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Reactive air surfaces for preventing pressure ulcers (Review)

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[Intervention Review]

Reactive air surfaces for preventing pressure ulcers

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ABSTRACT

Background

Pressure ulcers (also known as pressure injuries, pressure sores, decubitus ulcers and bed sores) are localised injuries to the skin or underlying soft tissue, or both, caused by unrelieved pressure, shear or friction. Reactive air surfaces (beds, mattresses or overlays) can be used for preventing pressure ulcers.

Objectives

To assess the effects of reactive air beds, mattresses or overlays compared with any support surface on the incidence of pressure ulcers in any population in any setting.

Search methods

In November 2019, we searched the Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL); Ovid MEDLINE (including In-Process & Other Non-Indexed Citations); Ovid Embase and EBSCO CINAHL Plus. We also searched clinical trials registries for ongoing and unpublished studies, and scanned reference lists of relevant included studies as well as reviews, meta-analyses and health technology reports to identify additional studies. There were no restrictions with respect to language, date of publication or study setting.

Selection criteria

We included randomised controlled trials that allocated participants of any age to reactive air beds, overlays or mattresses. Comparators were any beds, overlays or mattresses that were applied for preventing pressure ulcers.

Data collection and analysis

At least two review authors independently assessed studies using predetermined inclusion criteria. We carried out data extraction, 'Risk of bias' assessment using the Cochrane 'Risk of bias' tool, and the certainty of the evidence assessment according to Grading of Recommendations, Assessment, Development and Evaluations methodology. If a reactive air surface was compared with surfaces that were not clearly specified, then we recorded and described the concerned study but did not included it in further data analyses.

Main results

We included 17 studies (2604 participants) in this review. Most studies were small (median study sample size: 83 participants). The average participant age ranged from 56 to 87 years (median: 72 years). Participants were recruited from a wide range of care settings with the majority being acute care settings. Almost all studies were conducted in the regions of Europe and America. Of the 17 included studies, two (223 participants) compared reactive air surfaces with surfaces that were not well described and therefore could not be classified. We analysed data for five comparisons: reactive air surfaces compared with (1) alternating pressure (active) air surfaces (seven studies with 1728 participants), (2) foam surfaces (four studies with 229 participants), (3) reactive water surfaces (one study with 37 participants), (4) reactive gel surfaces (one study with 66 participants), and (5) another type of reactive air surface (two studies with 223 participants). Of the 17 studies, seven (41.2%) presented findings which were considered at high overall risk of bias.

Primary outcome: Pressure ulcer incidence

Reactive air surfaces may reduce the proportion of participants developing a new pressure ulcer compared with foam surfaces (risk ratio (RR) 0.42; 95% confidence interval (CI) 0.18 to 0.96; I^2 = 25%; 4 studies, 229 participants; low-certainty evidence). It is uncertain if there is a difference in the proportions of participants developing a new pressure ulcer on reactive air surfaces compared with: alternating pressure (active) air surfaces (6 studies, 1648 participants); reactive water surfaces (1 study, 37 participants); reactive gel surfaces (1 study, 66 participants), or another type of reactive air surface (2 studies, 223 participants). Evidence for all these comparisons is of very low certainty.

Included studies have data on time to pressure ulcer incidence for two comparisons. When time to pressure ulcer incidence is considered using a hazard ratio (HR), low-certainty evidence suggests that in the nursing home setting, people on reactive air surfaces may be less likely to develop a new pressure ulcer over 14 days' of follow-up than people on alternating pressure (active) air surfaces (HR 0.44; 95% CI 0.21 to 0.96; 1 study, 308 participants). It is uncertain if there is a difference in the hazard of developing new pressure ulcers between two types of reactive air surfaces (1 study, 123 participants; very low-certainty evidence).

Secondary outcomes

Support-surface-associated patient comfort: the included studies have data on this outcome for three comparisons. We could not pool any data as comfort outcome measures differed between included studies; therefore a narrative summary is provided. It is uncertain if there is a difference in patient comfort responses between reactive air surfaces and foam surfaces over the top of an alternating pressure (active) air surfaces (1 study, 72 participants), and between those using reactive air surfaces and those using alternating pressure (active) air surfaces (4 studies, 1364 participants). Evidence for these two comparisons is of very low certainty. It is also uncertain if there is a difference in patient comfort responses between two types of reactive air surfaces (1 study, 84 participants; low-certainty evidence).

All reported adverse events: there were data on this outcome for one comparison: it is uncertain if there is a difference in adverse events between reactive air surfaces and foam surfaces (1 study, 72 participants; very low-certainty evidence).

The included studies have no data for health-related quality of life and cost-effectiveness for all five comparisons.

Authors' conclusions

Current evidence is uncertain regarding any differences in the relative effects of reactive air surfaces on ulcer incidence and patient comfort, when compared with reactive water surfaces, reactive gel surfaces, or another type of reactive air surface. Using reactive air surfaces may reduce the risk of developing new pressure ulcers compared with using foam surfaces. Also, using reactive air surfaces may reduce the risk of developing new pressure ulcers within 14 days compared with alternating pressure (active) air surfaces in people in a nursing home setting.

Future research in this area should consider evaluation of the most important support surfaces from the perspective of decision-makers. Time-to-event outcomes, careful assessment of adverse events and trial-level cost-effectiveness evaluation should be considered in future studies. Trials should be designed to minimise the risk of detection bias; for example, by using digital photography and adjudicators of the photographs being blinded to group allocation. Further review using network meta-analysis adds to the findings reported here.

PLAIN LANGUAGE SUMMARY

Do beds, mattresses and mattress toppers with air-filled surfaces that apply constant pressure to the skin prevent pressure ulcers?

Key messages

Reactive, air-filled surfaces that apply constant pressure to the skin may reduce people’s chances of developing pressure ulcers compared with foam surfaces.

They may also be better at preventing pressure ulcers among people in nursing homes than air-filled surfaces that regularly redistribute pressure under the body.

More research is needed to strengthen the evidence. Future studies should focus on options and effects that are important to decision-makers, such as:

- Reactive, air-filled surfaces that apply constant skin pressure, compared with air-filled surfaces that regularly redistribute pressure; and

- whether and when pressure ulcers develop, unwanted effects and costs.

What are pressure ulcers?

Pressure ulcers are also known as pressure sores or bed sores. They are wounds to the skin and underlying tissue caused by prolonged pressure or rubbing. They often occur on bony parts of the body, such as heels, elbows, hips and the bottom of the spine. People who have mobility problems or who lie in bed for long periods are at risk of developing pressure ulcers.

What did we want to find out?

There are beds, mattresses and mattress toppers specifically designed for people at risk of pressure ulcers. These can be made of a range of materials (such as foam, air cells or water bags) and are divided into two groups:

- reactive (static) surfaces that apply a constant pressure to the skin, unless a person moves or is repositioned; and

- active (alternating pressure) surfaces that regularly redistribute the pressure under the body.

We wanted to find out if reactive, air-filled surfaces:

- prevent pressure ulcers;

- are comfortable and improve people's quality of life;

- have health benefits that outweigh their costs; and

- have any unwanted effects.

What did we do?

We searched the medical literature for studies that evaluated the effects of beds, mattresses and mattress toppers with a reactive, air-filled surface. We compared and summarised their results, and rated our confidence in the evidence, based on factors such as study methods and sizes.

What did we find?

We found 17 studies (2604 people, average age: 72 years) that lasted between five days and six months (average: 14 days). The studies compared reactive, air-filled surfaces with:

- foam surfaces;

- active, air-filled surfaces; and

- reactive surfaces filled with water, gel or other materials.

Pressure ulcer prevention

The evidence suggests that fewer people may develop pressure ulcers when lying on a reactive, air-filled surface compared with:

- foam surfaces (four studies, 229 people); and

- an active, air-filled surface (one study, 308 people in a nursing home, followed for 14 days).

It is unclear whether reactive, air-filled surfaces prevent ulcers more than other types of reactive surfaces.

Other effects

The studies did not provide sufficiently robust and clear evidence for us to determine how reactive, air-filled surfaces affect comfort and unwanted effects. No studies reported information about quality of life and cost.

What limited our confidence in the evidence?

Most studies were small (83 people on average). Seven studies used methods likely to introduce errors in their results. It was unclear whether the other 10 studies used robust methods.

How up-to-date is this review?

The evidence in this Cochrane Review is current to November 2019.

SUMMARY OF FINDINGS

Summary of findings 1. Reactive air surfaces compared with alternating pressure (active) air surfaces for pressure ulcer prevention

Reactive air surfaces compared with alternating pressure (active) air surfaces for pressure ulcer prevention

Patient or population: pressure ulcer prevention
Setting: any care setting
Intervention: reactive air surfaces
Comparison: alternating pressure (active) air surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with alternating pressure (active) air surfaces	Risk with reactive air surfaces				
Proportion of participants developing a new pressure ulcer Follow-up: range 5 days to 15 days	Study population		RR 0.62 (0.35 to 1.11)	1648 (6 RCTs)	⊕⊖⊖⊖ Very low[a,b]	It is uncertain if there is a difference in the proportion of participants developing a new ulcer between reactive air surfaces and alternating pressure (active) air surfaces.
	40 per 1,000	25 per 1,000 (14 to 44)				
Time to pressure ulcer incidence Follow-up: 14 days	Study population		HR 0.44 (0.21 to 0.96)	308 (1 RCT)	⊕⊕⊖⊖ Low[c]	People treated with reactive air surfaces may be at lower risk of developing a new pressure ulcer than those treated with alternating pressure (active) air surfaces over 14 days of follow-up in the nursing home setting.
	117 per 1,000	53 per 1,000 (26 to 112)				
Support surface associated patient comfort (median follow-up duration 11 days, minimum 5 days, maximum 14 days)	The 4 studies report a range of different measures for this outcome and they cannot be pooled.		-	1364 (4 RCTs)	⊕⊖⊖⊖ Very low[d,e]	It is uncertain if there is a difference in support surface associated patient comfort between reactive air surfaces and alternating pressure (active) air surfaces.
All reported adverse events	Included studies did not report this outcome.					
Health-related quality of life	Included studies did not report this outcome.					
Cost-effectiveness	Included studies did not report this outcome.					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio; **HR:** Hazard ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded twice for high risk of bias in domains other than performance bias for four studies contributing over 54% weight in the meta-analysis.
[b]Downgraded once for imprecision as, despite the fact that the optimal information size (OIS) was met, the confidence interval was wide and crossed RR = 0.75.
[c]Downgraded twice for high risk of detection bias.
[d]Downgraded once for high overall risk of bias in 3 small studies but unclear risk of bias in 1 large study.
[e]Downgraded twice for substantial inconsistency.

Summary of findings 2. Reactive air surfaces compared with foam surfaces for pressure ulcer prevention

Reactive air surfaces compared with foam surfaces for pressure ulcer prevention

Patient or population: pressure ulcer prevention
Setting: acute care setting, intensive care unit, and nursing home
Intervention: reactive air surfaces
Comparison: foam surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with foam surfaces	Risk with reactive air surfaces				
Proportion of participants developing a new pressure ulcer Follow-up: range 13 days to 6 months	Study population		RR 0.42 (0.18 to 0.96)	229 (4 RCTs)	⊕⊕⊖⊖ Low[a,b]	Reactive air surfaces may reduce the proportion of participants developing new pressure ulcers compared with foam surfaces.
	276 per 1,000	116 per 1,000 (50 to 265)				
Time to pressure ulcer incidence	Included studies did not report this outcome.					
Support surface associated patient comfort	Allman 1987 reported this outcome in which participants were asked to choose a response to a com-		-	72	⊕⊖⊖⊖ Very low[c,d]	It is uncertain if there is a difference in patient comfort re-

Follow-up: 13 days	fort-related question from categories: 'Very comfortable', 'Comfortable', 'Uncomfortable', or 'Very uncomfortable'. More people using reactive air surfaces may have responded that they were comfortable or very comfortable than those using foam surfaces on top of an alternating pressure (active) air surfaces (P = 0.04).		(1 RCT)		sponses between reactive air surfaces and foam surfaces on top of an alternating pressure (active) air surfaces.
All reported adverse events Follow-up: 13 days	Only Allman 1987 (72 participants) reported this outcome (see Table 1).	-	72 (1 RCT)	⊕⊖⊖⊖ Very low[c,d]	It is uncertain if there is a difference in adverse event rates between reactive air surfaces and foam surfaces.
Health-related quality of life	Included studies did not report this outcome.				
Cost-effectiveness	Included studies did not report this outcome.				

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

__CI:__ Confidence interval; __RR:__ Risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded once for risk of bias (1 study contributing 8% weight in the meta-analysis had domains other than performance bias at high risk of bias and all the remaining studies had domains other than performance bias at low or unclear risk of bias).
[b]Downgraded once for imprecision as, despite the fact that the optimal information size was met, the 95% CI crossed RR = 0.75.
[c]Downgraded once for unclear risk of bias.
[d]Downgraded twice for imprecision due to the small sample size.

Summary of findings 3. Reactive air surfaces compared with reactive water surfaces for pressure ulcer prevention

Reactive air surfaces compared with reactive water surfaces for pressure ulcer prevention

Patient or population: pressure ulcer prevention
Setting: intensive care unit
Intervention: reactive air surfaces

Comparison: reactive water surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with reactive water surfaces	Risk with reactive air surfaces				
Proportion of participants developing a new pressure ulcer Follow-up: 9.5 days	Study population 118 per 1,000	51 per 1,000 (5 to 505)	RR 0.43 (0.04 to 4.29)	37 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	It is uncertain if there is a difference in the proportion of participants developing a new ulcer between reactive air surfaces and reactive water surfaces.
Time to pressure ulcer incidence	The included study did not report this outcome.					
Support surface associated patient comfort Follow-up: 13 days	The included study did not report this outcome.					
All reported adverse events Follow-up: 13 days	The included study did not report this outcome.					
Health-related quality of life	The included study did not report this outcome.					
Cost-effectiveness	The included study did not report this outcome.					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

[a]Downgraded once for unclear overall risk of bias.
[b]Downgraded twice for substantial imprecision because the OIS was not met and the confidence interval was very wide and crossed RRs = 0.75 and 1.25.

Summary of findings 4. Reactive air surfaces compared with reactive gel surfaces for pressure ulcer prevention

Reactive air surfaces compared with reactive gel surfaces for pressure ulcer prevention

Patient or population: pressure ulcer prevention
Setting: nursing home
Intervention: reactive air surfaces
Comparison: reactive gel surfaces

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with reactive gel surfaces	Risk with reactive air surfaces				
Proportion of participants developing a new pressure ulcer Follow-up: 6 months	Study population 242 per 1,000	302 per 1,000 (136 to 670)	RR 1.25 (0.56 to 2.77)	66 (1 RCT)	⊕⊖⊖⊖ Very low[a,b]	It is uncertain if there is a difference in the proportion of participants developing a new ulcer between reactive air surfaces and reactive gel surfaces.
Time to pressure ulcer incidence	The included study did not report this outcome.					
Support surface associated patient comfort Follow-up: 13 days	The included study did not report this outcome.					
All reported adverse events Follow-up: 13 days	The included study did not report this outcome.					
Health-related quality of life	The included study did not report this outcome.					
Cost-effectiveness	The included study did not report this outcome.					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited; the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate; the true effect is likely to be substantially different from the estimate of effect.

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[a]Downgraded once for unclear overall risk of bias.
[b]Downgraded twice for imprecision because the OIS was not met and the confidence interval was very wide and crossed RRs = 0.75 and 1.25.

BACKGROUND

Description of the condition

Pressure ulcers — also known as pressure injuries, pressure sores, decubitus ulcers and bed sores — are localised injuries to the skin or underlying soft tissue (or both) caused by unrelieved pressure, shear or friction (NPIAP 2016). Pressure ulcer severity is generally classified as follows, using the National Pressure Injury Advisory Panel (NPIAP) system (NPIAP 2016).

- Stage 1: intact skin with a local appearance of non-blanchable erythema
- Stage 2: partial-thickness skin loss with exposed dermis
- Stage 3: full-thickness skin loss
- Stage 4: full-thickness skin and tissue loss with visible fascia, muscle, tendon, ligament, cartilage or bone
- Unstageable pressure injury: full-thickness skin and tissue loss that is obscured by slough or eschar so that the severity of injury cannot be confirmed
- Deep tissue pressure injury: local injury of persistent, non-blanchable deep red, maroon, purple discolouration or epidermal separation revealing a dark wound bed or blood-filled blister

The stages described above are consistent with those described in another commonly used system, the International Classification of Diseases for Mortality and Morbidity Statistics (World Health Organization 2019).

Pressure ulcers are complex wounds that are relatively common, affecting people across different care settings. A systematic review found that prevalence estimates for people affected by pressure ulcers in communities of the UK, USA, Ireland and Sweden ranged from 5.6 to 2300 per 10,000 depending on the nature of the population surveyed (Cullum 2016). A subsequent cross-sectional survey of people receiving community health services in one city in the UK estimated that 1.8 people per 10,000 have a pressure ulcer (Gray 2018).

Pressure ulcers confer a heavy burden in terms of personal impact and use of health-service resources. Having a pressure ulcer may impair physical, social and psychological activities (Gorecki 2009). Ulceration impairs health-related quality of life (Essex 2009); can result in longer institution stays (Theisen 2012); and increases the risk of systemic infection (Espejo 2018). There is also substantial impact on health systems: a 2015 systematic review of 14 studies across a range of care settings in Europe and North America showed that costs related to pressure ulcer treatment ranged between EUR 1.71 and EUR 470.49 per person, per day (Demarré 2015). In the UK, the annual average cost to the National Health Service for managing one person with a pressure ulcer in the community was estimated to be GBP 1400 for a Stage 1 pressure ulcer and more than GBP 8500 for more severe stages (2015/2016 prices; Guest 2018). In Australia, the annual cost of treating pressure ulcers was estimated to be AUD 983 million (95% confidence interval (CI) 815 million to 1151 million) at 2012/2013 prices (Nguyen 2015). The serious consequences of pressure ulceration have led to an intensive focus on their prevention.

Description of the intervention

Pressure ulcers are considered largely preventable. Support surfaces are specialised medical devices designed to relieve or redistribute pressure on the body, or both, in order to prevent pressure ulcers (NPIAP S3I 2007). Types of support surface include, but are not limited to, integrated bed systems, mattresses and overlays (NPIAP S3I 2007).

The NPIAP Support Surface Standards Initiative (S3I) system can be used to classify types of support surface (NPIAP S3I 2007). According to this system support surfaces may:

- be powered (i.e. require electrical power to function) or non-powered;
- passively redistribute body weight (i.e. reactive pressure redistribution), or mechanically alternate the pressure on the body to reduce the duration of pressure (i.e. active pressure redistribution);
- be made of a range of materials, including but not limited to: air cells, foam materials, fibre materials, gel materials, sheepskin for medical use and water-bags;
- be constructed of air-filled cells that have small holes on the surface for blowing out air to dry skin (i.e. low air-loss feature) or have fluid-like characteristics via forcing filtered air through ceramic beads (i.e. air-fluidised feature), or have neither of these features.

Full details of classifications of support surfaces are listed in Appendix 1. A widely used type of support surface is the reactive air bed or mattress (traditionally termed static air-filled bed or mattress). These beds or mattresses are made of air cells that remain constantly inflated with or without using electrically powered pumps (i.e. being static rather than dynamic) (Clark 2011 ; NPIAP S3I 2007). Reactive air beds or mattresses can have low-air-loss features designed to influence the microclimate environment by keeping the skin dry (since moisture is thought to potentially increase friction on skin and increase the risk of skin damage) (Clark 2011 ; Wounds International 2010). Some reactive air mattresses can have air-fluidised features.

Types of reactive air beds or mattresses include: powered or non-powered reactive air mattresses (e.g. Repose static air mattress); powered or non-powered reactive low-air-loss mattresses (e.g. Low Air Loss mattress); and powered or non-powered reactive air-fluidised air mattresses (e.g. Clinitron air-fluidised bed) (Shi 2018a).

How the intervention might work

The aim of using support surfaces to prevent pressure ulceration is to redistribute pressure beneath the body, thereby increasing blood flow to tissues and relieving the distortion of skin and soft tissue (Wounds International 2010). Reactive support surfaces achieve pressure redistribution by passive mechanisms, including immersion (i.e. 'sinking' of the body into a support surface) and envelopment (i.e. conforming of a support surface to the irregularities in the body). These devices distribute the pressure over a greater area, thereby reducing the magnitude of the pressure at specific sites (Clark 2011).

Why it is important to do this review

Support surfaces are widely used for preventing pressure ulcers, and are the focus of recommendations in international and

national guidelines (EPUAP/NPIAP/PPPIA 2019 ; NICE 2014). Since the publication of the Cochrane Review, 'Support surfaces for pressure ulcer prevention' (McInnes 2015), there has been a substantial increase in the number of relevant randomised controlled trials published in this area. The NPIAP S3I 2007 support surface-related terms and definitions have also been internationally recognised, and Cochrane has developed new methodological requirements, such as the use of GRADE assessments (Guyatt 2008). These developments necessitate an update of the evidence base.

In considering this evidence update, we took into account the size and complexity of the previously published review (McInnes 2015), which includes all types of support surface. An alternative approach is to split the original review into multiple new titles, each with a narrower focus. We consulted on this splitting option via an international survey in August 2019. The potential new titles suggested were based on clinical use, the new terms and definitions related to support surfaces (NPIAP S3I 2007), a relevant network meta-analysis (Shi 2018a), and current clinical practice guidelines (EPUAP/NPIAP/PPPIA 2019; NICE 2014). We received responses from 29 health professionals involved in pressure ulcer prevention activity in several countries (Australia, Belgium, China, Italy, the Netherlands and the UK). In total, 83% of respondents supported splitting the review into suggested titles and 17% were unsure (no respondent voted against splitting). The new review titles are as follows:

- alternating pressure (active) air surfaces for preventing pressure ulcers
- foam surfaces for preventing pressure ulcers
- reactive air surfaces for preventing pressure ulcers
- alternative reactive support surfaces (non-foam and non-air-filled) for preventing pressure ulcers

We bring the results of these new reviews together in an overview with a network meta-analysis (Salanti 2012), in order to simultaneously compare all support surfaces and to rank them based on the probabilities of each being the most effective for preventing pressure ulcers (Shi 2021).

This particular review compares reactive air beds, mattresses or overlays with any surface.

OBJECTIVES

To assess the effects of reactive air beds, mattresses or overlays compared with any support surface on the incidence of pressure ulcers in any population in any setting.

METHODS

Criteria for considering studies for this review

Types of studies

We included published and unpublished randomised controlled trials (RCTs), including multi-armed studies, cluster-RCTs and cross-over trials, regardless of the language of publication. We excluded studies using quasi-random allocation methods (e.g. alternation).

Types of participants

We included studies in any population, including those defined as being at risk of ulceration, as well as those with existing pressure ulcers at baseline (when the study measured pressure ulcer incidence).

Types of interventions

This review focused on reactive air beds or mattresses in general. Eligible studies included a specific bed, overlay or mattress with reactive or static pressure redistribution capabilities. These included, but were not limited to, specific reactive air mattresses identified in Shi 2018a; namely:

- powered or non-powered reactive air mattresses (e.g. Sofflex static air mattress); or
- powered or non-powered reactive low-air-loss mattresses (e.g. low-air-loss Hydrotherapy); or
- powered or non-powered reactive air-fluidised mattresses (e.g. Clinitron air-fluidised bed).

We included studies where two or more support surfaces were used sequentially over time or in combination, where the support surface(s) of interest were included in one of the study arms.

