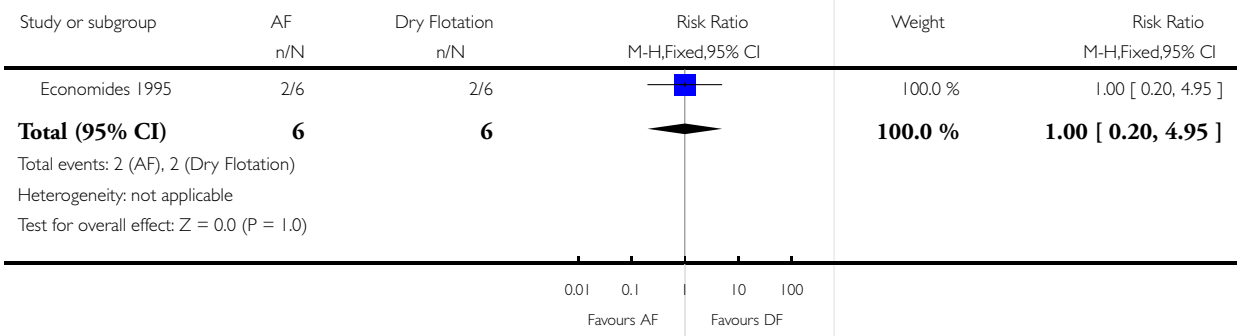


Analysis 10.1. Comparison 10 Air-Fluidised Therapy v Dry Flotation, Outcome 1 Rate of wound breakdown.

Review: Support surfaces for pressure ulcer prevention

Comparison: 10 Air-Fluidised Therapy v Dry Flotation

Outcome: 1 Rate of wound breakdown



Analysis 11.1. Comparison 11 Kinetic Treatment Table v Standard, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 11 Kinetic Treatment Table v Standard

Outcome: 1 Pressure ulcer incidence

Study or subgroup	KTT n/N	Standard n/N	Risk Ratio M-H,Fixed,95% CI	Risk Ratio M-H,Fixed,95% CI
Gentilello 1988	8/27	10/38		1.13 [0.51, 2.48]
Summer 1989	1/43	0/43		3.00 [0.13, 71.65]

Analysis 12.1. Comparison 12 Operating Table Overlay v No Overlay, Outcome 1 Pressure ulcer incidence.

Review: Support surfaces for pressure ulcer prevention

Comparison: 12 Operating Table Overlay v No Overlay

Outcome: 1 Pressure ulcer incidence

Study or subgroup	Overlay n/N	No Overlay n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Viscoelastic polymer pad v No overlay					
Nixon 1998	22/205	43/211		100.0 %	0.53 [0.33, 0.85]
Subtotal (95% CI)	**205**	**211**		**100.0 %**	**0.53 [0.33, 0.85]**
Total events: 22 (Overlay), 43 (No Overlay)					
Heterogeneity: not applicable					
Test for overall effect: Z = 2.64 (P = 0.0083)					
2 Viscoelastic foam overlay v No overlay					
Feuchtinger 2006	13/85	9/90		100.0 %	1.53 [0.69, 3.39]
Subtotal (95% CI)	**85**	**90**		**100.0 %**	**1.53 [0.69, 3.39]**
Total events: 13 (Overlay), 9 (No Overlay)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.05 (P = 0.30)					

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: Chi^2 = 0.40, df = 1 (P = 0.53); I^2 =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]

APPENDICES

Appendix 1. Search strategy for the first update of this review

The Wounds Group Specialised Trials Register was searched up to January 2004, this register is maintained by regular searching of the following databases: CENTRAL, MEDLINE, EMBASE and CINAHL and hand searching conference proceedings.
The Cochrane Central Register of Controlled Trials (CENTRAL) was searched, Issue 4 2003 using the following strategy:
1. BEDS single term (MeSH)
2. (bed or beds or bedding)
3. mattress*
4. cushion*
5. foam or transfoam
6. overlay*
7. (pad or pads)
8. gel
9. (pressure near relie*)
10. (pressure near device*)
11. (pressure near reduction)
12. (pressure near reducing)
13. (positioning* or repositioning*)
14. ((low next pressure) and support*)
15. ((low next pressure) and device*)
16. (constant near pressure)
17. (alternat* near pressure)
18. (air near suspension*)
19. (water near suspension*)
20. clinifloat
21. vaperm
22. therarest
23. maxifloat
24. sheepskin*
25. hammock*
26. (foot next waffle)
27. silicore
28. pegasus
29. (cairwave near therapy)
30. (turning near table*)
31. (kinetic near table*)
32. (kinetic near therapy)
33. (air next bag*)
34. (elevation near device*)
35. (static next air)
36. (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10)
37. (#11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20)
38. (#21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30)
39. (#31 or #32 or #33 or #34 or #35)
40. (#36 or #37 or #38 or #39)
41. DECUBITUS ULCER single term (MeSH)
42. (decubitus next ulcer*)
43. (bed near ulcer*)
44. (bed near sore*)
45. (pressure near sore*)
46. (pressure near ulcer*)

47. (#41 or #42 or #43 or #44 or #45 or #46)
48. (#40 and #47)

WHAT'S NEW

Last assessed as up-to-date: 17 July 2008.

13 May 2009	Amended	No changes - republished to fix technical problem.

HISTORY

Protocol first published: Issue 3, 1998

Review first published: Issue 2, 2000

18 July 2008	New citation required and conclusions have changed	Second update with the inclusion of 11 additional trials.
18 July 2008	New search has been performed	second update of review
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 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 and contributed to the text for both updates.

SBS undertook searching, inclusion decisions, analysis and contributed text for both updates.

RL made inclusion decisions, extracted data, assessed study quality and contributed to the text for the first update.

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

SOURCES OF SUPPORT

Internal sources

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

External sources

- NIHR (all versions), UK.
- NHS Health Technology Assessment Programme (original review), UK.
- National Institute of Clinical Excellence Guidelines Programme (first update), UK.

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: Support surfaces for pressure ulcer prevention has been prepared by Cullum N, McInnes E, Bell-Syer SEM, Legood R and includes only trials which consider interventions which aim to prevent pressure ulcers. The title of the review has been changed to more accurately reflect the scope of the review.

INDEX TERMS

Medical Subject Headings (MeSH)

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

MeSH check words

Humans