We included studies comparing eligible reactive air beds, overlays or mattresses against any comparator defined as a support surface. Comparators could be:

- non-reactive air surfaces, including: alternating pressure (active) air surfaces such as alternating pressure (or dynamic) air mattresses, foam mattresses, and non-foam and non-air-filled surfaces (e.g. reactive gel surfaces such as a gel pad used on an operating table, reactive fibre surfaces such as Silicore fibre overlay, reactive water surfaces, reactive sheepskin surfaces such as Australian Medical Sheepskins overlay), or
- a different type of reactive air surface.

We included studies in which co-interventions (e.g. repositioning) were delivered, provided that the co-interventions were the same in all arms of the study (i.e. interventions randomised were the only systematic difference).

Types of outcome measures

We considered the primary and secondary outcomes described below. If a study did not report any review-relevant outcomes but was otherwise eligible (i.e. eligible study design, participants and interventions), we contacted the study authors (where possible) to clarify whether they had measured a relevant outcome but did not report it. We considered the study as 'awaiting classification' if we could not establish whether it measured an outcome or not. We excluded the study if the study authors confirmed that they did not measure any review-relevant outcomes.

If a study measured an outcome at multiple time points, we considered the outcome measures at three months to be the primary endpoint for this review (Schoonhoven 2007), regardless of the time points specified as being of primary interest by the study. If the study did not report three-month outcome measures, we considered those closest to three months. Where a study only reported a single time point, we included this in this review. Where

the study did not specify a time point for outcome measurement, we assumed this was the final duration of follow-up noted.

Primary outcomes

Our primary outcome was pressure ulcer incidence. We recorded two outcome measures (the proportion of participants developing a new pressure ulcer; and time to pressure ulcer incidence), where available. We considered the proportion of participants developing a new pressure ulcer as the primary outcome for this review. Our preferred measure was time to pressure ulcer incidence; however, we did not expect it to be reported in many studies. We extracted and analysed time-to-event data but focused on the binary outcome in our conclusions. We accepted the study authors' definitions of an incident ulcer regardless of which pressure ulcer severity classification system was used to measure or grade new pressure ulcers. We also considered the outcome of pressure ulcer incidence irrespective of whether studies reported ulcers by stages or as a non-stratified value.

We did not consider subjective outcome measures (e.g. 'better' or 'worse' skin condition) as measures of pressure ulcer incidence.

Secondary outcomes

- **Support-surface-associated patient comfort.** We considered patient comfort outcome data in this review only if the evaluation of patient comfort was pre-planned and was systematically conducted across all participants in the same way in a study. The definition and measurement of this outcome varied from one study to another; for example, the proportion of participants who report comfort, or comfort measured by a scale with continuous (categorical) numbers. We planned to include these data with different measurements in separate meta-analyses when possible.
- **All reported adverse events** (measured using surveys or questionnaires, other data capture process or visual analogue scale). We included data where study authors specified a clear method for collecting adverse event data. Where available, we extracted data on all serious and all non-serious adverse events as an outcome. We recorded where it was clear that events were reported at the participant level or whether multiple events per person were reported, in which case appropriate adjustments were required for data clustering (Peryer 2019). We considered the assessment of any event in general defined as adverse by participants, health professionals, or both.
- **Health-related quality of life** (measured using a standardised generic questionnaire such as EQ-5D (Herdman 2011), 36-item Short Form (SF-36; Ware 1992), or pressure ulcer-specific questionnaires such as the PURPOSE Pressure Ulcer Quality of Life (PU-QOL) questionnaire (Gorecki 2013), at noted time points). We did not include ad hoc measures of quality of life or qualitative interviews of quality of life because these measures were unlikely to be validated.
- **Cost-effectiveness:** within-trial cost-effectiveness analysis comparing mean differences in effects with mean cost differences between the two arms. We extracted data on incremental mean cost per incremental gain in benefit (incremental cost-effectiveness ratio (ICER)). We also considered other measures of relative cost-effectiveness (e.g. net monetary benefit, net health benefit).

Search methods for identification of studies

Electronic searches

We searched the following electronic databases to identify reports of relevant clinical trials:

- the Cochrane Wounds Specialised Register (searched 14 November 2019);
- the Cochrane Central Register of Controlled Trials (CENTRAL; 2019, Issue 10) in the Cochrane Library (searched 14 November 2019);
- Ovid MEDLINE including In-Process & Other Non-Indexed Citations (1946 to 14 November 2019);
- Ovid Embase (1974 to 14 November 2019);
- EBSCO CINAHL Plus (Cumulative Index to Nursing and Allied Health Literature; 1937 to 14 November 2019).

The search strategies for the Cochrane Wounds Specialised Register, CENTRAL, Ovid MEDLINE, Ovid Embase and EBSCO CINAHL Plus can be found in Appendix 2. We combined the Ovid MEDLINE search with the Cochrane Highly Sensitive Search Strategy for identifying randomised trials in MEDLINE: sensitivity- and precision-maximising version (2008 revision) (Lefebvre 2019). We combined the Embase search with the Ovid Embase filter developed by the UK Cochrane Centre (Lefebvre 2019). We combined the CINAHL Plus search with the trial filter developed by (Glanville 2019). There were no restrictions with respect to language, date of publication or study setting.

We also searched the following clinical trials registries:

- US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (clinicaltrials.gov) (searched 20 November 2019);
- World Health Organization (WHO) International Clinical Trials Registry Platform (https://www.who.int/clinical-trials-registry-platform) (searched 20 November 2019).

Search strategies for clinical trials registries can be found in Appendix 2.

Searching other resources

For previous versions of McInnes 2015, the review authors of McInnes 2015 contacted experts in the field of wound care to enquire about potentially relevant studies that are ongoing or recently published. In addition, the review authors of McInnes 2015 contacted manufacturers of support surfaces for details of any studies manufacturers were conducting. This approach did not yield any additional studies; therefore, we did not repeat it for this review.

We identified other potentially eligible studies or ancillary publications by searching the reference lists of retrieved included studies, as well as relevant systematic reviews, meta-analyses and health technology assessment reports.

When necessary, we contacted authors of key papers and abstracts to request further information about their trials.

We did not perform a separate search for adverse effects of interventions used. We considered adverse effects described in included studies only.

Data collection and analysis

We carried out data collection and analysis according to the methods stated in the published protocol (Shi 2020), which were based on the *Cochrane Handbook for Systematic Reviews of Interventions* (Li 2019). Changes from the protocol or previous published versions of the review are documented in Differences between protocol and review.

Selection of studies

One review author re-checked the RCTs included in McInnes 2015 for eligibility (CS). Two review authors or researchers (CS and Asmara Jammali-Blasi, or JCD) independently assessed the titles and abstracts of the new search results for relevance using Rayyan (Ouzzani 2016) (Differences between protocol and review), and then independently inspected the full text of all potentially eligible studies. The two review authors or researchers (CS and Asmara Jammali-Blasi, or JCD) resolved any disagreements through discussion or by involving another review author if necessary.

Data extraction and management

One review author checked data from the studies included in McInnes 2015 and extracted additional data where necessary (CS). A second review author or researcher checked any new data extracted (SR, VL, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens). For new included studies, one review author (CS) independently extracted data and another review author or researcher checked all data (SR, VL, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) (Differences between protocol and review). Any disagreements were resolved through discussion and, if necessary, with the involvement another review author. Where necessary, we contacted the authors of included studies to clarify data.

We extracted these data using a pre-prepared data extraction form:

- basic characteristics of studies (first author, publication type, publication year and country);
- funding sources;
- care setting;
- characteristics of participants (trial eligibility criteria, average age in each arm or in a study, proportions of participants by gender and participants' baseline skin status);
- support surfaces being compared (including their descriptions);
- details on any co-interventions;
- duration of follow-up;
- the number of participants enrolled;
- the number of participants randomised to each arm;
- the number of participants analysed;
- participant withdrawals with reasons;
- the number of participants developing new ulcers (by ulcer stages where possible);
- data on time to pressure ulceration;
- support-surface-associated patient comfort;
- adverse event outcome data;
- health-related quality of life outcome data; and
- cost-effectiveness outcome data.

We (CS and NC) classified specific support surfaces in the included studies into intervention groups using the NPIAP S3I support surface-related terms and definitions (NPIAP S3I 2007). Therefore, to accurately assign specific support surfaces to intervention groups, we extracted full descriptions of support surfaces from included studies, and when necessary supplemented the information with that from external sources such as other publications about the same support surface, manufacturers' or product websites and expert clinical opinion (Shi 2018b). If we were unable to define any of the specific support surfaces evaluated in an included study, we extracted available data and reported these as additional data outside the main review results.

Assessment of risk of bias in included studies

Two review authors or researchers (CS and SR, VL, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) independently assessed risk of bias of each included study using the Cochrane 'Risk of bias' tool (see Appendix 3). This tool has seven specific domains: sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete data (attrition bias), selective outcome reporting (reporting bias), and other issues (Higgins 2017). We assessed performance bias, detection bias and attrition bias separately for each of the review outcomes (Higgins 2017). We noted that it is often impossible to blind participants and personnel in device trials. In this case, performance bias may be introduced if knowledge of treatment allocation results in deviations from intended interventions, differential use of co-interventions or care between groups not specified in the study protocol that may influence outcomes. We attempted to understand if, and how, included studies compensated for challenges in blinding; for example, implementing strict protocols to maximise consistency of co-interventions between groups to reduce the risk of performance bias. We also noted that pressure ulcer incidence is a subjective outcome. Compared with blinded assessment, non-blinded assessment of subjective outcomes tends to be associated with more optimistic effect estimates of experimental interventions in RCTs (Hróbjartsson 2012). Therefore, we judged non-blinded outcome assessment as being at high risk of detection bias. In this review, we included the issues of differential diagnostic activity and unit of analysis under the domain of 'other issues'. For example, unit of analysis issues occurred where a cluster-randomised trial had been undertaken but analysed at the individual level in the study report.

For the studies included in McInnes 2015, one review author (CS) checked the 'Risk of bias' judgements and, where necessary, updated them. A second review author or researcher (SR, VL, EM, Zhenmi Liu, Gill Norman, or Melanie Stephens) checked any updated judgement. We assigned each 'Risk of bias' domain a judgement of high, low, or unclear risk of bias. We resolved any discrepancy through discussion and by involving another review author where necessary. Where possible, useful and feasible, when a lack of reported information resulted in a judgement of unclear risk of bias, we planned to contact study authors for clarification.

We present our assessment of risk of bias for the proportion of participants developing a new pressure ulcer outcome using two 'Risk of bias' summary figures. One is a summary of bias for each item across all studies, and the second shows a cross-tabulation of each study by all of the 'Risk of bias' items.

Once we had given our judgements for all 'Risk of bias' domains, we judged the overall risk of bias for each outcome across studies as:

- low risk of bias, if we judged all domains to be at low risk of bias;
- unclear risk of bias, if we judged one or more domains to be at unclear risk of bias and other domains were at low risk of bias but no domain was at high risk of bias; or
- high risk of bias, as long as we judged one or more domains as being at high risk of bias, or all domains had unclear 'Risk of bias' judgements, as this could substantially reduce confidence in the result.

We resolved any discrepancy between review authors through discussion and by involving another review author where necessary. For studies using cluster randomisation, we planned to consider the risk of bias in relation to recruitment bias, baseline imbalance, loss of clusters, incorrect analysis and comparability with individually randomised studies (Eldridge 2019; Higgins 2019; Appendix 3). However, we did not include any studies with a cluster design.

Measures of treatment effect

For meta-analysis of pressure ulcer incidence data, we present the risk ratio (RR) with its 95% confidence interval (CI). For continuous outcome data, we present the mean difference (MD) with 95% CIs for studies that use the same assessment scale. If studies reporting continuous data used different assessment scales, we planned to report the standardised mean difference (SMD) with 95% CIs. However, this was not undertaken in the review.

For time-to-event data (time to pressure ulcer incidence), we present the hazard ratio (HR) with its 95% CI. If included studies reporting time-to-event data did not report an HR, when feasible, we estimated this using other reported outcomes (such as numbers of events) through employing available statistical methods (Parmar 1998; Tierney 2007).

Unit of analysis issues

We noted whether studies presented outcomes at the level of cluster (e.g. ward, research site) or at the level of participants. We also recorded whether the same participant was reported as having multiple pressure ulcers.

Unit of analysis issues may occur if studies randomise at the cluster level but the incidence of pressure ulcers is observed and data are presented and analysed at the level of participants (clustered data). We noted whether data regarding participants within a cluster were (incorrectly) treated as independent within a study, or were analysed using within-cluster analysis methods. If clustered data were incorrectly analysed, we recorded this as part of the 'Risk of bias' assessment.

If a cluster-RCT was not correctly analysed, we planned to use the following information to adjust for clustering ourselves where possible, in accordance with guidance in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2019).

- The number of clusters randomly assigned to each intervention, or the average (mean) number of participants per cluster.
- Outcome data ignoring the cluster design for the total number of participants.
- Estimate of the intra-cluster (or intra-class) correlation coefficient (ICC).

However, we did not identify any cluster-RCTs in this review.

Cross-over trials

For cross-over trials, we only considered outcome data at the first intervention phase (i.e. prior to cross-over) as eligible.

Studies with multiple treatment groups

If a study had more than two eligible study groups, where appropriate, we combined results across these arms to make single pair-wise comparisons (Higgins 2019).

Dealing with missing data

Data are commonly missing from study reports. Reasons for missing data could be the exclusion of participants after randomisation, withdrawal of participants from a study, or loss to follow-up. The exclusion of these data from analysis may break the randomisation and potentially introduces bias.

Where there were missing data, and where relevant, we contacted study authors to pose specific queries about these data. In the absence of other information, for pressure ulcer incidence we assumed that participants with missing data did not develop new pressure ulcers for the main analysis (i.e. we added missing data to the denominator but not the numerator). We examined the impact of this assumption through undertaking a sensitivity analysis (see Sensitivity analysis). When a study did not specify the number of randomised participants prior to dropout, we used the available number of participants as the number randomised.

Assessment of heterogeneity

Assessing heterogeneity can be a complex, multifaceted process. Firstly, we considered clinical and methodological heterogeneity; that is, the extent to which the included studies varied in terms of participant, intervention, outcome, and other characteristics including duration of follow-up, clinical settings, and overall study-level 'Risk of bias' judgement (Deeks 2019). In terms of the duration of follow-up, in order to assess the relevant heterogeneity, we recorded and categorised assessment of outcome measures as follows:

- up to eight weeks (short-term);
- more than eight weeks to 16 weeks (medium-term); and
- more than 16 weeks (long-term).

We supplemented this assessment of clinical and methodological heterogeneity with information regarding statistical heterogeneity assessed using the Chi^2 test. We considered a P value of less than 0.10 to indicate statistically significant heterogeneity given that the Chi^2 test has low power, particularly in the case where studies included in a meta-analysis have small sample sizes. We carried out this statistical assessment in conjunction with the I^2 statistic (Higgins 2003), and the use of prediction intervals for random-effects meta-analyses (Borenstein 2017; Riley 2011).

The I^2 statistic is the percentage of total variation across studies due to heterogeneity rather than chance (Higgins 2003). Very broadly, we considered that I^2 values of 25% or less may indicate a low level of heterogeneity and values of 75% or more may indicate very high

heterogeneity (Higgins 2003). For random-effects models where the meta-analysis had more than 10 included studies and no clear funnel plot asymmetry, we also planned to present 95% prediction intervals (Deeks 2019). We planned to calculate prediction intervals following methods proposed by Borenstein 2017.

Random-effects analyses produce an average treatment effect, with 95% confidence intervals indicating where the true population average value is likely to lie. Prediction intervals quantify variation away from this average due to between-study heterogeneity. The interval conveys where a future study treatment effect estimate is likely to fall based on the data analysed to date (Riley 2011). Prediction intervals are always wider than confidence intervals (Riley 2011).

It is important to note that prediction intervals reflect heterogeneity of any source, including from methodological issues as well as clinical variation. For this reason some authors have suggested that prediction intervals are best calculated for studies at low risk of bias to ensure intervals that have meaningful clinical interpretation (Riley 2011). We had planned to calculate prediction intervals for all analyses to assess heterogeneity and then to explore the impact of risk of bias in subgroup analysis stratified by study risk of bias assessment as detailed below. However, we did not calculate any prediction interval because all conducted meta-analyses contained fewer than 10 studies.

Assessment of reporting biases

We followed the systematic framework recommended by Page 2019 to assess risk of bias due to missing results (non-reporting bias) in the meta-analysis of pressure ulcer incidence data. To make an overall judgement about risk of bias due to missing results, we did the following.

- Identified whether pressure ulcer incidence data were unavailable by comparing the details of outcomes in trials registers, protocols or statistical analysis plans (if available) with reported results. If the above information sources were unavailable, we compared outcomes in the conference abstracts or in the methods section of the publication, or both, with the reported results. If we found non-reporting of study results, we then judged whether the non-reporting was associated with the nature of findings by using the 'Outcome Reporting Bias In Trials' (ORBIT) system (Kirkham 2018).
- Assessed the influence of definitely missing pressure ulcer incidence data on meta-analysis.
- Assessed the likelihood of bias where a study had been conducted but not reported in any form. For this assessment, we considered whether the literature search was comprehensive and planned to produce a funnel plot for meta-analysis for seeking more evidence about the extent of missing results, provided there were at least 10 included studies (Peters 2008; Salanti 2014).

However, we did not produce a funnel plot for any meta-analysis because all analyses in this review had fewer than 10 included studies.

Data synthesis

We summarised the included studies narratively and synthesised included data by using meta-analysis where applicable. We structured comparisons according to type of comparator and then by outcomes, ordered by follow-up period.

We considered clinical and methodological heterogeneity and undertook pooling when studies appeared appropriately similar in terms of participants, support surfaces, and outcome type. Where statistical synthesis of data from more than one study was not possible or considered inappropriate, we conducted a narrative review of eligible studies.

Once the decision to pool was made, we used a random-effects model, which estimated an underlying average treatment effect from studies. Conducting meta-analysis with a fixed-effect model in the presence of even minor heterogeneity may provide overly narrow confidence intervals. We used the Chi^2 test and I^2 statistic to quantify heterogeneity but not to guide choice of model for meta-analysis (Borenstein 2009). We exercised caution when meta-analysed data were at risk of small-study effects because use of a random-effects model may be unsuitable in this situation. In this case, or where there were other reasons to question the choice of a fixed-effect or random-effects model, we assessed the impact of the approach using sensitivity analyses to compare results from alternate models (Thompson 1999).

We performed meta-analyses largely using Review Manager 5.4 (Review Manager 2020). We presented data using forest plots where possible. For dichotomous outcomes, we presented the summary estimate as a RR with 95% CIs. Where continuous outcomes were measured, we presented the MD with 95% CIs; we planned to report SMD estimates where studies measured the same outcome using different methods. For time-to-event data, we presented the summary estimates as HRs with 95% CIs.

Subgroup analysis and investigation of heterogeneity

Investigation of heterogeneity

When important heterogeneity occurred, we planned to follow these steps, proposed by Cipriani 2013 and Deeks 2019, to investigate further:

- check the data extraction and data entry for errors and possible outlying studies;
- if outliers existed, perform sensitivity analysis by removing them; and
- if heterogeneity was still present, we planned to perform subgroup analyses for study-level characteristics (see below) in order to explain heterogeneity as far as possible. However, we did not undertake any subgroup analysis because meta-analyses in this review included fewer than 10 studies.

Subgroup analysis

We investigated heterogeneity using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2019). We planned to perform subgroup analyses for binary and categorical factors (or meta-regression for continuous factors) to determine whether the size of treatment effects was influenced by these four study-level characteristics:

- risk of bias (binary: low or unclear risk of bias; and high risk of bias (Schulz 1995));

- settings (categorical: acute care and other hospital settings; long-term care settings; operating theatre setting; and intensive care unit);
- baseline skin status (categorical: participants at risk, of mixed skin status or non-reporting; non-blanchable erythema; existing ulcers of Stage 2 or serious (Shi 2018c)); and
- follow-up duration (continuous).

We did not perform subgroup analysis or meta-regression when the number of studies included in the meta-analysis was not reasonable (i.e. fewer than 10).

We planned to compare subgroup findings using the 'Test for Subgroup Differences' in Review Manager 5.4 (Review Manager 2020).

Sensitivity analysis

We conducted sensitivity analyses for the following factors, to assess the robustness of meta-analysis of data on pressure ulcer incidence.

- Impact of the selection of pressure ulcer incidence outcome measure. The proportion of participants developing a new pressure ulcer was the primary outcome measure for this review but we also analysed time to pressure ulcer development, where data were available.
- Impact of missing data. The primary analysis assumed that participants with missing data did not develop new pressure ulcers. We also analysed pressure ulcer incidence by only including data for the participants for whom we had endpoint data (complete cases). We noted that when a study only had complete case data (i.e. missing data or the numbers of participants randomised were not reported), complete case data were considered in the related main analysis (Differences between protocol and review).
- Impact of altering the effects model used. We used a random-effects model for the main analysis followed by a fixed-effect analysis.

Summary of findings and assessment of the certainty of the evidence

We presented the main, pooled results of the review in 'Summary of findings' tables, which we created using GRADEpro GDT software. These tables present key information concerning the certainty of evidence, the magnitude of the effects of the interventions examined and the sum of available data for the main outcomes (Schünemann 2019). The tables also include an overall grading of the certainty of the evidence associated with each of the main outcomes that we assessed using the GRADE approach. The GRADE approach defines the certainty of a body of evidence as the extent to which one can be confident that an estimate of effect or association is close to the true quantity of specific interest.

The GRADE assessment involves consideration of five factors: within-trial risk of bias, directness of evidence, heterogeneity, precision of effect estimates, and risk of publication bias (Schünemann 2019). The certainty of evidence can be assessed as being high, moderate, low or very low; RCT evidence has the potential to be high-certainty. We did not downgrade the certainty of evidence for the risk of bias factor in a specific circumstance. That is, if the blinding of participants and personnel was the only domain resulting in our judgement of overall high risk of bias for the included studies; however for these studies it was impossible to blind participants and personnel.

When downgrading for imprecision, we followed the methods described in Guyatt 2011: either considering both the optimal information size (OIS) and the 95% CI of each meta-analysis if they were estimable; or considering the sample size, the number of events and other effectiveness indicators if the calculation of OIS and undertaking a meta-analysis were not applicable. Where necessary, we used the GRADE 'default' minimum important difference values (RR = 1.25 and 0.75) as the thresholds to judge if a 95% CI was wide (imprecise) so as to include the possibility of clinically important harm and benefit (Guyatt 2011).

We presented a separate 'Summary of findings' table for all but one comparison evaluated in this review. The exception was the comparison of reactive air surfaces versus another type of reactive air surface (Differences between protocol and review). We presented these outcomes in the 'Summary of findings' tables:

- proportion of participants developing a new pressure ulcer;
- time to pressure ulcer incidence;
- support-surface-associated patient comfort;
- all reported adverse events;
- health-related quality of life; and
- cost-effectiveness.

We prioritised the time points and method of outcome measurement specified in Types of outcome measures for presentation in 'Summary of findings' tables. Where we did not pool data for some outcomes within a comparison, we conducted a GRADE assessment for each of these outcomes and presented these assessments in a narrative format in 'Summary of findings' tables (Differences between protocol and review).

RESULTS

Description of studies

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

Results of the search

The electronic searches identified 1624 records, including 1164 from electronic databases and 460 from trial registries. We excluded 218 duplicate records and screened 1406 records, of which 233 were identified as potentially eligible and obtained as full-text. Following full-text screening, we considered 18 records of 16 studies eligible for inclusion in this review (Beeckman 2019; Bennett 1998; Cavicchioli 2007; Cobb 1997; Cooper 1998; Finnegan 2008; Inman 1993; Jiang 2014; Lazzara 1991; Malbrain 2010; Price 1999; Sideranko 1992; Takala 1996; Van Leen 2011; Van Leen 2013; Vermette 2012).

From other resources, one further eligible study, Allman 1987, was identified by scanning the reference lists of the 14 systematic reviews or meta-analyses that were identified from electronic searches (Chou 2013; Huang 2013; McGinnis 2011; McInnes 2015; McInnes 2018; Mistiaen 2010a; De Oliveira 2017; Rae 2018; Reddy 2006; Reddy 2008; Serraes 2018; Shi 2018a; Smith 2013; Yao 2018),

as well as the clinical practice guidelines listed in Searching other resources.

In total, we included 17 studies (with 19 publications) in the review, of which one was an unpublished report (Cobb 1997). See Figure 1.

Figure 1. Study flow diagram

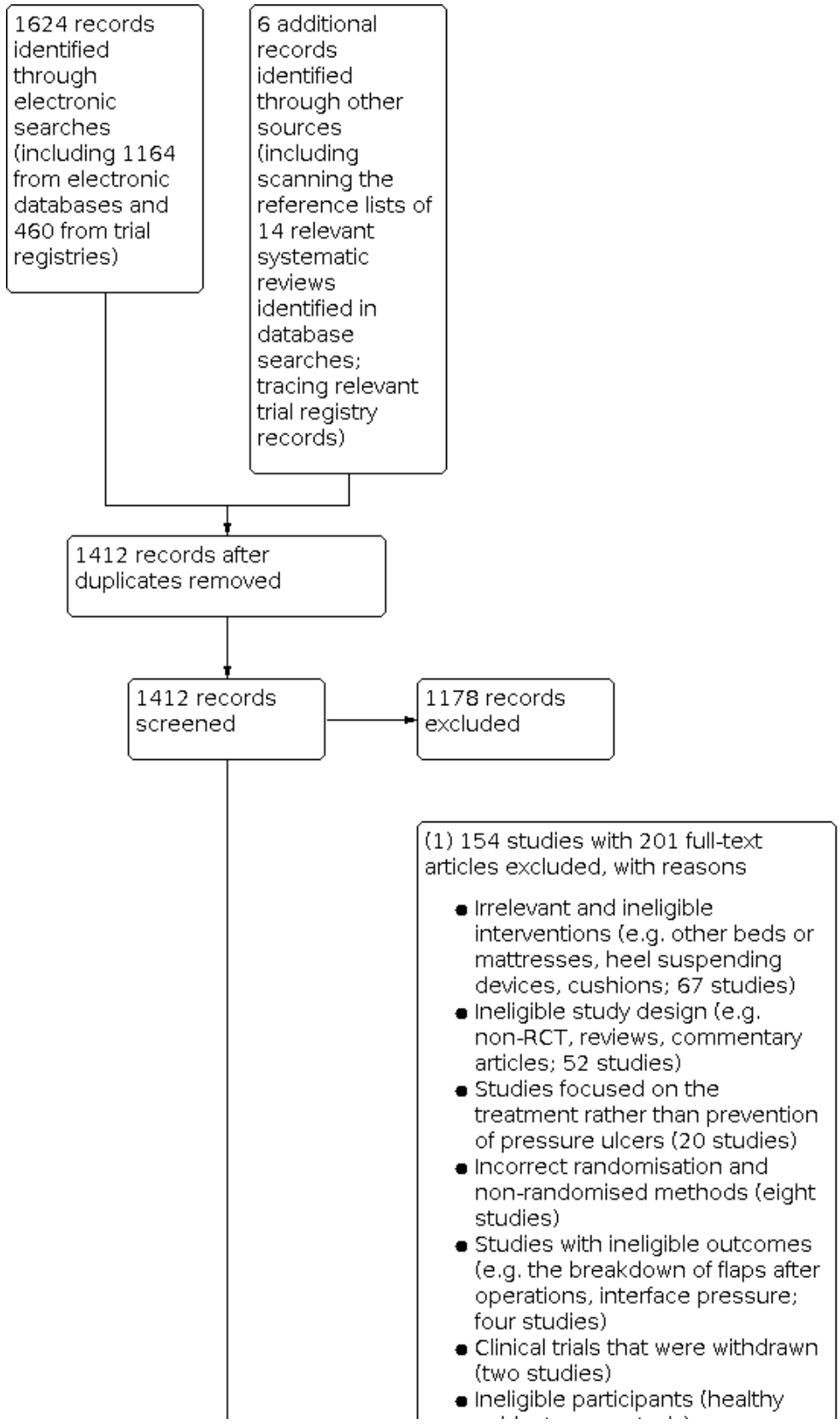
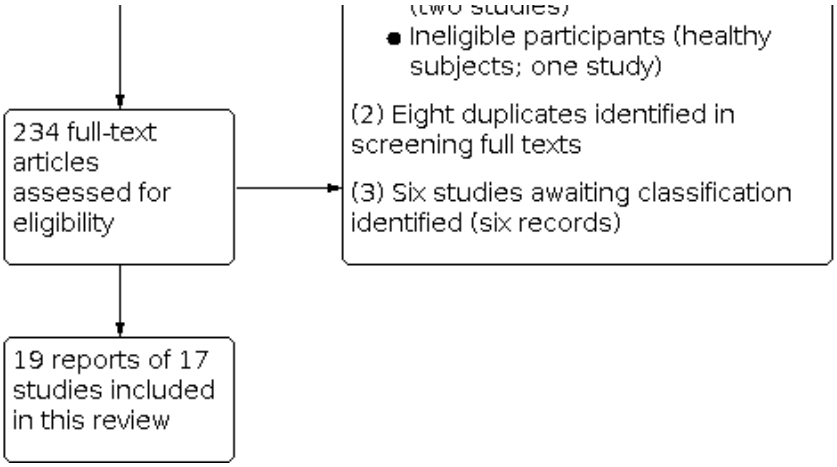


Figure 1. (Continued)



Included studies

Types of studies

Of the 17 included RCTs, 16 had a parallel group design; 15 with two arms, and one with three arms (Sideranko 1992). One study was a two-arm, cross-over design trial and we only considered data prior to cross-over in this review (Van Leen 2013).

Of the 17 studies, four were conducted at more than one research site (Beeckman 2019; Bennett 1998; Cavicchioli 2007; Jiang 2014). Except for one study conducted in China (Jiang 2014), all of the included studies were conducted in high-income and upper-middle-income economies in Europe and North America, including Belgium (Beeckman 2019; Malbrain 2010), Canada (Inman 1993; Vermette 2012), Finland (Takala 1996), Italy (Cavicchioli 2007), the Netherlands (Van Leen 2011; Van Leen 2013), the UK (Cooper 1998; Price 1999) and the USA (Allman 1987; Bennett 1998; Cobb 1997; Finnegan 2008; Lazzara 1991; Sideranko 1992).

Of the included studies, the median of the duration of follow-up was 14 days (range: five days to six months).

Types of participants

Age and sex at baseline

The 17 included studies enrolled a total of 2604 participants (median study sample size: 83 participants; range: 16 to 1074). The average participant age was specified for 16 studies and ranged between 56 and 87 years (median: 72 years). Bennett 1998 did not specify the average participant age but stated that all participants were more than 80 years old. The sex of the participants was specified for 2511 participants in the 17 studies: 1125 (44.8%) were male and 1386 (55.2%) were female.

Skin status at baseline

Of the 17 studies, 13 (2335 participants) recruited people at risk of having a new ulcer with risk assessed largely using the Waterlow, Norton or Braden scales. In 10 of the 13 studies, 2033 (87.1%) participants were free of pressure ulcers at baseline. In three studies, 302 (12.9%) participants with superficial ulcers were enrolled (Bennett 1998; Cavicchioli 2007; Malbrain 2010). In two studies, 112 participants with existing severe full-thickness pressure ulcers were enrolled (Allman 1987; Finnegan 2008). One study (100 participants; Inman 1993) did not specify the skin status at baseline, and the final included study (57 participants; Sideranko 1992) stated that all participants were free of ulcers at baseline.

Care settings

Participants were recruited from a variety of settings, including:

- a mixture of acute care and long-term care settings (two studies: Bennett 1998; Cavicchioli 2007);
- acute care settings (including accident and emergency departments, and hospitals in general) (seven studies: Allman 1987; Cobb 1997; Cooper 1998; Finnegan 2008; Jiang 2014; Price 1999; Vermette 2012);
- intensive care units (four studies: Inman 1993; Malbrain 2010; Sideranko 1992; Takala 1996); and
- community and long-term care settings (including nursing homes and geriatric units) (four studies: Beeckman 2019; Lazzara 1991; Van Leen 2011; Van Leen 2013).

Types of interventions

A wide range of reactive air surfaces was investigated, including: air-fluidised beds (Allman 1987; Finnegan 2008); Repose static air mattress (Beeckman 2019; Price 1999); Sofflex mattress (Cooper 1998); the continuous low pressure modality of Hill-Rom Duo2 (Cavicchioli 2007); EHOB WAFFLE static air mattress (Jiang 2014; Cobb 1997; Vermette 2012); ROHO dry flotation mattress overlay (Malbrain 2010; Cooper 1998); Gaymar SofCare air-filled overlay (Lazzara 1991; Sideranko 1992); low-air-loss hydrotherapy (Bennett 1998); KinAir air suspension bed (Inman 1993; Cobb 1997); Carital Optima constant low pressure air mattress (Takala 1996); and static air overlay applied on top of foam mattresses (Van Leen 2011; Van Leen 2013). Of these reactive air surfaces, low-air-loss hydrotherapy (Bennett 1998) and KinAir air suspension bed (Inman 1993; Cobb 1997) have a low-air-loss feature.

Full details of reactive air surfaces and comparators are listed in Effects of interventions below. Three studies (326 participants) used comparator group surfaces that we could not classify using the NPIAP S3I support surface terms and definitions: two (216 participants) termed their control surfaces as 'standard hospital surfaces' (Bennett 1998; Inman 1993) and one (110 participants) used alternating pressure (active) air surfaces for 5 of 55 control

participants and RIK® microfluid static overlay for the remaining 50 of 55 control participants (Vermette 2012).

Eleven studies specified the co-interventions they applied (e.g. repositioning, cushions) (Beeckman 2019; Bennett 1998; Cooper 1998; Finnegan 2008; Inman 1993; Jiang 2014; Malbrain 2010; Price 1999; Van Leen 2011; Van Leen 2013; Vermette 2012). All but one of these stated or indicated that the same co-interventions were applied in all study groups. However, Inman 1993 stated that two-hourly repositioning was applied in the standard hospital surface arm but did not specify if any co-intervention was applied in the reactive air surfaces arm.

Funding sources

Of the 17 studies, 12 specified the details of funding sources, including nine that were completely or partly funded by industry or received mattresses under evaluation from industries (Allman 1987; Beeckman 2019; Bennett 1998; Cooper 1998; Finnegan 2008; Inman 1993; Lazzara 1991; Price 1999; Takala 1996). Jiang 2014 was supported by public funding, and two studies noted no funding support (Van Leen 2011; Vermette 2012).

Excluded studies

We excluded 154 studies (with 201 records). The main reasons for exclusion were: irrelevant or ineligible interventions (67 studies); ineligible study design (e.g. non-RCT, reviews, commentary articles; 52 studies); studies focused on the treatment rather than prevention of pressure ulcers (20 studies); incorrect randomisation and non-randomised methods (eight studies); studies with ineligible outcomes (four studies); clinical trials that were withdrawn (two studies; NCT02634892; NCT02735135); and ineligible participants (healthy subjects; one study). We also identified eight duplicates in screening the full-texts (see Figure 1).

Ongoing studies

We did not identify any ongoing studies.

Studies awaiting classification

There were six studies (six records) for which we could not make eligibility decisions. In one case (Gardner 2008), we were unable to determine whether the study used foam surfaces. For the five remaining studies, we were unable to obtain the full-texts (in part due to more limited access to intra-library loans during the COVID-19 period) despite making extensive efforts (Chaloner 2000b; Henn 2004; Knight 1999; Mastrangelo 2010a; Melland 1998).

Risk of bias in included studies

We summarise 'Risk of bias' assessments for the primary outcome of this review in Figure 2 and Figure 3.

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

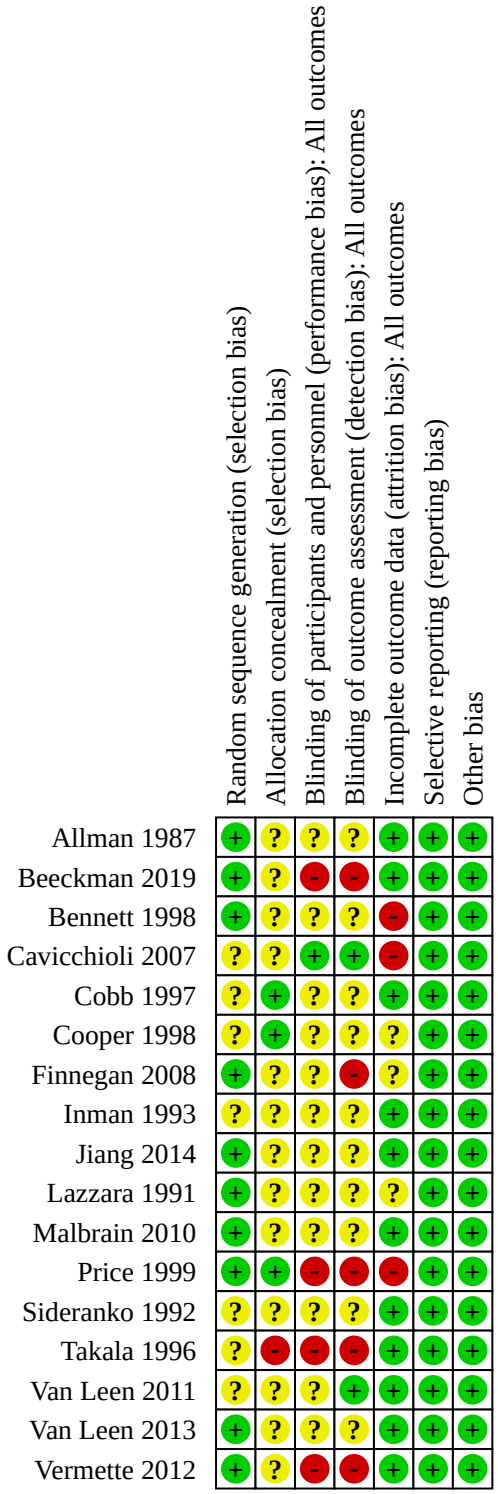
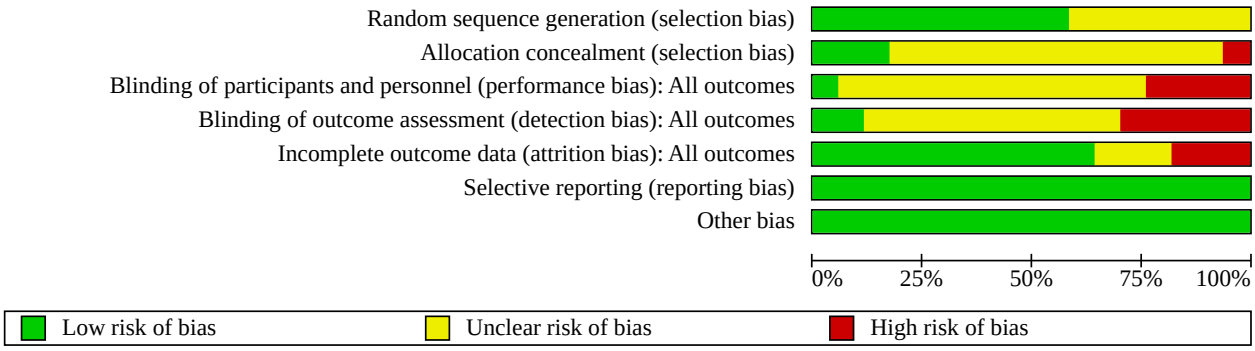


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



We judged 10 of the 17 studies to have an unclear overall risk of bias for the primary outcome (Allman 1987; Cobb 1997; Cooper 1998; Inman 1993; Jiang 2014; Lazzara 1991; Malbrain 2010; Sideranko 1992; Van Leen 2011; Van Leen 2013). We judged all remaining seven studies as having findings at high overall risk of bias, all having one or more domains with high risk of bias judgement (Beeckman 2019; Bennett 1998; Cavicchioli 2007; Finnegan 2008; Price 1999; Takala 1996; Vermette 2012). Of these seven studies, five had high risk of bias judgement for the primary outcome in the domains of blinding of participants and personnel, blinding of outcome assessment, or both (Beeckman 2019; Finnegan 2008; Price 1999; Takala 1996; Vermette 2012).

Publication bias

We ran a comprehensive search and considered the risk of having missed published reports to be low. We were able to locate one study from other resources and one unpublished report (Allman 1987 and Cobb 1997, respectively). We were unable to assess the risk of non-publication of studies with negative findings as we could not present funnel plots given the small number of included studies in each analysis.

Effects of interventions

See: **Summary of findings 1** Reactive air surfaces compared with alternating pressure (active) air surfaces for pressure ulcer prevention; **Summary of findings 2** Reactive air surfaces compared with foam surfaces for pressure ulcer prevention; **Summary of findings 3** Reactive air surfaces compared with reactive water surfaces for pressure ulcer prevention; **Summary of findings 4** Reactive air surfaces compared with reactive gel surfaces for pressure ulcer prevention

See Summary of findings 1; Summary of findings 2; Summary of findings 3; Summary of findings 4.

Unless otherwise stated, random-effects analysis was used throughout. Each pooled result presented is an average effect, rather than a common effect and should be interpreted as such.

We have not reported data from the three studies with comparator group surfaces that we could not classify in the main body of the results (Bennett 1998; Inman 1993; Vermette 2012). For completeness, we summarise the results of these studies in Appendix 4.

We performed data analyses for the following comparisons and outcomes. Where applicable, we performed pre-specified sensitivity analyses as noted in Sensitivity analysis.

Comparison 1: Reactive air surfaces versus alternating pressure (active) air surfaces (seven studies, 1728 participants)

Seven studies compared reactive air surfaces with alternating pressure (active) air surfaces (Beeckman 2019; Cavicchioli 2007; Finnegan 2008; Jiang 2014; Malbrain 2010; Price 1999; Sideranko 1992).

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration median 14 days, minimum 5 days, maximum 15 days)

Six studies (1648 participants) reported this outcome (Beeckman 2019; Cavicchioli 2007; Finnegan 2008; Jiang 2014; Malbrain 2010; Sideranko 1992) and their data were pooled. It is uncertain if there is a difference in the proportion of participants developing a new ulcer between reactive air surfaces (19/849 (2.2%)) and alternating pressure (active) air surfaces (32/799 (4.0%)). The RR is 0.62 (95% CI 0.35 to 1.11; I^2 = 3%; Analysis 1.1). Evidence is of very low certainty, downgraded twice for high risk of bias in domains other than performance bias for four studies contributing over 54% weight in the meta-analysis, and once for imprecision as, despite the fact that the OIS was met, the 95% CI was wide and crossed RR = 0.75.

Subgroup analysis

We considered the studies in Analysis 1.1 as heterogeneous in terms of care settings, skin status at baseline and overall 'Risk of bias. However, we did not perform any pre-specified subgroup analysis because, as noted in Subgroup analysis and investigation of heterogeneity, the number of included studies was fewer than 10, meaning it would be difficult to meaningfully interpret the results.

Sensitivity analyses

- ***Sensitivity analysis with complete case data*** . This resulted in a RR of 0.62 (95% CI 0.35 to 1.11; I^2 = 3%). The result was consistent with the main analysis (Appendix 5).
- ***Sensitivity analysis with fixed-effect (rather than random-effects) model*** . The use of a fixed-effect model resulted in a RR

of 0.58 (95% CI 0.34 to 1.00; I^2 = 3%) and this was consistent with the main analysis (Appendix 5).

- ***Sensitivity analysis with time to pressure ulcer incidence as the primary outcome (follow-up duration 14 days)*** . Only Beeckman 2019 (308 participants) reported this outcome. Low-certainty evidence suggests that people treated with reactive air surfaces may be at lower risk of developing a new pressure ulcer than those treated with alternating pressure (active) air surfaces over 14 days' follow-up in a nursing home setting (HR 0.44, 95% CI 0.21 to 0.96; Analysis 1.2). These results are sensitive to the choice of format for the primary outcome measure so they should be interpreted cautiously. Evidence certainty was downgraded twice for high risk of detection bias (Appendix 5).

Secondary outcomes

Support-surface-associated patient comfort (median follow-up duration 11 days, minimum 5 days, maximum 14 days)

Four studies (1364 participants) reported this outcome (Cavicchioli 2007; Finnegan 2008; Jiang 2014; Price 1999). The four studies reported a range of different measures for this outcome and they cannot be pooled (see Table 2). We are uncertain if there is a difference in patient comfort between reactive air surfaces and alternating pressure (active) air surfaces. Evidence was of very low certainty, downgraded once for high overall risk of bias in three small studies but unclear risk of bias in one large study, and twice for substantial inconsistency.

All reported adverse events

Not reported.

Health-related quality of life

Not reported.

Cost-effectiveness

Not reported.

Comparison 2: Reactive air surfaces versus foam surfaces (four studies, 236 participants)

Four studies (236 participants) compared reactive air surfaces with foam surfaces (Allman 1987; Takala 1996; Van Leen 2011; Van Leen 2013). Of these studies, Allman 1987 compared reactive air surfaces with the use of foam surfaces (19 mm thick foam pad) on top of alternating pressure (active) air surfaces.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration minimum 13 days, maximum 6 months)

All four studies (236 participants) reported this outcome and the data of 229 participants were available for analysis. Reactive air surfaces (12/113 (10.6%)) may reduce the proportion of participants developing a new pressure ulcer compared with foam surfaces (32/116 (27.6%)); however, the evidence is of low certainty. The RR is 0.42 (95% CI 0.18 to 0.96; I^2 = 25%; Analysis 2.1). Evidence certainty was downgraded once for risk of bias (one study contributing 8% weight in the meta-analysis had domains other than performance bias at high risk of bias and all the remaining studies had domains other than performance bias at unclear risk of bias) and once for imprecision as, despite the fact that the OIS was met, the 95% CI crossed RR = 0.75.

The included studies did not report data on time to pressure ulcer incidence.

Subgroup analysis

We considered the studies in Analysis 2.1 as heterogeneous in terms of follow-up durations, care settings, and overall 'risk of bias' and there was an indication of statistical heterogeneity (Tau^2 = 0.21, Chi^2 test P value = 0.26 and I^2 = 25%). We did not perform any pre-specified subgroup analysis because, as noted in Subgroup analysis and investigation of heterogeneity, the number of included studies was fewer than 10, meaning it would be difficult to meaningfully interpret the results.

Sensitivity analyses

- ***Sensitivity analysis with fixed-effect (rather than random-effects) model*** . The use of a fixed-effect model resulted in a RR of 0.40 (95% CI 0.23 to 0.72; I^2 = 25%). This remained consistent with the main analysis (Appendix 5).

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration 13 days)

Only Allman 1987 (72 participants) reported this outcome in which participants were asked to choose a response to a comfort-related question from these categories: 'Very comfortable', 'Comfortable', 'Uncomfortable', or 'Very uncomfortable'. It is uncertain if there is a difference in patient comfort responses between reactive air surfaces and foam surfaces on top of an alternating pressure (active) air surface (P = 0.04; very low-certainty evidence). Evidence certainty was downgraded once for unclear risk of bias, and twice for imprecision due to the small sample size.

All reported adverse events (follow-up duration 13 days)

Only Allman 1987 (72 participants) reported this outcome (see Table 1). It is uncertain if there is a difference in adverse event rates between reactive air surfaces and foam surfaces (very low-certainty evidence). Evidence certainty was downgraded once for unclear risk of bias, and twice for imprecision due to the small sample size.

Health-related quality of life

Not reported.

Cost-effectiveness

Not reported.

Comparison 3: Reactive air surfaces versus reactive water surfaces (one study, 37 participants)

Sideranko 1992 compared reactive air surfaces with a reactive water mattress.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration 9.5 days)

Sideranko 1992 (37 participants) reported this outcome. It is uncertain if there is a difference in the proportion of participants developing a new ulcer between reactive air surfaces (1/20 (5%)) and reactive water surfaces (2/17 (11.8%)). The RR is 0.43 (95% CI 0.04 to 4.29; Analysis 3.1). Evidence is of very low certainty, downgraded once for unclear overall risk of bias and twice for

substantial imprecision because the OIS was not met and the 95% CI was very wide and crossed both RRs = 0.75 and 1.25.

The included study did not report data on time to pressure ulcer incidence.

Secondary outcomes

Not reported.

Comparison 4: Reactive air surfaces versus reactive gel surfaces (one study, 74 participants)

Lazzara 1991 compared reactive air surfaces with a reactive gel mattress.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration of 6 months)

Lazzara 1991 (74 participants) reported this outcome and had analysable data for 66 participants. It is uncertain if there is a difference in the proportion of participants developing a new ulcer between reactive air surfaces (10/33 (30.3%)) and reactive gel surfaces (8/33 (24.2%)). The RR is 1.25 (95% CI 0.56 to 2.77; Analysis 4.1). Evidence is of very low certainty, downgraded once for unclear overall risk of bias and twice for imprecision because the OIS was not met and the confidence interval was very wide, and crossed both RRs = 0.75 and 1.25.

The included study did not report data on time to pressure ulcer incidence.

Secondary outcomes

Not reported.

Comparison 5: Comparison between two types of reactive air surfaces (two studies, 223 participants)

Two studies compared two different types of reactive air surfaces with each other: that is, EHOB versus KinAir (Cobb 1997) and Sofflex versus ROHO (Cooper 1998). We did not pool data from the two studies. We summarised study findings narratively below, and presented key outcome data in Table 3.

Primary outcomes

Proportion of participants developing a new pressure ulcer (follow-up duration 7 days and 40 days)

Both studies (223 participants) reported this outcome; see Table 3. Neither study found a difference in the proportions of participants developing a new pressure ulcer between EHOB and KinAir reactive air surface or between Sofflex and ROHO reactive air surface. Evidence is of very low certainty, downgraded once for unclear risk of bias (both studies were at unclear risk of bias in at least one domain), and twice for imprecision: sample sizes were small, there were very few events and both reported CIs crossed RRs = 0.75 and 1.25.

Cobb 1997 (123 participants; follow-up duration 40 days) reported time to pressure ulcer incidence but did not report analysable data. Cobb 1997 reported no statistically significant difference in survival analysis between the two types of reactive air surfaces (EHOB versus KinAir). Evidence is of very low certainty, downgraded once for unclear risk of bias, and twice for imprecision as the sample size was small and there were very few events.

Secondary outcomes

Support-surface-associated patient comfort (follow-up duration 7 days)

Only Cooper 1998 (84 complete cases) reported this outcome, defined as the participants' perception of comfort, rated using a 5-point visual rating scale. None of the participants selected 'Very uncomfortable' in either reactive air surface group; five selected 'Uncomfortable' (all using ROHO); eight selected 'Adequate' (four in each group); 48 selected 'Comfortable' (24 in each group), and 23 selected 'Very comfortable' (13 using Sofflex and 10 using ROHO). If we only considered the responses of 'Comfortable' and 'Very comfortable' for this outcome, it is uncertain if there is a difference in the support-surface-associated patient comfort between the two specific reactive air surfaces under evaluation (low-certainty evidence). Evidence certainty was downgraded once for unclear risk of bias and once for imprecision due to the small sample size.

All reported adverse events

Not reported.

Health-related quality of life

Not reported.

Cost-effectiveness

Not reported.

DISCUSSION

Summary of main results

We report evidence from 17 RCTs on the effects of reactive air surfaces compared with any support surface on the incidence of pressure ulcers in any population in any setting. We did not analyse data reported in the three studies that compared reactive air surfaces with surfaces that could not be classified. This review had evidence for five comparisons: reactive air surfaces compared with alternating pressure (active) air surfaces, foam surfaces, reactive water surfaces, reactive gel surfaces, and comparisons between two types of reactive air surface (EHOB versus KinAir, and Sofflex versus ROHO). We summarise key findings across these comparisons below.

Proportion of participants developing a new pressure ulcer

Five comparisons have evidence for this outcome. However, for most of these comparisons, it is uncertain if there is a difference in the proportions of participants developing a new pressure ulcer between reactive air surfaces and alternating pressure (active) air surfaces (six studies with 1648 participants), reactive water surfaces (one study with 37 participants), reactive gel surfaces (one study with 66 participants), or another type of reactive air surface (two studies with 223 participants). Using reactive air surfaces may reduce the risk of developing new pressure ulcers compared with foam surfaces (four studies with 229 participants; low-certainty evidence).

Time to pressure ulcer incidence

Two studies have evidence for this outcome. Low-certainty evidence suggests that people treated with reactive air surfaces are

at a lower risk of developing a new pressure ulcer than those treated with alternating pressure (active) air surfaces over 14 days' follow-up in a nursing home setting (one study with 308 participants). However, it is uncertain if there is a difference in the risk of developing new pressure ulcers between two types of reactive air surfaces (one study with 123 participants).

Support-surface-associated patient comfort

This review has evidence on this outcome for three comparisons. It is uncertain if there is a difference in patient comfort responses between reactive air surfaces and foam surfaces on top of an alternating pressure (active) air surface (one study with 72 participants; very low-certainty evidence); and between two types of reactive air surfaces under evaluation (one study with 84 participants; low-certainty evidence). It is uncertain if there is a difference in patient comfort responses between reactive air surfaces and alternating pressure (active) air surfaces (four studies with 1364 participants; very low-certainty evidence).

All reported adverse events

This review has adverse events evidence for one comparison only. It is uncertain if there is a difference in adverse events between reactive air surfaces and foam surfaces (one study with 72 participants; very low-certainty evidence).

Health-related quality of life

This review did not identify evidence for this outcome.

Cost-effectiveness

This review did not include data for this outcome for all five comparisons.

Overall completeness and applicability of evidence

As detailed in Search methods for identification of studies, we ran a comprehensive set of literature searches to maximise the relevant research included here.

The international pressure ulcer guideline recommends considering using a reactive air surface for people at risk for developing pressure ulcers (EPUAP/NPIAP/PPPIA 2019). Whilst this appears to recommend the applicability of reactive air surfaces for adults and children in any settings, all participants in included studies were adults (with the reported average age ranging from 56 to 87 years, median of 72 years). Across the included studies, more than half (55.2%) of enrolled participants were female. Almost all of enrolled participants (2335/2604; 89.7%) were at (high) risk of pressure ulceration, with risk assessed using a risk assessment tool (e.g. the Braden scale) and most of the 2335 participants (87.1%) were ulcer-free at the time of being recruited. Three included studies (with 302 participants) did include participants with superficial pressure ulcers at baseline.

Most of the included studies were small (half had fewer than 83 participants), whilst eight studies enrolled more than 100 participants, with two enrolling more than 200 participants. These eight studies together accounted for 80.7% (2101/2604) of the participants in this review.

The geographical scope of included studies was limited: almost all the studies were from Europe and North America, and one small study was from China (Jiang 2014).

Included studies recruited participants from a variety of care settings including: acute care settings (seven studies), community and long-term care settings (four studies), or both (two studies); and intensive care units (four studies). Whilst three of the five comparisons included studies from a variety of care settings, due to a limited number of included studies for these comparisons we could not perform pre-specified subgroup analysis by different care settings. Thus, for these three comparisons we are unable to drawn conclusions about potential modification of treatment effects in different care settings. Each of the remaining two comparisons only included one study: one was in an intensive care unit and another was in a nursing home. Therefore, their evidence is very limited. These comparisons are reactive air surfaces compared with reactive water surfaces, or reactive gel surfaces. Additionally, there were no data for operating rooms.

We recognise that reactive air surfaces can have a range of other features (e.g. air-fluidised, low-air-loss; see Included studies). In this review, we considered all specific types of reactive air surfaces as generic reactive air surfaces since they have the same underlying mechanism of redistributing pressure activity (i.e. distributing the pressure over a greater area via immersion and envelopment). We did not synthesise evidence for each specific type of reactive air surface.

There were no data for the comparison of reactive air surfaces versus reactive fibre surfaces. Further review work using network meta-analysis adds to the findings reported here (Shi 2021).

We did not analyse data reported in the three studies that compared reactive air surfaces with undefined surfaces as these comparator group surfaces could not be classified using the NPIAP S3I 2007 support surfaces terms and definitions. However, for completeness of all relevant evidence, we reported the data from these studies in Appendix 4.

Another limitation in the included studies was the large variation in terms of follow-up durations (with a range of five days to six months, median of 14 days). This is partly because different follow-up durations are appropriate in different care settings. For example, participants staying at acute care settings are more likely to be discharged after a short-term hospital stay whilst those staying at community and long-term care settings can have long-term follow-up. The short median duration of follow-up may contribute to an under-estimation of pressure ulcer incidence across study groups of the included studies because most pressure ulcers would occur in the first two to four weeks after hospital admission (Schoonhoven 2007), and some incident pressure ulcers may have been missed in these studies.

Quality of the evidence

We implemented the GRADE approach for assessing the certainty of the evidence and found that most of the included evidence from our 10 meta-analyses or syntheses across five comparisons was of low or very low certainty. Downgrading of evidence was all due to the unclear or high risk of bias of findings, and/or imprecision due to the small numbers of participants, events, wide confidence intervals that failed to exclude important benefits or harms, or all of these.

Limitations in study design

We downgraded once or twice for study limitations for all evidence. We assessed risk of bias according to seven domains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, selective outcome reporting, incomplete follow-up, and other potential biases. Of the 17 studies, we judged ten as being at unclear overall risk of bias; and seven at high overall risk of bias. The prevalence of high overall risk of bias is partly due to the non-blinding of participants and personnel for most comparisons. We acknowledged that such blinding of participants and personnel is impractical for most comparisons. Therefore, we did not downgrade certainty of evidence for studies at high overall risk of bias that was solely due to the possible presence of performance bias.

Five studies were also at high risk of bias due to unblinded outcome assessment. Unblinded assessment has been found to exaggerate odds ratios (from subjective binary outcomes) by, on average, 36% (Hróbjartsson 2012). The outcome assessment of pressure ulcer incidence is subjective, and blinded assessment - whilst operationally challenging - can be undertaken (e.g. masked adjudication of photographs of pressure areas) (Baumgarten 2009). Therefore, we considered unblinded pressure ulcer incidence assessment could substantially bias effect estimates in the included studies and downgraded the certainty of evidence for detection bias on a study-by-study basis.

Indirectness of evidence

We did not downgrade any result for indirectness of evidence. This was because we considered that the participants, interventions and outcomes in the included studies were within the scope of the published review protocol and there was no indirectness.

Inconsistency of results and unexplained heterogeneity

Statistical heterogeneity was low for nine of the 10 evidence syntheses we performed and we did not downgrade for inconsistency for them. We downgraded for inconsistency for the support-surface-associated patient comfort outcome in the comparison of reactive air surfaces versus alternating pressure (active) air surfaces; and the included studies of this synthesis reported heterogenous results. The low statistical heterogeneity was partly because seven of the 10 syntheses included only one study. None of the remaining meta-analyses or narrative syntheses included more than six studies. Despite the fact that we found heterogeneity in overall risk of bias, care settings, outcome measurement methods, or follow-up durations between included studies, we considered that heterogeneity (inconsistency) was low and explained, and we decided not to downgrade evidence certainty.

We have to note that although we planned to calculate prediction intervals to understand the implications of heterogeneity, all analyses included a small number (up to six) of included studies which was fewer than the 10 needed for this calculation.

Imprecision of results

We downgraded for imprecision for all pieces of evidence from the 10 evidence syntheses. Study sample sizes were small in most cases (median sample size: 83) with often a small number of events and wide associated confidence intervals around effect estimates. Confidence intervals often crossed the line of null effect, thus meaning we could not discern whether the true population effect was likely to be beneficial or harmful.

Publication bias

We did not downgrade the certainty of evidence for publication bias in all meta-analyses. This is because (1) we have confidence in the comprehensiveness of our literature searches; and (2) we did not find any clear evidence of non-reporting bias of study results. Although we planned to perform funnel plots for meta-analysis to visually inspect for publication bias, there was no analysis including more than ten studies.

Potential biases in the review process

We followed pre-specified methods to review evidence in order to prevent potential bias in the review process. For example, we ran comprehensive electronic searches, searched trials registries and checked the references of systematic reviews identified in electronic searches.

This review also has limitations. Firstly, some included studies may have considered co-interventions as 'usual care' but did not fully describe them. We assumed that all studies had provided co-interventions equally to participants in their study groups if there was nothing to indicate that this was not the case. Secondly, we did not implement pre-specified subgroup analysis as we mentioned above, mainly because no analysis included more than ten studies. Thirdly, the study with time to pressure ulcer data in this review, Beeckman 2019, did not fully report time-to-event data, and the HR and CI we used in Analysis 1.2 were calculated using the methods described in Tierney 2007. We recognise that those calculated data (and associated meta-analyses) might be inaccurate. Fourthly, two studies termed their controls as 'standard hospital surfaces' but did not specify the construction materials of these surfaces. Although we made efforts to collect information on these surfaces, we were not able to classify them. Traditionally, 'standard hospital surfaces' meant foam surfaces, but we felt adopting that assumption was unwarranted. Accurate classification of these surfaces in the future might change the results of some comparisons (e.g. reactive air surfaces versus foam surfaces). Finally, we were not able to pre-specify the comparisons included in this review. This is because specific support surfaces applied could only be known and defined once eligible studies were included. However, we pre-planned to use the NPIAP S3I 2007 support surface terms and definitions to define specific support surfaces in order to avoid any potential bias.

Agreements and disagreements with other studies or reviews

To our knowledge, among the 14 systematic reviews or meta-analyses we identified through electronic searches for this review (Chou 2013; Huang 2013; McGinnis 2011; McInnes 2015; McInnes 2018; Mistiaen 2010a; De Oliveira 2017; Rae 2018; Reddy 2006; Reddy 2008; Serraes 2018; Shi 2018a; Smith 2013; Yao 2018), two recent comprehensive reviews include reactive air surfaces evidence: Shi 2018a, and the Cochrane Review 'Support surfaces for pressure ulcer prevention' (McInnes 2015).

This review differs from Shi 2018a and McInnes 2015 in how specific support surfaces (including reactive air surfaces) are classified and labelled.

As mentioned above, the types of reactive air surfaces used in the included studies varied, and we labelled all these types as a single generic group 'reactive air surfaces'. However, Shi 2018a and McInnes 2015 considered individual types of reactive air surfaces (e.g. air-fluidised bed, low-air-loss hydrotherapy) separately in different comparisons. For example, McInnes 2015 classified support surfaces into 'low-tech' and 'high-tech' groups in general, and included 'static air mattresses' into low-tech 'constant low-pressure devices' but considered low-air-loss surfaces as 'high-tech' regardless of whether they were active or reactive.

Shi 2018a grouped some interventions under the term 'standard hospital surfaces' but concluded that the types of surfaces labelled in this way varied over time, and by setting. We noted that the NPIAP S3I 2007 recommends that the use of 'standard hospital surfaces' term should be avoided and the surface characteristics should be specified. In this review, we made great efforts to define surfaces, where these surfaces were described as a 'standard hospital surface' in the included studies to ensure they were placed in the correct comparisons. We classified those 'standard hospital surfaces' that had no characteristic details or could not be classified using the NPIAP S3I 2007 terms and definitions as undefined surfaces.

The re-definitions and re-classifications of specific support surfaces discussed above can explain some of the inconsistency between these reviews, but importantly, Shi 2018a was a network meta-analysis.

Shi 2018a considered pressure ulcer incidence and support-surface-associated patient comfort outcomes only, whilst this review added adverse effect evidence to the evidence base.

AUTHORS' CONCLUSIONS

Implications for practice

Using reactive air surfaces may reduce the risk of developing new pressure ulcers within 14 days compared with alternating pressure (active) air surfaces in people in a nursing home setting. Also, the use of reactive air surfaces may reduce pressure ulcer incidence compared with foam surfaces. However, evidence is uncertain about the relative effects of reactive air surfaces versus foam surfaces, reactive water surfaces, reactive gel surfaces, or another type of reactive air surface in preventing pressure ulcers.

Implications for research

Given the large number of different support surfaces available, future studies should prioritise which support surfaces to evaluate on the basis of the priorities of decision-makers. For example, reactive air surfaces versus alternating pressure (active) air surfaces may be a high priority for future evaluation. All interventions used should be clearly described using the current classification system. Researchers should avoid use of some terms, such as 'standard hospital surfaces'. Limitations in included studies are largely due to small sample size and sub-optimal RCT design. The incidence of pressure ulcers can be low in certain settings and this needs to be considered in sample size calculations and when considering the feasibility of trial conduct. Under-recruitment or over-estimation of event rates that then fail to occur, or both, can lead to imprecision and less robust effect estimates.

Future studies should also consider carefully the choice of outcomes they report; time-to-event data for pressure ulcer incidence should be used in trials. Careful and consistent assessment and reporting of adverse events needs to be undertaken to generate meaningful data that can be compared between studies. Likewise, patient comfort is an important outcome but it is poorly defined and reported, and this needs to be considered in future research studies. Further studies should aim to collect and report health-related quality of life using validated measures. Finally, future studies should nest cost-effectiveness analysis in their conduct where possible.

Any future studies must be undertaken to the highest standard possible. Whilst it is challenging to avoid the risk of performance bias in trials of support surfaces as blinding of participants and personnel is seldom possible, stringent protocols - for example, in terms of encouraging consistent care and blinded decision-making - can help to minimise risk. It is also important to fully describe co-interventions (e.g. repositioning) and ensure protocols mandate balanced use of co-interventions across trial arms. The risk of detection bias can also be minimised with the use of digital photography and adjudicators of the photographs being masked to support surfaces (Baumgarten 2009). Follow-up periods should be for as long as possible and clinically relevant in different settings. Where possible and useful, data collection after discharge from acute care settings may be considered.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Allman 1987

Study characteristics	
Methods	**Study objective**: to compare the effectiveness and adverse effects of air-fluidised beds and conventional therapy for patients with pressure sores **Study design including the number of centres**: randomised controlled trial, single centre **Study grouping**: parallel group **Duration of follow-up**: median 13 days **Number of arms**: 2 **Study start date and end date**: recruited between October 1984 and March 1986 **Care setting**: urban, academic referral, and primary care medical centre
Participants	**Baseline characteristics** **Inclusion criteria**: age greater than 18 years old; presence of a pressure sore on the sacrum, buttocks, trochanters, or back; activity expected to be limited to bed or chair in the hospital for at least 1 week; patient expected to live at least 1 week; informed consent obtained **Exclusion criteria**: had been in the trial previously or a skin graft or flap planned for the pressure sore within 1 week **Sex (M/F)**: 27/38 overall. 11/20 in air-fluidised bed; 16/18 in conventional therapy **Age (years)**: mean 65.5 (SD 15.6) in air-fluidised bed, 67.6 (18.3) in conventional therapy **The stage of pressure ulcers at baseline**: 16 superficial and 15 deep ulcers on air-fluidised bed; 20 superficial and 14 deep ulcers on conventional therapy. Median total surface area 7.8 cm^2 (range 0.3 to 83.2) on air-fluidised bed, 10.8 cm^2 (0.4 to 180.3) on conventional therapy

Allman 1987 *(Continued)*

Group difference: no difference

Total number of participants: 72 patients (65 completed the study)

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions	**Intervention characteristics** Air-fluidised bed • **Description of interventions**: air-fluidised bed (Clinitron Therapy, Support Systems International, Inc.) … contain ceramic beads … warm, pressurised air is forced up through the beads, on the characteristics of a fluid • **NPUAP S3I classification:** non-powered, reactive air-fluidised surface • **Number of participants randomised**: not given • **Number of participants analysed**: 31 • **Co-interventions**: repositioning every 4 hours without use of other antipressure devices Conventional therapy • **Description of interventions**: used a vinyl alternating air-mattress covered by a 19 mm thick foam pad (Lapidus Air Float System, American Pharmaceal Company) on a regular bed • **NPUAP S3I classification:** non-powered, reactive foam surface plus powered, alternating pressure (active) air surface • **Number of participants randomised**: not given • **Number of participants analysed**: 34 • **Co-interventions**: repositioning every 2 hours and elbow or heel pads as needed
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: median 13 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: skin breakdown or epidermal necrosis manifested by eschar over a bony prominence; defined by Shea system; not staged. • **Definition (including ulcer stage)**: new skin breakdown • **Dropouts**: 7 withdrawn prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed). • **Notes (e.g. other results reported)**: 9 of 31 on air-fluidised beds vs 15 of 34 on conventional therapy (P = 0.24). *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Outcome type**: categorical • **Time points**: median 13 days • **Reporting**: partially reported • **Definition and measurement method (e.g. scale, self-reporting)**: patients with change in comfort from baseline. Level of comfort assessed by asking the patient to respond to a second question scored from 1 to 4: “Which of the following best describes the bed you are using here in the hospital: very comfortable, comfortable, uncomfortable, or very uncomfortable?” • **Dropouts and reasons**: 7 withdrawn prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed)

Allman 1987 *(Continued)*

- **Data and results**: 8 comfort increased, 4 no change and 1 decreased on air-fluidised bed; 3 increased, 4 no change and 6 decreased on conventional therapy (P = 0.04)
- **Notes (e.g. other results reported)**:

All reported adverse events using allocated support surfaces

- **Outcome type**: binary
- **Time points**: median 13 days
- **Reporting**: partially reported
- **Definition and measurement method (e.g. scale, self-reporting)**: patients developing complications
- **Dropouts and reasons**: 7 withdrawn prior to follow-up and excluded from analysis (6 died, 1 withdrew due to nausea and dislike of the air-fluidised bed)
- **Data and results**: 8 died, 2 pneumonia, 10 urinary tract infections, 6 hypotension, 5 hypernatraemia, 5 oliguria, 7 sepsis, 16 fever, and 3 heart failure on air-fluidised bed; 7 died, 4 pneumonia, 7 urinary tract infections, 7 hypotension, 5 hypernatraemia, 8 oliguria, 6 sepsis, 22 fever, and 6 heart failure on conventional therapy
- **Notes (e.g. other results reported)**: some patients appeared to have multiple adverse events

Health-related quality of life (HRQOL)

- **Not reported**

Cost-effectiveness

- **Not reported**

Outcomes that are not considered in this review but reported in trials:

- Ulcer healing
- Change in total surface area
- Patients improved
- 50% reduction in total surface area
- Pain response

Notes	This is a treatment trial that contains ulcer incidence data.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomly allocated to treatment groups in two strata in balanced blocks of six with stratification … The randomization sequence was determined using a table of random numbers …" Comment: low risk of bias due to the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "… treatment allocations were placed in envelopes sealed and numbered sequentially. After establishing eligibility, one of the investigators selected the unopened envelope with the lowest number in the appropriate strata and allocated the patient to the treatment indicated on the enclosed card" Comment: unclear risk of bias because information is still insufficient to ensure if concealment is performed properly (e.g. it is unclear if the envelopes are opaque).
Blinding of participants and personnel (performance bias)	Unclear risk	Comment: no information provided.

Allman 1987 *(Continued)*
All outcomes

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: ulcer incidence*** Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes*** Comment: low risk of bias because of the low rate of attrition (7/72, 9.7%).
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Beeckman 2019

Study characteristics	
Methods	**Study objective:** to compare the effectiveness and cost of static air support surfaces versus alternating air pressure support surfaces in a nursing home population at high risk for pressure ulcers **Study design:** randomised controlled trial **Study grouping:** parallel group **Duration of follow-up:** 14 days **Number of arms:** 2 **Single centre or multi-sites:** multi-sites **Study start date and end date**: April 2017 to May 2018 **Setting:** nursing home
Participants	**Baseline characteristics** **Inclusion criteria:** (1) high risk of developing pressure ulcer (Braden score 12 and/or Braden subscale score for mobility 2) and/or pressure ulcer category 1; (2) being bed-bound (> 8 h in bed) and/or chair-bound (> 8 h sitting in a chair); (3) aged > 65 years; and (4) use of an alternating air pressure mattress **Exclusion criteria:** (1) nursing home residents with a pressure ulcer category II–IV upon admission; (2) those with an expected length of stay < 2 weeks; (3) those who received end-of-life care; or (4) those with medical contraindications for the use of static air support devices **Sex (M:F)**: 71:237 overall; 39:115 in static air support surfaces; 32:122 in alternating air pressure surfaces **Age (years)**: mean 87 (SD 7.6) overall; 86.9 (7.9) in static air support surfaces; 86.8 (7.3) in alternating air pressure surfaces **Baseline skin status**: mean Braden score 13 (SD 2.2) overall; all at risk according to the risk score used by the authors **Group difference:** no difference between groups **Total number of participants:** n = 308 **Unit of analysis:** individuals

Beeckman 2019 *(Continued)*

	Unit of randomisation (per patient): individuals
Interventions	**Intervention characteristics** Static air support surfaces • **Description of interventions**: provided with the static air support surfaces (Repose) ... Repose mattress overlay, Repose1 cushion and Repose1 wedge, or Repose1 foot protector (Frontier Medical Group, South Wales, the UK) ... consist of two urethane multidirectional stretch membranes. The inner membrane is inflated and provides static pressure redistribution throughout the tubular open cells that are oriented along the length of the device. The second membrane is formed from a multidirectional stretch, vapour-permeable material. • **NPUAP S3I classification:** non-powered, reactive air surface • **Co-interventions**: static air-filled cushion used in 81% of participants and usual seat cushion used in the remaining 19%, static air-filled foot protectors or wedges used in 100% of participants • **Number of participants randomised**: n = 154 • **Number of participants analysed**: n = 154 Alternating air pressure support surfaces • **Description of interventions**: all using alternating air pressure support surfaces, with a 3–30 minute cycle time. However, the surfaces were not standardised to reflect current clinical practice. • **NPUAP S3I classification**: powered, alternating pressure (active) air surface • **Co-interventions**: seat cushions used in 88% and heel protectors used in 34% • **Number of participants randomised**: n = 154 • **Number of participants analysed**: n = 154
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 14 days • **Reporting**: fully reported • **Measurement method (e.g. scale, self-reporting)**: graded using the International Pressure Ulcer Classification system (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and P.P.P.I.A., 2014) • **Definition (including ulcer stage)**: cumulative incidence and incidence density of the participants developing a new category II-IV pressure ulcer within a 14-day observation period; that is, the percentage of participants in the population at risk who developed a new pressure ulcer • **Dropouts**: intention-to-treat (ITT) analysis • **Notes (e.g. other results reported)**: 8 of 154 developing category II-IV pressure ulcer in static air support surfaces (6 category II; 2 category III); 18 of 154 in alternating air pressure support surfaces (15 category II; 1 category III; 2 category IV); (Chi^2 test P = 0.04). Ulcer incidence by areas reported also in the paper but not extracted for this review. Category II - IV ulcer incidence density 0.41/100 observed days (8 ulcers/1970 observed days) (95% CI 0.19 to 0.77) in static air surfaces; 0.89/100 observed days (18 ulcers/2013 observed days) (95% CI 0.55 to 1.39) in alternating pressure air surfaces. *Time to pressure ulcer incidence* • **Outcome type**: binary • **Time points**: 14 days • **Reporting**: fully reported • **Measurement method (e.g. scale, self-reporting)**: graded using the International Pressure Ulcer Classification system (National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and P.P.P.I.A., 2014) • **Definition (including ulcer stage)**: median time to develop a new ulcer • **Dropouts**: median time to develop an ulcer 10.5 days (interquartile range (IQR) 1 to 14) in static air support surfaces; 5.4 (1 to 12) in alternating air pressure support surfaces (Mann-Whitney U test P = 0.05); probability to remain pressure ulcer-free differed between groups (log-rank X = 4.051, df = 1, P

Beeckman 2019 *(Continued)*

= 0.04); Kaplan–Meier survival plot presented in Fig 2 and HR and 95% CI 0.45 (0.21 to 0.96) estimated by the review authors using the methods described in Tierney 2007.

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported
- **Notes**: purchase costs of the support surfaces calculated per participant per day given the 2-year lifespan for a static air mattress and 7-year for an alternating air pressure mattresses. The average lifespan of 2 years for a static air mattress resulted in a daily cost of 0.20 Euro; the average lifespan of 7 years for an alternating air pressure mattress resulted in a daily cost of 0.53 Euro.

Outcomes that are not considered in this review but reported in trials:

- None

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "The random allocation sequence was based on a computer-generated list of random numbers using an online tool (www.randomization.com)." Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "When the participants met the inclusion criteria and an informed consent was obtained, they received an allocation number (first available number on the computer-generated list)." Quote: "Subsequently, a random allocation of each eligible participant was performed based on a computer-generated list of random numbers." Comment: unclear risk of bias because the process of allocation is not clear for judging if concealment is properly performed and it is unclear who performed allocation.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: all outcomes*** Quote: "The study was not blinded due to the obvious visible difference between the support surfaces (e.g. external control unit)." Comment: high risk of bias because of the understandable challenge of performing blinding.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: all outcomes*** Quote: "The study was not blinded due to the obvious visible difference between the support surfaces (e.g. external control unit). Both support surface types were presented to ward nurses ..."

Beeckman 2019 *(Continued)*

		Quote: "During the follow-up period (days 1–14), the ward nurses collected all data" Quote: "Researchers performed independent and unannounced skin assessments and technical controls weekly" Comment: high risk of bias because of the understandable challenge of performing blinding.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "An intention-to-treat analysis was performed." Comment: low risk of bias.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is available and it is clear that the published reports include all outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Bennett 1998

Study characteristics	
Methods	**Study objective**: to determine whether low-air-loss hydrotherapy reduces the incidence of new skin lesions associated with incontinence in hospitalised patients ... compared with standard care. To assess subjectively patient and nursing satisfaction related to using low-air-loss hydrotherapy beds. **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 60 days; median 4 (range 1 to 60) days in low-air-loss hydrotherapy; median 6 (range 1 to 62) days in standard care **Number of arms**: 2 **Single centre or multi-sites**: multi-sites **Study start date and end date**: September 1993 to April 1994 **Setting**: acute and chronic hospital wards
Participants	**Baseline characteristics** **Inclusion criteria**: (1) incontinence of urine and/or liquid faeces was present; (2) treatment in bed for 16 hours or longer per day was expected; (3) the length of hospitalisation was expected to be 3 or more days; (4) in the opinion of the attending physician, death was not expected within the next 7 days; and (5) no other condition was present, e.g. excessive combativeness or morbid obesity, which, in the opinion of the principal investigator, would preclude the patient from fulfilling the objectives of the project **Exclusion criteria**: those who had a stage III or IV pressure sore if mechanical debridement of the sore was planned or an astringent dressing was ordered **Sex (M:F)**: 26:32 in low-air-loss hydrotherapy; 19:39 in standard care **Age (years)**: median = 80 years **Baseline skin status**: at high risk, 14 (9 to 28) in low-air-loss hydrotherapy, including 10 individuals with pressure ulcers; at high risk, 15 (8 to 19) in standard care, including 13 with pressure ulcers **Group difference**: no difference

Bennett 1998 *(Continued)*

Total number of participants: 116 individuals

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions	**Intervention characteristics** Low-air-loss hydrotherapy • **Description of interventions**: low-air-loss hydrotherapy beds (Clensicair, Support Systems International/Hill-Rom, Charleston, SC) used to maximise the amount of time incontinent patients remain dry; similar to low-air-loss beds e.g. Flexicair therapy beds in which air escapes continuously through the semipermeable fabric used to construct the multiple air cushions of the surface (Bennett 1998); "Model Clensicair; Power needed; Kind - Low air loss with incontinence management system" from product search http://www.medwow.com/med/alternating-pressure-bed/hill-rom/clensicair/15595.model-spec. • **NPUAP S3I classification**: powered, reactive low-air-loss air surface • **Co-interventions**: temperature monitoring every 4 hours • **Number of participants randomised**: n = 58 • **Number of participants analysed**: n = 42 enrolled for more than 24 hours Standard care • **Description of interventions**: standard care including regular beds, foam mattresses, air mattresses, alternating pressure mattresses, air-fluidised beds, or low-air-loss beds as ordered by physicians • **NPUAP S3I classification**: standard hospital surface • **Co-interventions**: not described • **Number of participants randomised**: n = 58 • **Number of participants analysed**: n = 56 enrolled for more than 24 hours
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: • **Definition (including ulcer stage)**: the number of participants who developed new stage II to IV pressure ulcers • **Dropouts**: not described • **Notes (e.g. other results reported)**: 8 of 42 in low-air-loss hydrotherapy; and 4 of 56 in standard care *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported

Bennett 1998 *(Continued)*

Outcomes that are not considered in this review but reported in trials:

- Numbers of participants who developed other skin lesions (including chemical irritation, candidiasis, blisters, bruises, abrasions, pressure marks) reported by the type of skin lesions
- Kaplan-Meiers plot for the cumulative development of all truncal skin lesions in the first 9 days
- Temperature on the first study day after enrolment
- Assessment of subjective nursing and patient satisfaction

Notes	This cannot be regarded as an ulcer healing trial.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Subjects ... were stratified based on whether any pressure sores were present at enrolment ... randomization of subjects ... was done by unblocked allocation using a table of random numbers stratified by pressure sore and by setting" Comment: low risk of bias due to the use of random number table.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "... the study nurse and/or research technicians ... performed a thorough examination of the truncal skin ... to identify new truncal skin lesions, including pressure sores, blisters, bruises, abrasions, chemical irritations, and candidiasis ... categorised all skin lesions based on objective appearance and/or treatment prescribed ..." Comment: unclear risk of bias because insufficient information to permit judgement of low or high risk of bias.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: primary outcome*** Comment: high risk of bias because (1) 16 of 58 individuals in low-air-loss hydrotherapy; and 2 of 58 in standard care were excluded from analysis; (2) 6 participants receiving low-air-loss hydrotherapy exited because of patient or family member complaints (e.g. being wet, cold or uncomfortable). Two participants were removed by researchers as a result of hypothermia.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Cavicchioli 2007

Study characteristics

Cavicchioli 2007 *(Continued)*

Methods	**Study objective**: to determine whether alternating low pressure or continuous low pressure is most effective in reducing the incidence of pressure ulcers in high risk patients **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 2 weeks **Number of arms**: 2 **Single centre or multi-sites**: multi-sites **Study start date and end date**: March 2004 to November 2006 **Setting**: acute, postacute and long-term care settings of 3 hospitals
Participants	**Baseline characteristics** **Inclusion criteria**: those admitted to the unit or deemed "at risk" of pressure ulceration as defined by the Braden Pressure Ulcer Risk Assessment Scale (a total Braden score of ≤ 17 and mobility and activity sub-scores of ≤ 3); their admission was expected to last at least 2 weeks and they had up to 1 grade I pressure ulcer **Exclusion criteria**: not at risk (Braden score ≥ 17 and activity or mobility sub-scales ≥ 3) **Sex (M:F)**: 20:49 in alternating low pressure; 20:51 in continuous low pressure **Age (years)**: mean 77 in alternating low pressure; 78 in continuous low pressure **Baseline skin status**: mean 11.4 (range 7 to 16) in alternating low pressure; 11.9 (6 to 17) in continuous low pressure **Group difference**: no difference **Total number of participants**: 170 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Alternating low pressure modality of Duo2 (Hill-Rom) • **Description of interventions**: Duo2 (Hill-Rom), "... electrically powered, air-filled mattresses in which adjacent cells inflate and deflate reciprocally underneath the patient" • **NPUAP S3I classification**: powered, alternating pressure (active) air surface • **Co-interventions**: not described • **Number of participants randomised**: n = 86 • **Number of participants analysed**: n = 69 Continuous low pressure modality of Duo2 (Hill-Rom) • **Description of interventions**: continuous low pressure modality of Duo2 (Hill-Rom) • **NPUAP S3I classification**: powered, reactive air surface • **Co-interventions**: not described • **Number of participants randomised**: n = 84 • **Number of participants analysed**: n = 71
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary

Cavicchioli 2007 *(Continued)*

- **Time points**: 2 weeks
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: assessed by the external observer
- **Definition (including ulcer stage)**: not described
- **Dropouts**: 17 dropouts in alternating low pressure (4 died, 8 discharged prior to assessment, 5 did not complete study due to non-concordance (uncomfortable) and not agreeing to use the modality); 13 dropouts in continuous low pressure (5 died, 4 discharged prior to assessment, 4 did not complete study due to non-concordance and not agreeing to use the modality)
- **Notes (e.g. other results reported)**: 2 of 69 individuals (1 stage 1 and 1 stage 2) in alternating low pressure; 1 of 71 individuals (stage 2) in continuous low pressure

Time to pressure ulcer incidence

- **Reporting**: not reported

Support -surface-associated patient comfort

- **Reporting**: not reported
- **Notes**: 5 dropouts due to discomfort and/or not agreeing to use the assigned modality in Alternating low pressure; 4 dropouts due to discomfort and/or not agreeing to use the assigned modality in continuous low pressure

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Not available

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients in the treatment group were randomised to receive either continuous or alternating low pressure on the high-tech mattress" Comment: the method of randomisation was not reported.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Low risk	***Outcome group: primary outcome*** Quote: "... independently from the blinded randomised treatment group (who received the Duo2 high-tech mattress)." Comment: low risk of bias because blinding method was implemented.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: primary outcome***

Cavicchioli 2007 *(Continued)*

		Quote: "As there is no visible difference between these two modes, the external observer was blinded as to which one was in use. The external observers assessed all study patients' ... presence (or absence) and grade of both existing and new pressure ulcers" Comment: low risk of bias because outcome assessment was blinded.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: primary outcome*** Comment: high risk of bias because of high proportions of dropouts in both groups and probably using incorrect analysis methods to address missing data.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Cobb 1997

Study characteristics	
Methods	**Study objective**: to compare outcomes related to pressure ulcer development when high-risk patients were placed on a KinAir specialty bed, a rented low-air-loss bed, compared to an EHOB Waffle air mattress, a purchased, 1-patient use, static air mattress overlay **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 40 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: all wards and intensive care units (ICU) of a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: over 18 years of age; weighed 290 lb or less; did not have a pre-existing pressure ulcer; were expected to have a length of stay (LOS) of 1 to 2 weeks; determined to be at “high risk” based on the Braden Scale for Predicting Pressure Sore Risk; could speak and read English to provide informed consent **Exclusion criteria**: not described **Sex (M:F)**: 34:27 in EHOB Waffle; 36:26 in KinAir Bed **Age (years)**: overall mean 58; 56 in EHOB Waffle; 60 in KinAir Bed **Baseline skin status**: mean Braden 10.26 (SD 1.61) in EHOB Waffle; 10.02 (1.57) in KinAir. At high risk (Braden score ≤ 12); free of existing ulcers **Group difference**: no difference **Total number of participants**: n = 123

Cobb 1997 *(Continued)*

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions

Intervention characteristics

EHOB

- **Description of interventions**: EHOB Waffle air mattress... a static air mattress overlay ... an air-filled bladder that is placed over a standard hospital mattress
- **NPUAP S3I classification:** non-powered, reactive air surface
- **Co-interventions**: not described
- **Number of participants randomised**: n = 61
- **Number of participants analysed**: n = 61

KinAir

- **Description of interventions**: low-air-loss bed ... a bed in which the standard mattress has been replaced by a series of air filled cushions inflated by a blower motor. Small amounts of air flow through the pores of the cushion fabric to the patient's skin, keeping it dry.
- **NPUAP S3I classification**: powered, reactive low-air-loss air surface
- **Co-interventions**: not described
- **Number of participants randomised**: n = 62
- **Number of participants analysed**: n = 62

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: 40 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: assessed using the Shea Staging system, staged from I to IV, based on the degree of tissue damage observed (NPUAP, 1989; Shea, 1975)
- **Definition (including ulcer stage)**: the number of patients developing ulcers of any stage
- **Dropouts**: no missing
- **Notes (e.g. other results reported)**: 20 patients developed pressure ulcers; 12 of 61 (1 stage I and 11 stage II) patients in the EHOB Waffle; 8 of 62 (3 stage I, 3 stage II, and 2 eschar) in KinAir

Time to pressure ulcer incidence

- **Outcome type**: time-to-event
- **Time points**: 40 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: see above
- **Definition (including ulcer stage)**: time to pressure ulcer incidence; see above
- **Dropouts**: not described
- **Notes**: the survival plot (Appendix F, Figure 1) "there is no statistically significant difference between the EHOB Waffle mattress or the KinAir bed, although the EHOB survival curve is lower than the KinAir curve"; no further data.

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cobb 1997 *(Continued)*

Cost-effectiveness

- **Reporting**: not reported
- **Notes**: mean costs associated with the pressure reduction surfaces USD 723 (SD 558) in KinAir; USD 49 (33) in EHOB.

Outcomes that are not considered in this review but reported in trials:

- Risk factors of pressure ulcer development
- Multivariate analysis of time to pressure ulcer development

Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Patients were placed into one of the study groups by random selection of a treatment card by a nurse not involved in the study" Comment: unclear risk of bias because the method of proper randomisation is not clearly specified.
Allocation concealment (selection bias)	Low risk	Quote: "Patients were placed into one of the study groups by random selection of a treatment card by a nurse not involved in the study" Comment: low risk of bias because concealment of the allocation process is likely through the involvement of an independent nurse.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "No attempt was made to alter the medical plan of care related to use of specialty beds/overlays" Comment: unclear risk of bias because of the lack of specific information on performance bias though no attempt to change care plan is stated. ***Outcome group: cost outcome*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "A skin assessment tool was used to document presence or absence of skin breakdown, the stage of injury when it occurred, and progression of the skin breakdown. The skin assessment tool also included an anterior and posterior diagram of the human body that allowed the investigator to draw the site of pressure ulcer(s)" Comment: unclear risk of bias because of lack of relevant information. ***Outcome group: cost outcome*** Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes*** Comment: no attrition identified.

Cobb 1997 *(Continued)*

Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Cooper 1998

Study characteristics	
Methods	**Study objective**: to compare 2 dry-flotation pressure-reducing surfaces in pressure sore incidence, patient comfort and the appropriate use of equipment in 100 orthopaedic patients **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 7 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: January to October 1997 **Setting**: 3 emergency trauma orthopaedic wards in a teaching hospital
Participants	**Baseline characteristics** **Inclusion criteria**: "... patients over 65 years of age with no existing pressure damage and a Waterlow risk assessment score of 15 and over" **Exclusion criteria**: not described **Sex (M:F)**: 7:44 in Sofflex group; 9:40 in ROHO group **Age (years)**: mean 83 (SD 7.7) in Sofflex; 83 (7.6) in ROHO **Baseline skin status**: median Waterlow score 17 (interquartile range (IQR) 15 to 19) in Sofflex; 16 (15 to 18) in ROHO **Group difference**: no difference **Total number of participants**: 100 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Sofflex mattress • **Description of interventions**: "similar to the ROHO but consists of larger cells ... requires only three sections to make a full mattress ... constructed with flexible interconnecting air cells manufactured from neoprene ... achieve a reduction in interface pressure by the principle of immersion ... immersion increases the surface contact area ... achieved by having a minimal amount of inflation ..." • **NPUAP S3I classification**: powered, reactive air surface • **Co-interventions**: ROHO Quatro cushion • **Number of participants randomised**: n = 51

Cooper 1998 *(Continued)*

- **Number of participants analysed**: n = 41

ROHO mattress

- **Description of interventions**: "... consisted of four separate sections - three ROHO sections and a foam section for the head ... constructed with flexible interconnecting air cells manufactured from neoprene ... achieve a reduction in interface pressure by the principle of immersion ... immersion increases the surface contact area ... achieved by having a minimal amount of inflation ..."
- **NPUAP S3I classification**: powered, reactive air surface
- **Co-interventions**: ROHO Quatro cushion
- **Number of participants randomised**: n = 49
- **Number of participants analysed**: n = 43

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: 7 days
- **Reporting**: fully reported
- **Measurement method (e.g. scale, self-reporting)**: graded by the Stirling Pressure Sore Severity Scale
- **Definition (including ulcer stage)**: ulcers of any grades
- **Dropouts**: 10 (4 died, 6 transferred/discharged) in Sofflex; 6 (3 died, 3 transferred/discharged)
- **Notes (e.g. other results reported)**: 3 of 41 individuals in Sofflex (1 grade 1, 1 grade 1.1, 1 grade 2.4); 5 of 43 in ROHO (1 grade 1, 2 grade 1.1, 2 grade 1.2). Of the 8, only 1 had skin breakdown.

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Outcome type**: binary
- **Time points**: 7 days
- **Reporting**: fully reported
- **Measurement method (e.g. scale, self-reporting)**: 5-point visual rating scale (very uncomfortable, uncomfortable, adequate, comfortable, very comfortable)
- **Definition**: the patients' perception of comfort
- **Dropouts**: 10 (4 died, 6 transferred/discharged) in Sofflex; 6 (3 died, 3 transferred/discharged)
- **Notes**: Sofflex (n = 41) vs ROHO (n = 43); very uncomfortable 0 vs 0; uncomfortable 0 vs 5; adequate 4 vs 4; comfortable 24 vs 24; very comfortable 13 vs 10

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported:

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Equipment setting

Notes

Risk of bias

Cooper 1998 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "The subjects were then randomly allocated to one of the two types of mattress using consecutively numbered sealed opaque envelopes" Comment: the method of randomisation was not described.
Allocation concealment (selection bias)	Low risk	Quote: "The subjects were then randomly allocated to one of the two types of mattress using consecutively numbered sealed opaque envelopes" Comment: low risk of bias due to the use of proper concealment method.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "The patient's skin integrity was assessed ... " Comment: unclear risk of bias because efforts to prevent detection bias were not described. ***Outcome group: comfort outcome*** Quote: "the patients' perception of comfort was recorded using a standardised question and a five-point visual rating scale" Comment: high risk of bias because comfort outcome is self-reported and blinding is impossible.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Quote: "16 patients had withdrawn ... four had died in the Sofflex group, and three in the ROHO group. The remaining nine patients were withdrawn ...: five were transferred to other specialities and four were discharged..." Comment: unclear risk of bias because 16% of 100 participants missed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Finnegan 2008

Study characteristics	
Methods	**Study objective**: to compare the effectiveness of a specialised alternating air pressure mattress replacement system and an air-fluidised integrated bed in the management of post-operative flap patients **Study design**: pilot randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: mean length of stage 8.0 days (range 0 to 21)

Finnegan 2008 *(Continued)*

	Number of arms: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: tertiary referral centre
Participants	**Baseline characteristics** **Inclusion criteria**: 18 years or older who were admitted for reconstructive surgery to repair a tissue deficit (full-thickness pressure ulcer involving muscle, fascia and, in some cases, bone) in the sacral-coccygeal, trochanteric or ischial region **Exclusion criteria**: unlikely or unwilling to comply with the treatment protocol, which included a minimum of 7 days bed rest within the surgical unit, or unable to consent **Sex (M:F)**: overall 21:12; 7:8 in alternating therapy; 14:4 in air-fluidised bed **Age (years)**: mean 56 (range 20 to 80); 62 in alternating therapy; 50 in air-fluidised bed **Baseline skin status**: severe full-thickness pressure ulcers **Group difference**: not described **Total number of participants**: 40 randomised, 33 analysed **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Alternating therapy • **Description of interventions**: a specialised alternating therapy support surface (Nimbus 3 Professional, Huntleigh Healthcare LLC). Specialised by means of Vent Valve Technology, not a standard alternating pressure therapy. Single cells to be isolated and permanently deflated beneath the operative site. This deflation completely off-loads the most vulnerable tissue while the mattress continues to deliver optimised cyclic pressure redistribution to other vulnerable areas. • **NPUAP S3I classification**: powered, alternating pressure (active) air surface • **Co-interventions**: all other care including repositioning, nutrition and continence management in line with the wound centre's protocol • **Number of participants randomised**: n = 19 • **Number of participants analysed**: n = 15 Air-fluidised bed • **Description of interventions**: air-fluidised bed system (Clinitron, Hill-Rom Inc.); "Clinitron® Air Fluidized Therapy beds ... minimizes interface pressure, while maximizing the surface's immersion and envelopment properties to support healing ... providing statistically lower interface pressure ... Medical grade, silicone-coated bead fluidization promotes a flotation environment " from Hill-Rom website (https://www.hill-rom.com/ca/Products/Products-by-Category/Hospital-Beds-and-Long-Term-Care-Beds/Clinitron-RiteHite-Air-Fluidized-Beds/). • **NPUAP S3I classification:** non-powered, reactive air-fluidised surface • **Co-interventions**: all other care including repositioning, nutrition and continence management in line with the wound centre's protocol • **Number of participants randomised**: n = 21 • **Number of participants analysed**: n = 18
Outcomes	*Proportion of participants developing a new pressure ulcer*

Finnegan 2008 *(Continued)*

- **Outcome type**: binary
- **Time points**: unspecified; hospital stay of 8 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: assessed by surgical team
- **Definition (including ulcer stage)**: tissue integrity at other vulnerable anatomical locations
- **Dropouts**: 4 in alternating therapy; 3 in air-fluidised bed (all due to not receiving the allocated intervention)
- **Notes (e.g. other results reported)**: 0 of 15 in alternating therapy; 0 of 18 in air-fluidised bed

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Outcome type**: binary
- **Time points**: unspecified; hospital stay of 8 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: self-reported
- **Definition**: subject acceptability - numbers of patients having comfortable response on support surfaces
- **Dropouts**: 4 in alternating therapy; 3 in air-fluidised bed (all due to not receiving the allocated intervention)
- **Notes (e.g. other results reported)**: comfortable: 11 of 15 in alternating therapy; 4 of 18 in air-fluidised bed; uncomfortable: 2 of 15 vs 7 of 18; the rest of patients had no view.

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported
- **Notes**: cost of support surface provision based on rental costs per day of inpatient care (USD 35/day for alternating therapy; USD 65/day for air-fluidised bed).

Outcomes that are not considered in this review but reported in trials:

- Integrity of the surgical site

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "allocation was determined by using web-based random-number software" Comment: low risk of bias due to the use of a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "Groups were concealed in sealed envelopes" Comment: unclear risk of bias because a proper concealment method is not specified.

Finnegan 2008 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "Tissue integrity on discharge was not blinded and determined by the surgical team responsible for this pilot phase." Comment: high risk of bias because no blinding was undertaken. ***Outcome group: comfort outcome*** Comment: unclear risk of bias because it is not specified if patients who reported comfort data were blinded.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: all outcomes*** Quote: "four subjects in Group A and three subjects in Group B did not receive the allocated intervention (Fig. 2) and were not included in the follow-up" Comment: unclear risk of bias because a fair proportion of subjects lost to follow-up.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Inman 1993

Study characteristics	
Methods	**Study objective**: to determine, in critically ill patients at risk, both the clinical utility and cost-effectiveness of using an air suspension bed in the prevention of pressure ulcers **Study design**: randomised controlled trial with cost-effectiveness analysis **Study grouping**: parallel group **Duration of follow-up**: mean intensive care unit (ICU) stay 18.8 days (SE 18.1) in air suspension; 15.4 (13.9) in standard ICU bed **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: March 1989 to November 1990 **Setting**: intensive care unit of a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients over 17 years of age, had an admission Acute Physiology and Chronic Health Evaluation II (APACHE II) score greater than 15, had an expected stay in the ICU of at least 3 days **Exclusion criteria**: not described **Sex (M:F)**: 29:20 in air suspension; 22:27 in standard ICU bed

Inman 1993 *(Continued)*

Age (years): mean 63.4 (SE 14.4) in air suspension; 65.4 (13.9) in standard ICU bed

Baseline skin status: not described

Group difference: no difference in baseline demographics; patients in standard ICU bed had shorter lengths of stay than those in air suspension bed

Total number of participants: 100 randomised; 98 completed (neither of the exclusions developed a pressure ulcer during their hospitalisation)

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions

Intervention characteristics

Air suspension bed

- **Description of interventions**: air suspension bed (KinAir, Kinetic Concepts Inc, San Antonio, Tex) ... provides a smooth, low-friction, low-shear surface with a high moisture vapor transmission rate, decreasing physical stresses on the skin (Inman 1993); the patent of this product can be seen in https://patentimages.storage.googleapis.com/27/6f/0f/f80303c8fcec2a/US5983429.pdf.
- **NPIAP S3I classification:** powered, reactive low-air-loss air surface
- **Co-interventions**: not described
- **Number of participants randomised**: n = 50
- **Number of participants analysed**: n = 49

Standard intensive care unit bed

- **Description of interventions**: not described
- **NPIAP S3I classification**: standard hospital surface
- **Co-interventions**: rotated every 2 hours unless contraindicated
- **Number of participants randomised**: n = 50
- **Number of participants analysed**: n = 49

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: not specified
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: measured by research nurses using Shea criteria
- **Definition (including ulcer stage)**: the development of pressure ulcers of a severity score greater than 1 graded by Shea criteria
- **Dropouts**: 2 (1 in each group)
- **Notes (e.g. other results reported)**: number of patients with ulcers of greater than 1 presented in Figure and WebPlotDigitizer reads: 3 of 49 in air suspension bed; 14 of 49 in standard bed. No. of patients with single ulcer clearly reported: 6 of 49 in air suspension and 25 of 49 in standard bed (this probably included those with erythema). No. of patients with multiple ulcers clearly reported: 1 of 49 in air suspension and 12 of 49 in standard bed

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Inman 1993 *(Continued)*

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Outcome type**: continuous
- **Time points**: not described
- **Reporting**: fully reported
- **Measurement method (e.g. scale, self-reporting)**: cost-effectiveness estimated from a third-party payer's perspective; effectiveness measured as the number of ICU patients at risk in whom pressure ulcers developed and expressed per 100 patients at risk; cost estimates reported in both US and Canadian 1988 dollars; incremental cost-effectiveness ratio calculated (the cost per pressure ulcer prevented).
- **Notes**: cost per 100 patients at risk 56,347.40 Canadian dollars in standard bed vs 50,044.80 Canadian dollars in air suspension; cost saved per 100 patients at risk 6302.60 Canadian dollars due to air suspension; pressure ulcers prevented per 100 patients at risk 64 due to air suspension; cost-effectiveness ratio (cost per pressure ulcer prevented) < 0 (air suspension bed), meaning air suspension bed was dominant, providing increased effectiveness in the form of fewer pressure ulcers, for less money than the current program of standard ICU bed and frequent patient rotation.

Outcomes that are not considered in this review but reported in trials:

- No

Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "... consecutive patients were randomly assigned to receive treatment with either the air suspension bed or a standard ICU bed" Comment: the method of randomisation is not described.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "... a visual skin inspection of 13 bony prominences was performed by a trained critical care research nurse, and the presence or absence of pressure ulcers was recorded" Comment: unclear risk of bias because blinding of outcome assessment is not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: primary outcome*** Quote: "Of the 100 patients randomised, 98 successfully completed the study protocol. One patient from each study group was excluded from the analysis, as they did not have an ICU stay of at least 3 days. Neither of these patients developed a pressure ulcer during their hospitalisation"

Inman 1993 *(Continued)*

		Comment: low risk of bias due to the small proportion of missing data.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Jiang 2014

Study characteristics	
Methods	**Study objective**: to investigate the efficacy of static low-air-loss mattress (static LALM) and power pressure air mattress (PPAM) in prevention of pressure ulcers **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 5 days after surgery **Number of arms**: 2 **Single centre or multi-sites**: multi-sites **Study start date and end date**: not described **Setting**: hospitals
Participants	**Baseline characteristics** **Inclusion criteria**: age ≥ 18 years; male or female with Braden score ≤ 16 points; general anaesthesia for surgery with operating time ≥ 120 min; admitted to the ICU or surgical wards after surgery; clear consciousness; able to express their feelings correctly; had contraindications for using air mattress (doctor's orders: lying on hard-bed or flat-bed); completed informed consent and related information **Exclusion criteria**: refused to participate in research; in critical condition and repositioning limited by doctor's orders; using ice blanket; withdrew interventions within 72 h of being offered them; unable to determine the efficacy; incomplete information for the assessment of efficacy or safety outcomes **Sex (M:F)**: overall 621:453 **Age (years)**: overall mean 57.94 (SD 15.54) years (range 18 to 88) **Baseline skin status**: overall mean Braden scores 13.15 (SD 2.25) (range 6 to 17) **Group difference**: no difference **Total number of participants**: n = 1074 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Static air mattress • **Description of interventions**: static air mattress (®WAFFLE static air mattress, EHOB, United States) • **NPIAP S3I classification:** non-powered, reactive air surface • **Co-interventions**: repositioning every 2 hours • **Number of participants randomised**: n = 562

Jiang 2014 *(Continued)*

- **Number of participants analysed**: no data available

Dynamic air mattress

- **Description of interventions**: dynamic air mattress (Sanma mattress manufacturing factory, Shanghai in China)
- **NPIAP S3I classification:** powered, alternating pressure (active) air surface
- **Co-interventions**: repositioning every 2 hours
- **Number of participants randomised**: n = 512
- **Number of participants analysed**: no data available

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: not given
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: graded by the NPIAP 2007 criteria
- **Definition (including ulcer stage)**:
- **Dropouts**: no missing
- **Notes (e.g. other results reported)**: static air mattress group 1.07% (6/562); dynamic air mattress 0.98% (5/512) $\chi 2 = 0.148$, P = 0.882

Time to pressure ulcer incidence

- **Not reported**

Support-surface-associated patient comfort

- **Outcome type**: binary
- **Time points**: post-operative 5 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: asking patients' feelings after using the mattress: 1 = very uncomfortable, 2 = uncomfortable, 3 = just comfortable, 4 = comfortable, 5 = very comfortable
- **Definition**: the level of patients' comfort
- **Dropouts**: 80 of 562 missing in static air mattress; 100 of 562 missing in dynamic air mattress
- **Notes**: 68 of 482 patients having a comfort level rating more than the median of 4 in static air mattress and 414 of 482 less than the median level; 68 of 462 more than the median of 4 in dynamic air mattress and 394 less than the median ($Chi^2 = 0.071$, P = 0.789)

All reported adverse events using allocated support surfaces

- **Not reported**

Health-related quality of life (HRQOL)

- **Not reported**

Cost-effectiveness

- **Not reported**

Outcomes that are not considered in this review but reported in trials:

None

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement

Jiang 2014 *(Continued)*

Random sequence generation (selection bias)	Low risk	Quote: "We used a random number table to randomize and parallel control design" Comment: low risk of bias because the sequence generation process is proper.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: ulcer incidence*** Comment: low risk of bias because intention-to-treat (ITT) analysis performed. ***Outcome group: comfort*** Comment: unclear risk of bias because the rates of missing data in both groups is between 10% to 20%.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Lazzara 1991

Study characteristics	
Methods	**Study objective**: to compare the effectiveness of 2 pressure-reducing devices [an air-filled overlay and a gel mattress] in a group of elderly nursing home residents **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 6 months **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: a nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: all residents determined to be at risk for pressure ulcer development (defined by Norton scale, with a score of greater than 15 as high risk) **Exclusion criteria**: not specified

Lazzara 1991 *(Continued)*

Sex (M:F): 4:11 in SofCare overlay; 2:10 in Gel mattress (sex was specified for only some of the participants)

Age (years): mean 83.7 (SD 6.87) in SofCare overlay; mean 83.5 (SD 9.22) in Gel mattress

Baseline skin status: mean Norton score 18.06 (SD 3.94) in SofCare overlay; 17.88 (3.80) in Gel mattress

Group difference: no difference

Total number of participants: 74 (those followed up for 4 to 6 months were analysed)

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions

Intervention characteristics

SofCare overlay

- **Description of interventions**: air-filled overlay (SofCare overlay) Gaymar Industries. Additional source of information "Gaymar SofCare air mattress ... composed of three distinct layers of more than 300 compensating air cells. The cells are interconnected through a series of air channels. As the cells exchange air, the patient's weight is redistributed over the entire surface of the cushion ... SofCare is unlike any other inflated device ... SofCare looks as soft as it feels, "customizing" itself to the body weight and configuration of each individual patient. By conforming to the patient ... (http://www.rehabmart.com/pdfs/gaymar_sof_care_overlay_brochure.pdf)"
- **NPIAP S3I classification:** non-powered, reactive air surface
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 33

Gel mattress

- **Description of interventions**: Gel mattress
- **NPIAP S3I classification:** non-powered, reactive gel surface
- **Co-interventions**: not described
- **Number of participants randomised**: not described
- **Number of participants analysed**: n = 33

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: 6 months
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: not reported
- **Definition (including ulcer stage)**: no. of patients with new ulcers of any grade
- **Dropouts**: specified; but patient flow is not clear enough
- **Notes (e.g. other results reported)**: 10 of 33 in SofCare (5 grade 1 and 5 grade 2); 8 of 33 in Gel mattress (4 grade 1 and 4 grade 2)

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Lazzara 1991 *(Continued)*

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- No

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Using a table of random numbers, each subjected was placed into ..." Comment: low risk of bias because a proper randomisation was done.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "Patients in both study groups were assessed by the same researcher for the presence of pressure ulcer development over areas of bony prominence" Comment: unclear risk of bias because no information on blinding was reported.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "... the initial study population was 76 subjects ..." Quote: "A total of 74 subjects were in the study ... Two subjects were excluded from the study ... Those subjects who participated in the study for four to six months were included in the data analysis. Eighteen residents developed pressure ulcers during the course of the study, nine residents had preexisting pressure ulcers, and 36 residents did not develop a pressure ulcer" Comment: unclear risk of bias because the patient flow is not clear enough and the proportion of missing data is probably between 10/74 (13.5%) and 13/74 (17.6%).
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Malbrain 2010

Study characteristics	
Methods	**Study objective**: to compare pressure ulcer outcomes in medical intensive care unit (ICU) patients nursed on either a reactive mattress overlay (ROHO®, ROHO Inc, Belleville, IL, USA) or an active alternating pressure mattress (NIMBUS®3, ArjoHuntleigh, Luton Bedfordshire, UK) **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: not specified; mean study duration reported 12.2 days (SD 5.5) in ROHO and 15 (14) in NIMBUS 3 **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: medical ICU of a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: patients admitted to the ICU with a high pressure ulcer risk (Norton score ≤ 8) and requiring mechanical ventilation for an estimated duration of at least 5 days either (a) with intact skin or (b) with pressure ulcers on admission **Exclusion criteria**: refused to consent to the study; either of 2 mattresses unavailable for patients admitted **Sex (M:F)**: 8:8 across groups; 5:3 in ROHO; 3:5 in NIMBUS 3 **Age (years)**: mean 64.7 (SD 15.6) across groups; 71.6 (11.9) in ROHO overlay; 56.9 (16.3) in NIMBUS 3 mattress **Baseline skin status**: mean Norton score 7.2 (SD 0.7) across groups; 7 (0) in ROHO and 7.4 (1.1) in NIMBUS 3 **Group difference**: different age distributions between groups **Total number of participants**: n = 16 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** ROHO dry flotation mattress overlay • **Description of interventions**: the ROHO DRY FLOTATION mattress overlay (ROHO Inc, Belleville, IL, USA) ... a manually inflatable reactive low-pressure mattress, overlaying a normal hospital mattress that moulds to the body surface in order to distribute the pressure over an area as large as possible. • **NPIAP S3I classification:** non-powered, reactive air surface • **Co-interventions**: Belgian consensus protocol for ulcer prevention and treatment (including 2-hourly repositioning) • **Number of participants randomised**: n = 8 • **Number of participants analysed**: n = 8 assumed NIMBUS 3 mattress

Malbrain 2010 *(Continued)*

- **Description of interventions**: a fully automatic active alternating pressure mattress replacement consisting of 20 individual cells (3 head, 8 torso, 4 leg and 5 heel) that alternatively inflate and deflate over a 10 min cycle repeatedly off-loading the tissues
- **NPIAP S3I classification:** powered, alternating pressure (active) air surface
- **Co-interventions**: Belgian consensus protocol for ulcer prevention and treatment (including 2-hourly repositioning)
- **Number of participants randomised**: n = 8
- **Number of participants analysed**: n = 8 assumed

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: not specified
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: nurse/clinician-rated ulcers using EPUAP system
- **Definition (including ulcer stage)**: pressure ulcer incidence of stage 1 and incidence of stage 2 to 4 according to EPUAP system
- **Dropouts**: no missing data
- **Notes (e.g. other results reported)**: 3 of 8 individuals (2 stage 3 or 4 and 1 stage 1) in ROHO and 2 of 8 individuals (both stage 1) in NIMBUS 3

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Pressure ulcer healing outcome (reported but not extracted because patients with ulcers are not units of randomisation)

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation of patients to products was performed blinded by the insertion of equivalent numbers of labels written with ‘‘active’’ or ‘‘reactive’’ placed in identical sealed envelopes that were shuffled and placed in a box and drawn in sequence" Comment: low risk of bias because a simple randomisation was applied.
Allocation concealment (selection bias)	Unclear risk	Quote: "Randomisation of patients to products was performed blinded by the insertion of equivalent numbers of labels written with ‘‘active’’ or ‘‘reactive’’

Malbrain 2010 *(Continued)*

		placed in identical sealed envelopes that were shuffled and placed in a box and drawn in sequence. When a patient was admitted who fulfilled the inclusion criteria the next envelope was opened by a ward nurse and the patient was assigned to the mattress on the label" Comment: unclear risk of bias because it is unclear if envelopes are opaque.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: primary outcome*** Quote: "skin overlying bony prominences was thoroughly inspected in appropriate light by the ICU nurse; the outcome was documented ... any PU's were assessed independently by the study nurse and study doctor, using ... pressure ulcer scale for healing [PUSH] tool ... category according to EPUAP definitions" Comment: unclear risk of bias because blinding of outcome assessment is not reported.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: primary outcome*** Comment: low risk of bias because it is likely to have no missing data.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Price 1999

Study characteristics	
Methods	**Study objective**: to compare the effects on pressure damage prevalence by using 2 different support systems in patients with fractured neck of femur who were at high risk **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: post-operation 7 days; post-operation 14 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: hospital ward
Participants	**Baseline characteristics** **Inclusion criteria**: patients with fractured neck of femur (confirmed by X-ray), who were over 60 years old and identified as being 'at very high risk' of developing tissue damage (Medley score > 25) **Exclusion criteria**: not specified **Sex (M:F)**: 11:29 in Repose; 5:35 in NIMBUS II

Price 1999 *(Continued)*

Age (years): mean 83.5 (range 67.3 to 96.2) in Repose and 80.9 (64.4 to 98.4) in NIMBUS II

Baseline skin status: at very high risk defined by Medley score > 25

Group difference: no difference

Total number of participants: 80

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions	**Intervention characteristics** Repose • **Description of interventions**: a low-unit-cost system (Repose) ... comprising a low-pressure inflatable mattress and cushion that are readily portable and require little maintenance ... manufactured using a special polyurethane material that has a multidirectional stretch, is vapour permeable, waterproof and x-ray translucent • **NPIAP S3I classification:** non-powered, reactive air surface • **Co-interventions**: standard best practice as appropriate to condition, including regular repositioning • **Number of participants randomised**: n = 40 • **Number of participants analysed**: n = 24 at 14-day time point NIMBUS II plus Alpha TranCell • **Description of interventions**: the system ... comprised a dynamic flotation mattress (Nimbus II) together with an alternating-pressure cushion for a chair (Alpha TranCell) ... The alternating pressure cushion is designed for use on a chair or wheelchair • **NPIAP S3I classification:** powered, alternating pressure (active) air surface • **Co-interventions**: standard best practice as appropriate to condition, including regular repositioning • **Number of participants randomised**: n = 40 • **Number of participants analysed**: n = 26 at 14-day time-point
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 7 days; 14 days • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: classified as 0 = normal skin; 1 = persistent erythema of the skin; 2 = blister formation; 3 = superficial sub/cutaneous necrosis; 4 = deep subcutaneous necrosis (not specified which classification system was used) • **Definition (including ulcer stage)**: no. of patients with a pressure ulcer at any stage [note: not new pressure ulcer incidence]. • **Dropouts**: 16 in Repose and 14 in NIMBUS II plus Alpha TranCell • **Notes (e.g. other results reported)**: at 7 days: 6 of 32 in Repose (3 grade 1; 2 grade 2 and 1 grade 3) and 5 of 31 in NIMBUS II (4 grade 1; 1 grade 2 and 0 grade 3); at 14 days: 5 of 24 in Repose (2 grade 1; 0 grade 2 and 3 grade 3) and 4 of 26 in NIMBUS II (2 grade 1; 1 grade 2 and 1 grade 3). Data may not be useful because they are a mixture of new ulcers and pre-existing ulcers not just new ulcers. *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Outcome type**: continuous • **Time points**: 14 days • **Reporting**: partially reported

Price 1999 *(Continued)*

- **Measurement method (e.g. scale, self-reporting)**: measured using a 100 mm visual analogue scale
- **Definition**: not specified what patient comfort is
- **Dropouts**: 16 in Repose and 14 in NIMBUS II plus Alpha TranCell
- **Notes**: mean 67 (SD 18) for 24 individuals in Repose; 60 (25) for 26 individuals in NIMBUS II

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- No

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "a concealed computer generated list was used to randomise eligible consecutive consenting patients to one of the support systems" Comment: low risk of bias because of the use of a proper randomisation method.
Allocation concealment (selection bias)	Low risk	Quote: "a concealed computer generated list was used to randomise eligible consecutive consenting patients to one of the support systems" Comment: low risk of bias because of a proper concealment method.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: primary outcome*** Comment: high risk of bias because blinding is not possible for this comparison.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "Patients were not assessed blindly as it was considered that displacement for examination would cause excessive discomfort. A team of trained researchers completed all assessments" Comment: high risk of bias because no blinding is done.
Incomplete outcome data (attrition bias) All outcomes	High risk	***Outcome group: primary outcome*** Quote: "No patient was excluded from all the analyses" Quote: "Data were not available for the 14-day follow-up assessment for a further 12 patients who were transferred to wards or hospitals that were not involved in the study or were discharged home" Comment: high risk of bias because 16 in Repose and 14 in NIMBUS II plus Alpha TranCell actually missed and were not included in analysis.

Price 1999 *(Continued)*

Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Sideranko 1992

Study characteristics	
Methods	**Study objective**: to compare the pressure-reducing properties of 3 types of mattress overlays (water, alternating air and static air mattress surfaces) as used with bedbound patients in a clinical setting **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: mean 10.0 (SD 10.9) days of surgical intensive care unit (SICU) stay in alternating air; 9.4 (8.8) in static air; 8.9 (7.1) in water **Number of arms**: 3 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: 2 surgical ICUs of a hospital
Participants	**Baseline characteristics** **Inclusion criteria**: a minimum SICU stay of 48 hr; presence of ventilatory support, or some form of haemodynamic support on admission **Exclusion criteria**: those with any evidence of existing skin breakdown upon admission to the SICUs **Sex (M:F)**: 33:24 across groups **Age (years)**: mean 67.9 (SD 11.1) in alternating air; 63.6 (18.6) in static air; 66.1 (15.6) in water **Baseline skin status**: free of existing skin breakdown **Group difference**: no difference **Total number of participants**: n = 57 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Alternating air • **Description of interventions**: "a 1.5-in. thick, alternating air mattress, the Lapidus Airfloat System manufactured by the American Hospital Supply Corp., Valencia, CA" • **NPIAP S3I classification:** powered, alternating pressure (active) surface • **Co-interventions**: not described • **Number of participants randomised**: n = 20 • **Number of participants analysed**: n = 20 Static air

Sideranko 1992 *(Continued)*

- **Description of interventions**: "A 4-in. thick static air mattress, the Gaymar Sof Care bed cushion, manufactured by Gaymar Industries Inc., Orchard Park, NY"
- **NPIAP S3I classification:** non-powered, reactive air surface
- **Co-interventions**: not described
- **Number of participants randomised**: n = 20
- **Number of participants analysed**: n = 20

Water

- **Description of interventions**: "A 4-in. thick water mattress, the Lotus PXM 3666, manufactured by Connecticut Artcraft Corp., Naugatuck, CT"
- **NPIAP S3I classification:** non-powered, reactive water surface
- **Co-interventions**: not described
- **Number of participants randomised**: n = 17
- **Number of participants analysed**: n = 17

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: not reported
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: not reported
- **Definition (including ulcer stage)**: the number of patients developing pressure ulcers
- **Dropouts**: not described; no missing assumed
- **Notes (e.g. other results reported)**: 5 of 20 in alternating air; 1 of 20 in static air; 2 of 17 in water

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Interface pressure

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "... subjects were randomly assigned to be placed on one of the three surfaces studied"

Sideranko 1992 *(Continued)*

		Comment: unclear risk of bias because the method of randomisation was not specified.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: no information provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Comment: no missing assumed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Takala 1996

Study characteristics	
Methods	**Study objective**: to test the hypothesis that this device [a new, easily adjustable antidecubitus mattress] would be clinically effective in the prevention of pressure sores in patients requiring prolonged intensive care **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 14 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: intensive care unit (hospital)
Participants	**Baseline characteristics** **Inclusion criteria**: non-trauma patients admitted to intensive care unit (ICU) expected to stay > 5 days **Exclusion criteria**: patients with accidental injuries **Sex (M:F)**: 12:9 in Carital Optima; 13:6 in standard hospital foam mattress **Age (years)**: mean 60 (SD 16) in Carital Optima; 63 (12) in standard hospital foam mattress **Baseline skin status**: Norton below 8 across groups (high risk) **Group difference**: no difference

Takala 1996 *(Continued)*

Total number of participants: n = 40

Unit of analysis: individuals

Unit of randomisation (per patient): individuals

Interventions

Intervention characteristics

Pressure-relieving mattress

- **Description of interventions**: pressure-relieving mattress (Carital Optima, Carital Ltd, Tuusula, Finland). Carital Optima, constant low pressure mattress comprising 21 double air bags on a base, reduce the pressure on the skin by distributing the patient's weight over a maximum contact area. Formed of the separate upper layer of the cells ... pressure within the upper layer of cells and in the three compartments of the lower layer of cells can be adjusted separately. Additional source of information from Carital-Optima-Brochure-2.pdf (directhealthcaregroup.com) indicates that Carital Optima needs electricity to be functional.
- **NPIAP S3I classification:** powered, reactive air surface
- **Co-interventions**: not described
- **Number of participants randomised**: n = 21
- **Number of participants analysed**: n = 21

Standard hospital mattress

- **Description of interventions**: standard hospital mattress (10 cm thick foam mattress, density 35 kg/m3, Espe Inc, Kouvola, Finland)
- **NPIAP S3I classification:** non-powered, reactive foam surface; high specification (density 35 kg/m3) foam
- **Co-interventions**: not described
- **Number of participants randomised**: n = 19
- **Number of participants analysed**: n = 19

Outcomes

Proportion of participants developing a new pressure ulcer

- **Outcome type**: binary
- **Time points**: 14 days
- **Reporting**: partially reported
- **Measurement method (e.g. scale, self-reporting)**: graded by Shea criteria
- **Definition (including ulcer stage)**: the development of pressure ulcers graded by Shea criteria
- **Dropouts**: intention-to-treat (ITT) analysis
- **Notes (e.g. other results reported)**: 0 of 21 in pressure-relieving mattress; 7 of 19 in standard hospital mattress (with a totality of 13 ulcers: 9 Shea grade 1A; 4 grade 1B)

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

Takala 1996 *(Continued)*

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Interface pressure

Notes		
Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Quote: "Those with an expected ICU stay exceeding five days were randomly assigned to be treated on either ..." Comment: unclear risk of bias because a proper randomisation criteria is unspecified.
Allocation concealment (selection bias)	High risk	Comment: randomisation influenced by mattress availability, therefore, allocation not concealed.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: pressure ulcer outcome*** Quote: “The study was not blinded, since the severity of illness of the patients precluded their transfer for evaluation of the skin condition by a blinded reviewer, and the type of mattress in the bed could not be blinded” Comment: high risk of bias because this statement implies blinding of participants and personnel is likely impossible.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: pressure ulcer outcome*** Quote: “The study was not blinded, since the severity of illness of the patients precluded their transfer for evaluation of the skin condition by a blinded reviewer, and the type of mattress in the bed could not be blinded” Comment: high risk of bias as it is clearly stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: pressure ulcer outcome*** Quote: "Sequential analysis of the primary outcome variable (pressure sore formation) on an intention-to-treat basis was done after each block of four patients had completed the treatment" Comment: low risk of bias because intention-to-treat (ITT) analysis was conducted.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Van Leen 2011

Study characteristics	
Methods	**Study objective**: to evaluate the clinical efficacy of combining a standard 15 cm cold foam mattress with a static air overlay mattress versus a cold foam mattress alone in preventing pressure ulcers

Van Leen 2011 *(Continued)*

	Study design: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: 6 months **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: March 2002 and October 2004 **Setting**: nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: age > 65, a Norton score between 5-12 and informed consent of the patients or their representatives in case of mental disorders **Exclusion criteria**: a pressure ulcer in the previous 6 months **Sex (M:F)**: 9:33 in static air; 7:34 in cold foam **Age (years)**: mean 81.1 (SD 8.37) in static air; 83.1 (7.86) in cold foam **Baseline skin status**: Norton score presented by subgroups; Norton scale score lower than 12 (lower than 14 = at risk for pressure ulcers) and no existing ulcers **Group difference**: more patients in static air having a very low Norton score (i.e. more pressure ulcer prone patients) **Total number of participants**: n = 83 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Cold foam mattress • **Description of interventions**: standard 15 cm cold foam mattress • **NPIAP S3I classification:** non-powered, reactive foam surface • **Co-interventions**: standardised the pressure reduction in sitting position by using a static air cushion • **Number of participants randomised**: n = 42 • **Number of participants analysed**: n = 42 Static air overlay • **Description of interventions**: a combination of standard 15 cm cold foam mattress with static air overlay • **NPIAP S3I classification:** non-powered, reactive air surface • **Co-interventions**: standardised the pressure reduction in sitting position by using a static air cushion • **Number of participants randomised**: n = 41 • **Number of participants analysed**: n = 41
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: not specified • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: pressure ulcers classified by using EPUAP system

Van Leen 2011 *(Continued)*

- **Definition (including ulcer stage)**: the number of individuals developing a pressure ulcer grade 2, 3 and 4 at the heel or in the sacral/hip region
- **Dropouts**: not described
- **Notes (e.g. other results reported)**: 2 of 41 in Static air mattress (1 grade 2 and 1 grade 3); 7 of 42 in Cold foam mattress (2 grade 2; and 5 grade 3)

Time to pressure ulcer incidence

- **Reporting**: not reported

Support-surface-associated patient comfort

- **Reporting**: not reported

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported

Outcomes that are not considered in this review but reported in trials:

- Treatment data on the new ulcers reported but not extracted

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Randomization into two groups was performed after informed consent using numbered envelopes" Comment: unclear risk of bias because the randomisation method used is not sufficiently clear.
Allocation concealment (selection bias)	Unclear risk	Comment: no information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes (primary outcome)*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Quote: "A weekly inspection of the skin to assess the possible occurrence of a skin lesion was done by an independent nurse" Comment: low risk of bias because the attempt was made to blind outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Comment: no attrition identified.

Van Leen 2011 *(Continued)*

Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Van Leen 2013

Study characteristics	
Methods	**Study objective**: to evaluate the clinical efficacy of a combination of a standard 15 cm viscoelastic foam mattress with a static air overlay mattress vs a standard 15 cm visco-elastic foam mattress alone in preventing pressure ulcers **Study design**: randomised controlled trial **Study grouping**: cross-over design (data at the first stage extracted) **Duration of follow-up**: 6 months **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: not described **Setting**: nursing home
Participants	**Baseline characteristics** **Inclusion criteria**: age > 65, a Braden score between 6 and 19, and informed consent of the patients or their representatives in case of dementia or other mental disorder **Exclusion criteria**: patients with an existing pressure ulcer **Sex (M:F)**: 14:6 in static air; 18:3 in foam **Age (years)**: mean 79.1 (no SD) in static air; 80.8 in foam **Baseline skin status**: at risk and without existing ulcers. Braden scores classified into 2 subgroups and reported accordingly; not extracted **Group difference**: no difference **Total number of participants**: n = 41 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Standard visco-elastic foam mattress • **Description of interventions**: standard visco-elastic foam mattress • **NPIAP S3I classification:** non-powered, reactive foam surface; visco-elastic foam • **Co-interventions**: when out of bed, all patients sat on a static air pillow • **Number of participants randomised**: n = 20 • **Number of participants analysed**: n = 20

Van Leen 2013 *(Continued)*

	Static air overlay • **Description of interventions**: a combination of a standard visco-elastic foam mattress with a static air overlay • **NPIAP S3I classification:** non-powered, reactive air surface • **Co-interventions**: when out of bed, all patients sat on a static air pillow • **Number of participants randomised**: n = 21 • **Number of participants analysed**: n = 21
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 6 months • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: not reported; probably measured by the primary investigator • **Definition (including ulcer stage)**: the development of category 2, 3, or 4 pressure ulcers (PUs) (EPUAP-classification) • **Dropouts**: no missing • **Notes (e.g. other results reported)**: 1 of 20 in static air; 3 of 21 in foam *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Reporting**: not reported *All reported adverse events using allocated support surfaces* • **Reporting**: not reported *Health-related quality of life (HRQOL)* • **Reporting**: not reported *Cost-effectiveness* • **Reporting**: not reported **Outcomes that are not considered in this review but reported in trials**: • Treatment data on the new ulcers reported but not extracted
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomised into 2 groups using numbered envelopes" Comment: low risk of bias because the randomisation method is not sufficiently clearly presented in the paper; author response suggests remote computer randomisation sequence generation.
Allocation concealment (selection bias)	Unclear risk	Comment: unclear risk of bias because author responded that sealed envelopes were opened by nurse but it's unclear if envelopes were sequentially numbered and opaque.

Van Leen 2013 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	***Outcome group: all outcomes (primary outcome)*** Comment: no information provided.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	***Outcome group: all outcomes (primary outcome)*** Quote: "Patients' skin was inspected weekly to assess the possible occurrence of a skin lesion" Comment: no information provided on the blinding of outcome assessment.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: all outcomes (primary outcome)*** Comment: no attrition identified; 2 cases were transferred to low-air-loss bed treatments after they developed category III ulcers.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

Vermette 2012

Study characteristics	
Methods	**Study objective**: to compare the efficacy of different surfaces in the prevention of pressure ulcers; to compare costs associated with the use of an inflated static overlay (ISO) with the standard treatment, which in the first author's facility consists of renting a microfluid static overlay (MSO) or a low-air-loss dynamic mattress (LALDM) with pulsation for moderate-risk to very high-risk patients; to evaluate patient comfort **Study design**: randomised controlled trial **Study grouping**: parallel group **Duration of follow-up**: maximum 14 days **Number of arms**: 2 **Single centre or multi-sites**: single centre **Study start date and end date**: recruited from September 2009 to mid-April 2010 **Setting**: acute care setting (a medical, surgical, active geriatric, or an intensive care unit (ICU) ward of a hospital)
Participants	**Baseline characteristics** **Inclusion criteria**: had a Braden score of ≤ 14, had no skin lesion(s); were ≥ 18 years; weighed < 300lb; and submitted signed consent **Exclusion criteria**: not described **Sex (M:F)**: 21:34 in MSO or LALDM; 23:32 in ISO **Age (years)**: mean 77.7 (SD 10.6) in MSO or LALDM, 77.9 (14.6) in ISO

Vermette 2012 *(Continued)*

	Baseline skin status: mean Braden 11.8 (SD 1.6) in MSO or LALDM; 12.3 (1.3) in ISO; at risk and no skin lesions **Group difference**: no difference **Total number of participants**: n = 110 **Unit of analysis**: individuals **Unit of randomisation (per patient)**: individuals
Interventions	**Intervention characteristics** Microfluid static overlay or low-air-loss dynamic mattress • **Description of interventions**: the rented surfaces used in the study are RIK® and TheraKair® (KCI Medical, San Antonio, TX) ... RIK® overlay ... consists of an microfluid static overlay (MSO) that has no memory foam ... The TheraKair® Visio is a low-air-loss dynamic mattress (LALDM) with pulsation ... 50 patients used an MSO and 5 patients used an LALDM • **NPIAP S3I classification:** non-powered, reactive surface; undefined in NPIAP S3I & powered, alternating pressure (active) low-air-loss air surface • **Co-interventions**: identical positioning protocols • **Number of participants randomised**: n = 55 • **Number of participants analysed**: n = 55 Inflated static overlay • **Description of interventions**: the Waffle® overlay (EHOB, Indianapolis, IN) is a plastic, inflated static overlay (ISO) that reduces pressure and requires proper inflation (air between the mattress and skin) to optimise prevention of pressure ulcers • **NPIAP S3I classification:** non-powered, reactive air surface • **Co-interventions**: identical positioning protocols • **Number of participants randomised**: n = 55 • **Number of participants analysed**: n = 55
Outcomes	*Proportion of participants developing a new pressure ulcer* • **Outcome type**: binary • **Time points**: 14 days • **Reporting**: fully reported • **Measurement method (e.g. scale, self-reporting)**: classified according to the 6 grades of the National Pressure Ulcer Advisory Panel as Stage I, Stage II, Stage III, Stage IV, suspected deep tissue • **Definition (including ulcer stage)**: the development of a pressure ulcer within the maximum 2-week period of participation • **Dropouts**: no missing • **Notes (e.g. other results reported)**: 6 of 55 in MSO or LALDM; 2 of 55 in ISO *Time to pressure ulcer incidence* • **Reporting**: not reported *Support-surface-associated patient comfort* • **Outcome type**: binary • **Time points**: not specified • **Reporting**: partially reported • **Measurement method (e.g. scale, self-reporting)**: patients-self rated comfort level on a scale of 1 to 5, 1 indicating very comfortable and 5 indicating not comfortable • **Definition**: the number of subjects with ratings of 1, 2 or 3 (indicating comfort) • **Dropouts**: 68 expressed opinions regarding comfort

Vermette 2012 *(Continued)*

- **Notes**: 27 of 30 in MSO or LALDM, 29 of 34 in ISO

All reported adverse events using allocated support surfaces

- **Reporting**: not reported

Health-related quality of life (HRQOL)

- **Reporting**: not reported

Cost-effectiveness

- **Reporting**: not reported
- **Notes**: total costs associated with the surfaces 16,086 Canadian dollars in MSO or LALDM and 3,364 Canadian dollars in ISO

Outcomes that are not considered in this review but reported in trials:

- Costs

Notes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants were randomly assigned a rented surface (MSO or LALDM) or an ISO. Once subject consent was obtained and signed, the allocation sequence for mattress type was done by draw by the research nurse using an opaque envelope and the subject witnessing the draw" Comment: low risk of bias because it is likely trial used a proper randomisation method.
Allocation concealment (selection bias)	Unclear risk	Quote: "The allocation sequence was concealed from the research nurse enrolling and assessing the participants" Comment: unclear risk of bias because concealment approach is not specified.
Blinding of participants and personnel (performance bias) All outcomes	High risk	***Outcome group: all outcomes*** Quote: "The purpose of this unblinded, randomised, prospective study ..." Quote: "Blinding was not obtained for the patient, the clinical staff, or the research evaluator because the surfaces were visible" Comment: high risk of bias because non-blinding is clearly stated.
Blinding of outcome assessment (detection bias) All outcomes	High risk	***Outcome group: all outcomes*** Quote: "The purpose of this unblinded, randomised, prospective study ..." Quote: "Blinding was not obtained for the patient, the clinical staff, or the research evaluator because the surfaces were visible" Comment: high risk of bias because non-blinding is clearly stated.
Incomplete outcome data (attrition bias) All outcomes	Low risk	***Outcome group: primary outcome*** Quote: "Analyses were performed in intention-to-treat involving all 110 randomly assigned patients" Comment: intention-to-treat (ITT) analysis conducted.

Vermette 2012 *(Continued)*

		Outcome group: comfort outcome Quote: "Of the 110 participants, 68 expressed opinions regarding comfort" Comment: high risk of bias because 42 of 110 missed.
Selective reporting (reporting bias)	Low risk	Comment: the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified.
Other bias	Low risk	Comment: the study appears to be free of other sources of bias.

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

Study	Reason for exclusion
ACTRN12618000319279	Treatment study
Andersen 1982	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Andrews 1988	Ineligible study design - not a RCT
Anonymous 2006	Ineligible study design - review article
Aronovitch 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Ballard 1997	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Bell 1993	Ineligible study design - not a RCT
Berthe 2007	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Bliss 1966	Ineligible study design - not a RCT
Bliss 1967	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Bliss 1993	Ineligible study design - review article
Bliss 1995a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Bliss 1995b	Ineligible study design - review article
Bliss 2003	Reproduction of previous work
Bliss 2004	Commentary on a trial
Branom 1999	Treatment study
Branom 2001	Treatment study

Study	Reason for exclusion
Brown 2001	Summary of the Cochrane Review McInnes 2015
Bueno de Camargo 2018	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Cadue 2008	This RCT was to compare heel suspending device with the package of interventions
Caley 1994	Treatment study
Cassino 2013a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Cassino 2013b	Incorrect randomisation method (alternation to allocate patients into groups)
Chaloner 2000a	Incorrect randomisation method (quasi-randomisation)
ChiCTR1800017466	Ineligible interventions
Chou 2013	Review articles
Collier 1996	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Conine 1990	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Cummins 2019	Ineligible study design - quality improvement project without RCT design
Daechsel 1985	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Day 1993	Treatment study
Defloor 2005	Ineligible interventions - different combinations of turning and support surfaces under evaluations
Demarre 2012	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
De Oliveira 2017	Review article
Devine 1995	Treatment study
Economides 1995	This RCT was to observe the breakdown of flaps after operations rather than the incidence of new ulcers
Evans 2000	Treatment study
Ewing 1964	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Exton-Smith 1982	This trial used alternation to allocate patients into groups. Proper randomisation not completed.
Ferrell 1993	Treatment study
Ferrell 1995	Treatment study

Study	Reason for exclusion
Feuchtinger 2006	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Fleischer 1997	Ineligible study design
García Fernández 2004	Commentary on a RCT
Gazzerro 2008	Ineligible outcome (wound healing of flap surgery)
Gebhardt 1994a	Incorrect randomisation method (randomisation based on participants' hospital numbers)
Gebhardt 1994b	Incorrect randomisation method (randomisation based on participants' hospital numbers)
Gebhardt 1996	Incorrect randomisation method
Geelkerken 1994	Commentary
Goldstone 1982	Incorrect randomisation method
Gray 1994	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Gray 2000	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Gray 2008	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Greer 1988	Treatment study
Grindley 1996	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Groen 1999	Treatment study
Gunningberg 2000	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Gunningberg 2001	Ineligible study design (cross sectional design)
Haalboom 1994	Commentary
Hale 1990	Ineligible study design (cost analysis without RCT data)
Hampton 1997	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Hampton 1998	Ineligible study design (not a RCT)
Hampton 1999	Ineligible study design (not a RCT)
Hawkins 1997	Ineligible study design (not a RCT)
Hofman 1994	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)

Study	Reason for exclusion
Holzgreve 1993	Ineligible study design (not a RCT)
Hommel 2008	Ineligible study design (not a RCT)
Hoshowsky 1994	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Hoskins 2007a	Summary of findings of Nixon 2006
Hoskins 2007b	Summary of findings of Nixon 2006
Huang 2013	Review article
Huang 2018	Ineligible interventions (head pad rather than beds or mattresses)
Hungerford 1998	Commentary on a RCT
Iglesias 2006	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
IRCT2015110619919N3	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
IRCT2016091129781N1	Ineligible interventions (cushions rather than beds or mattresses)
Ismail 2001	Support surfaces used were not clearly specified. Unable to know if the interventions were eligible for this review
Jolley 2004	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
JPRN-UMIN000029680	Treatment study
Kemp 1993	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Keogh 2001	Ineligible interventions (profiling bed rather than beds or mattresses)
Klein 1989	Review article
Laurent 1998	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Lee 1974	Ineligible study design (not a RCT)
Maklebust 1988	Ineligible interventions (cushions rather than beds or mattresses)
Marutani 2019	Incorrect randomisation method
Mastrangelo 2010a	Treatment study
McGinnis 2011	Review article
McGowan 2000	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)

Study	Reason for exclusion
McInnes 2015	Review article
McInnes 2018	Review article
Mendoza 2019	Ineligible participants and outcome (flap closure)
Mistiaen 2010a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Mistiaen 2010b	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Nakahara 2012	Ineligible study design (not a RCT)
NCT01402765	Ineligible outcome (interface pressure)
NCT02565797	Ineligible study design (case control design)
NCT02634892	RCT with the comparison of reactive air surfaces versus standard hospital surfaces withdrawn due to funding issue
NCT02735135	Withdrew trial record with the reason of 'methodological difficulties'
NCT03048357	Ineligible interventions (rotation therapy versus turning)
NCT03211910	Ineligible interventions (not beds or mattresses)
NCT03351049	Ineligible interventions (reactive air surfaces versus reactive surfaces)
Nixon 1998	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Nixon 2006	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Nixon 2019	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Ooka 1995	Ineligible study design (not a RCT)
Osterbrink 2005	Treatment study
Ozyurek 2015	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Park 2017	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Phillips 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Pring 1998	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Rae 2018	Review article

Study	Reason for exclusion
Rafter 2011	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Reddy 2006	Review article
Reddy 2008	Review article
Ricci 2013a	Treatment study
Ricci 2013b	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Rithalia 1995	Ineligible participants (healthy people)
Rosenthal 2003	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Russell 1999	Treatment study
Russell 2000a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Russell 2000b	Treatment study
Russell 2000c	Treatment study
Russell 2003a	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Russell 2003b	Treatment study
Sanada 2003	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Santy 1994	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Santy 1995	Review article
Sauvage 2017	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Scheffel 2011	Summary of a review
Schultz 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Scott 2000	Ineligible interventions
Scott-Williams 2006	Ineligible study design (not a RCT)
Serraes 2018	Review article
Shakibamehr 2019	Ineligible interventions (cushions rather than beds or mattresses)

Study	Reason for exclusion
Sharp 2007	Ineligible study design
Shi 2018a	Review article
Smith 2013	Review article
Stannard 1993	Commentary on a RCT
Stapleton 1986	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Sterzi 2003	Ineligible study design (not a RCT)
Strauss 1991	Treatment study
Takala 1994	Ineligible study design (not a RCT)
Taylor 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Tewes 1993	Review article
Theaker 2005	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Vanderwee 2005	Ineligible intervention (imbalanced use of co-interventions between study arms)
Van Leen 2018	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Van Rijswijk 1994	Commentary
Vyhlidal 1997	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Wallace 2009	Review article
Whitney 1984	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Whittingham 1999	Ineligible interventions (i.e. comparisons of interventions that are ineligible for inclusion in this review)
Yao 2018	Review article

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

Chaloner 2000b

Methods	Not available
Participants	Not available
Interventions	Two types of alternating pressure air surfaces

Chaloner 2000b *(Continued)*

Outcomes	Not available
Notes	Unable to obtain its full text

Gardner 2008

Methods	Randomised controlled trial (two-arm)
Participants	**Inclusion criteria**: patients at risk of pressure injury (Waterlow score > 9) **Exclusion criteria**: under 16 years; unable to tolerate extended time lying supine; and with sacral pressure injury of Stage 2 or above. **Number of participants**: 66 **Age**: on average 68 years **Gender** (M:F): 34:25 **Baseline skin status**: at risk of ulcer (Waterlow score > 9), without existing severe ulcers.
Interventions	Airflotation and Ruby mattress • **Description of interventions**: an alternating pressure air mattress • **NPIAP S3I classification:** powered, alternating pressure, active, air surface ComfortPlus mattress • **Description of interventions**: unspecified, probably foam surfaces • **NPIAP S3I classification:** non-powered, reactive, foam surfaces
Outcomes	**Outcomes of interest to this review** • Unspecified **Outcomes unrelated to this review** • Interface pressure
Notes	

Henn 2004

Methods	Not available
Participants	Not available
Interventions	Alternating pressure air surfaces and a type of surface that cannot be defined
Outcomes	Not available
Notes	Unable to obtain its full text

Knight 1999

Methods	Not available
Participants	Not available
Interventions	Pressure relieving surfaces that cannot be defined
Outcomes	Not available
Notes	Unable to obtain its full text

Mastrangelo 2010b

Methods	Not available
Participants	Not available
Interventions	'Anti-decubitis lesion mattress cover' that cannot be defined
Outcomes	Not available
Notes	Unable to obtain its full text

Melland 1998

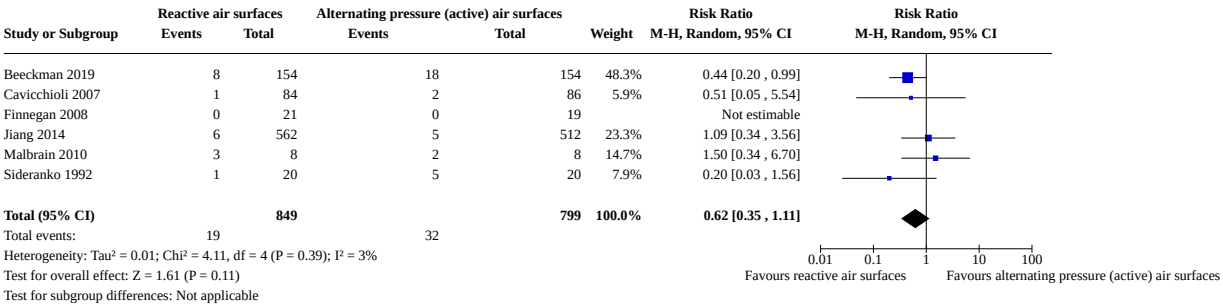
Methods	Not available
Participants	Not available
Interventions	'Freedom bed' that cannot be defined
Outcomes	Not available
Notes	Unable to obtain its full text

DATA AND ANALYSES

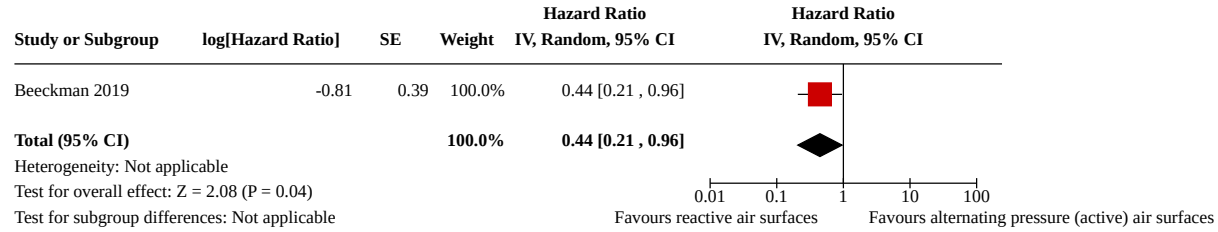
Comparison 1. Reactive air surfaces compared with alternating pressure (active) air surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Proportion of participants developing a new pressure ulcer	6	1648	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.35, 1.11]
1.2 Time-to-pressure ulcer incidence	1		Hazard Ratio (IV, Random, 95% CI)	0.44 [0.21, 0.96]

Analysis 1.1. Comparison 1: Reactive air surfaces compared with alternating pressure (active) air surfaces, Outcome 1: Proportion of participants developing a new pressure ulcer



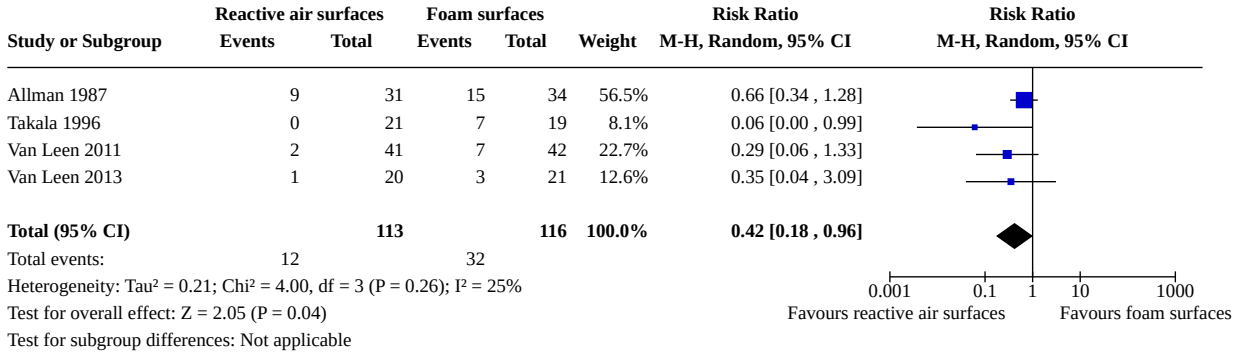
Analysis 1.2. Comparison 1: Reactive air surfaces compared with alternating pressure (active) air surfaces, Outcome 2: Time-to-pressure ulcer incidence



Comparison 2. Reactive air surfaces compared with foam surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Proportion of participants developing a new pressure ulcer	4	229	Risk Ratio (M-H, Random, 95% CI)	0.42 [0.18, 0.96]

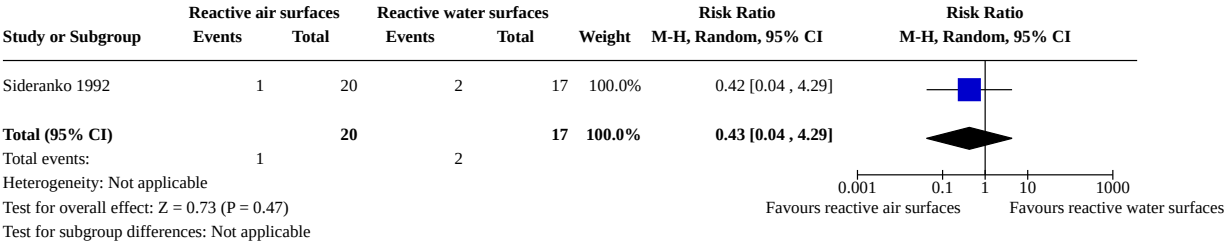
Analysis 2.1. Comparison 2: Reactive air surfaces compared with foam surfaces, Outcome 1: Proportion of participants developing a new pressure ulcer



Comparison 3. Reactive air surfaces compared with reactive water surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Proportion of participants developing a new pressure ulcer	1	37	Risk Ratio (M-H, Random, 95% CI)	0.43 [0.04, 4.29]

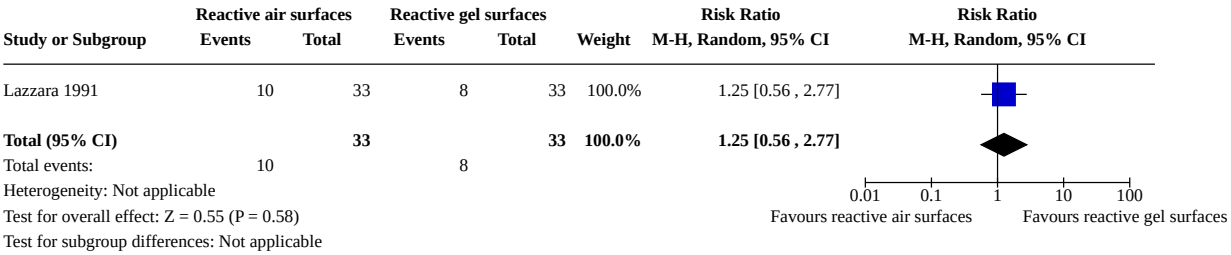
Analysis 3.1. Comparison 3: Reactive air surfaces compared with reactive water surfaces, Outcome 1: Proportion of participants developing a new pressure ulcer



Comparison 4. Reactive air surfaces compared with reactive gel surfaces

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Proportion of participants developing a new pressure ulcer	1	66	Risk Ratio (M-H, Random, 95% CI)	1.25 [0.56, 2.77]

Analysis 4.1. Comparison 4: Reactive air surfaces compared with reactive gel surfaces, Outcome 1: Proportion of participants developing a new pressure ulcer



ADDITIONAL TABLES

Table 1. All reported adverse events

Study ID	Reactive air surfaces	Foam surfaces on top of alternating pressure (active) air surfaces	Comment
Allman 1987	Death: 8	Death: 7	Some patients appeared to have

Table 1. All reported adverse events *(Continued)*

	Pneumonia: 2 Urinary tract infections: 10 Hypotension: 6 Hypernatraemia: 5 Oliguria: 5 Sepsis: 7 Fever: 16 Heart failure: 3	Pneumonia: 4 Urinary tract infections: 7 Hypotension: 7 Hypernatraemia: 5 Oliguria: 8 Sepsis: 6 Fever: 22 Heart failure: 6	multiple adverse events.

Table 2. Support-surface-associated patient comfort results in the included studies

Study ID	Reactive air surfaces	Alternating pressure (active) air surfaces	Comment
Cavicchioli 2007	Dropouts due to discomfort and/or not agreeing to use the assigned modality in continuous low pressure: n = 4	Dropouts due to discomfort and/or not agreeing to use the assigned modality in alternating low pressure: n = 5	
Finnegan 2008	Comfortable: 4/18 Uncomfortable: 7/18 No view: 7/18	Comfortable: 11/15 Uncomfortable: 2/15 No view: 2/15	Subject acceptability - numbers of patients having comfortable response on support surfaces.
Jiang 2014	More than the median of score four: 68/482 Less than the median: 414/482	More than the median of score four: 68/462 Less than the median: 394/462	The level of patients' comforts measured via asking patients' feelings after using the mattress (1 = very uncomfortable, 2 = uncomfortable, 3 = just comfortable, 4 = comfortable, 5 = very comfortable). $Chi^2 = 0.071$, P = 0.789
Price 1999	Mean 67 (SD 18) for 24 individuals in Repose	Mean 60 (SD 25) for 26 individuals in NIMBUS II	Patient comfort measured using a 100 mm visual analogue scale.

Table 3. Pressure ulcer incidence results reported in studies that compared different types of reactive air surfaces

Study ID	Results		Comment
Comparison: reactive air surfaces compared with other types of reactive air surfaces			
Cobb 1997	Reactive air surfaces (KinAir) • Proportion of participants developing a new pressure ulcer: 8 of 62 (12.9%)	Reactive air surfaces (EHOB Waffle) • Proportion of participants developing a new pressure ulcer: 12 of 61 (19.7%)	• Proportion of participants developing a new pressure ulcer: RR 0.66 (95% CI 0.29 to 1.49). • Time to pressure ulcer incidence: Mann-Whitney U-test = 113, P = 0.182 for median time to ulcer incidence; Kaplan Meier plot reported (log-rank $Chi^2 = 0.013$, df = 1, P = 0.911); HR 0.96 (95% CI 0.50 to 1.87) estimat-

Table 3. Pressure ulcer incidence results reported in studies that compared different types of reactive air surfaces *(Continued)*

	• Time to pressure ulcer incidence: see comment	• Time to pressure ulcer incidence: see comment	ed by the review authors using the methods of Tierney 2007.
Cooper 1998	Reactive air surfaces (Softflex) • Proportion of participants developing a new pressure ulcer: 3/51 (5.9%)	Reactive air surfaces (ROHO) • Proportion of participants developing a new pressure ulcer: 5/49 (10.2%)	• Proportion of participants developing a new pressure ulcer: RR 0.58 (95% CI 0.15 to 2.28).

APPENDICES

Appendix 1. Full details of support surfaces classifications

Overarching class of support surface (as used in this review)	Corresponding subclasses of support surfaces used in Shi 2018a	Descriptions of support surfaces	Selected examples (with example brands where possible)
Reactive air surfaces	Powered/non-powered reactive air surfaces	A group of support surfaces constructed of air cells, which redistribute body weight over a maximum surface area (i.e. has reactive pressure redistribution mode), with or without the requirement for electrical power	Static air mattress overlay, dry flotation mattress (e.g. ROHO, Softflex), static air mattress (e.g. EHOB), and static mode of Duo 2 mattress
	Powered/non-powered reactive low-air-loss air surfaces	A group of support surfaces made of air cells, which have reactive pressure redistribution modes and a low-air-loss function, with or without the requirement for electrical power	Low-air-loss Hydrotherapy
	Powered reactive air-fluidised surfaces	A group of support surfaces made of air cells, which have reactive pressure redistribution modes and an air-fluidised function, with the requirement for electrical power	Air-fluidised bed (e.g. Clinitron)
Foam surfaces	Non-powered reactive foam surfaces	A group of support surfaces made of foam materials, which have a reactive pressure redistribution function, without the requirement for electrical power	Convoluted foam overlay (or pad), elastic foam overlay (e.g. Aiartex, microfluid static overlay), polyether foam pad, foam mattress replacement (e.g. MAXIFLOAT), solid foam overlay, viscoelastic foam mattress/overlay (e.g. Tempur, CONFOR-Med, Akton, Thermo)
Alternative reactive support surfaces (non-foam or air-filled): reactive fibre surfaces	Non-powered reactive fibre surfaces	A group of support surfaces made of fibre materials, which have a reactive pressure redistribution function, without the requirement for electrical power	Silicore (e.g. Spenco) overlay/pad

(Continued)

Alternative reactive support surfaces (non-foam or air-filled): reactive gel surfaces	Non-powered reactive gel surfaces	A group of support surfaces made of gel materials, which have a reactive pressure redistribution function, without the requirement for electrical power	Gel mattress, gel pad used in operating theatre
Alternative reactive support surfaces (non-foam or air-filled): reactive sheepskin surfaces	Non-powered reactive sheepskin surfaces	A group of support surfaces made of sheepskin, which have a reactive pressure redistribution function, without the requirement for electrical power	Australian Medical Sheepskins overlay
Alternative reactive support surfaces (non-foam or air-filled): reactive water surfaces	Non-powered reactive water surfaces	A group of support surfaces based on water, which has the capability of a reactive pressure redistribution function, without the requirement for electrical power	Water mattress
Alternating pressure (active) air surfaces	Powered active air surfaces	A group of support surfaces made of air cells, which mechanically alternate the pressure beneath the body to reduce the duration of the applied pressure (mainly via inflating and deflating to alternately change the contact area between support surfaces and the body) (i.e. alternating pressure, or active, mode), with the requirement for electrical power	Alternating pressure-relieving air mattress (e.g. Nimbus II, Cairwave, Airwave, MicroPulse), large-celled ripple
	Powered active low-air-loss air surfaces	A group of support surfaces made of air cells, which have the capability of alternating pressure redistribution as well as low-air-loss for drying local skin, with the requirement for electrical power	Alternating pressure low-air-loss air mattress
	Powered hybrid system air surfaces	A group of support surfaces made of air cells, which offer both reactive and active pressure redistribution modes, with the requirement for electrical power	Foam mattress with dynamic and static modes (e.g. Softform Premier Active)
	Powered hybrid system low-air-loss air surfaces	A group of support surfaces made of air cells, which offer both reactive and active pressure redistribution modes as well as a low-air-loss function, with the requirement for electrical power	Stand-alone bed unit with alternating pressure, static modes and low air-loss (e.g. TheraPulse)
Standard hospital surfaces	Standard hospital surfaces	A group of support surfaces made of any materials, used as-usual in a hospital and without reactive or active pressure redistribution capabilities, nor any other functions (e.g. low-air-loss, or air-fluidised).	Standard hospital (foam) mattress, National Health Service Contract hospital mattress, standard operating theatre surface configuration, standard bed unit and usual care

Appendix 2. Search strategies

Cochrane Wounds Specialised Register

1 MESH DESCRIPTOR beds EXPLODE ALL AND INREGISTER

2 mattress* AND INREGISTER

3 (foam or transfoam) AND INREGISTER

4 overlay* AND INREGISTER

5 (pad or pads) AND INREGISTER

6 gel AND INREGISTER

7 (pressure NEXT relie*) AND INREGISTER

8 (pressure NEXT reduc*) AND INREGISTER

9 (pressure NEXT alleviat*) AND INREGISTER

10 ("low pressure" near2 device*) AND INREGISTER

11 ("low pressure" near2 support) AND INREGISTER

12 (constant near2 pressure) AND INREGISTER

13 "static air" AND INREGISTER

14 (alternat* next pressure) AND INREGISTER

15 (air next suspension*) AND INREGISTER

16 (air next bag*) AND INREGISTER

17 (water next suspension*) AND INREGISTER

18 sheepskin AND INREGISTER

19 (turn* or tilt*) next (bed* or frame*) AND INREGISTER

20 kinetic next (therapy or table*) AND INREGISTER

21 (net next bed*) AND INREGISTER

22 #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 AND INREGISTER

23 MESH DESCRIPTOR Pressure Ulcer EXPLODE ALL AND INREGISTER

24 (pressure next (ulcer* or sore* or injur*)) AND INREGISTER

25 (decubitus next (ulcer* or sore*)) AND INREGISTER

26 ((bed next sore*) or bedsore*) AND INREGISTER

27 #23 OR #24 OR #25 OR #26 AND INREGISTER

28 #22 AND #27 AND INREGISTER

The Cochrane Central Register of Controlled Clinical Trials (CENTRAL)

#1 MeSH descriptor: [Beds] explode all trees

#2 mattress*:ti,ab,kw

#3 (foam or transfoam):ti,ab,kw

#4 overlay*:ti,ab,kw

#5 "pad" or "pads":ti,ab,kw

#6 "gel":ti,ab,kw

#7 (pressure next relie*):ti,ab,kw

#8 (pressure next reduc*):ti,ab,kw

#9 (pressure next alleviat*):ti,ab,kw

#10 ("low pressure" near/2 device*):ti,ab,kw

#11 ("low pressure" near/2 support):ti,ab,kw

#12 (constant near/2 pressure):ti,ab,kw

#13 "static air":ti,ab,kw

#14 (alternat* next pressure):ti,ab,kw

#15 (air next suspension*):ti,ab,kw

#16 (air next bag*):ti,ab,kw

#17 (water next suspension*):ti,ab,kw

#18 sheepskin:ti,ab,kw

#19 (turn* or tilt*) next (bed* or frame*):ti,ab,kw

#20 kinetic next (therapy or table*):ti,ab,kw

#21 (net next bed*):ti,ab,kw

#22 {or #1-#21}

#23 MeSH descriptor: [Pressure Ulcer] explode all trees

#24 (pressure next (ulcer* or sore* or injur*)):ti,ab,kw

#25 (decubitus next (ulcer* or sore*)):ti,ab,kw

#26 ((bed next sore*) or bedsore*):ti,ab,kw

#27 {or #23-#26}

#28 (#22 and #27) in Trials

Ovid MEDLINE

1 exp Beds/

2 mattress*.mp.

3 (foam or transfoam).mp.

4 overlay*.mp.

5 (pad or pads).ti,ab.

6 gel.ti,ab.

7 pressure relie*.mp.

8 pressure reduc*.mp.

9 pressure alleviat*.mp.

10 (low pressure adj2 device*).mp.

11 (low pressure adj2 support).mp.

12 (constant adj2 pressure).mp.

13 static air.mp.

14 (alternat* adj pressure).mp.

15 air suspension*.mp.

16 air bag*.mp.

17 water suspension*.mp.

18 sheepskin.mp.

19 ((turn* or tilt*) adj (bed* or frame*)).mp.

20 (kinetic adj (therapy or table*)).mp.

21 net bed*.mp.

22 or/1-21

23 exp Pressure Ulcer/

24 (pressure adj (ulcer* or sore*)).mp.

25 (decubitus adj (ulcer* or sore*)).mp.

26 (bed adj (ulcer* or sore*)).mp.

27 or/23-26

28 and/22,27

29 randomized controlled trial.pt.

30 controlled clinical trial.pt.

31 randomi?ed.ab.

32 placebo.ab.

33 clinical trials as topic.sh.

34 randomly.ab.

35 trial.ti.

36 or/29-35

37 exp animals/ not humans.sh.

38 36 not 37

39 28 and 38

Ovid Embase

1 exp Bed/

2 mattress*.mp.

3 (foam or transfoam).mp.

4 overlay*.mp.

5 (pad or pads).ti,ab.

6 gel.ti,ab.

7 pressure relie*.mp.

8 pressure reduc*.mp.

9 pressure alleviat*.mp.

10 (low pressure adj2 device*).mp.

11 (low pressure adj2 support).mp.

12 (constant adj2 pressure).mp.

13 static air.mp.

14 (alternat* adj pressure).mp.

15 air suspension*.mp.

16 air bag*.mp.

17 water suspension*.mp.

18 sheepskin.mp.

19 ((turn* or tilt*) adj (bed* or frame*)).mp.

20 (kinetic adj (therapy or table*)).mp.

21 net bed*.mp.

22 or/1-21

23 exp Decubitus/

24 (pressure adj (ulcer* or sore*)).mp.

25 (decubitus adj (ulcer* or sore*)).mp.

26 (bed adj (ulcer* or sore*)).mp.

27 or/23-26

28 and/22,27

29 Randomized controlled trials/

30 Controlled clinical study/

31 Single-Blind Method/

32 Double-Blind Method/

33 Crossover Procedure/

34 (random* or factorial* or crossover* or cross over* or cross-over* or placebo* or assign* or allocat* or volunteer*).ti,ab.

35 (doubl* adj blind*).ti,ab.

36 (singl* adj blind*).ti,ab.

37 or/29-36

38 exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal tissue/ or animal cell/ or nonhuman/

39 human/ or human cell/

40 and/38-39

41 38 not 40

42 37 not 41

43 28 and 42

EBSCO CINAHL Plus

S50 S26 AND S49

S49 S48 NOT S47

S48 S27 OR S28 OR S29 OR S30 OR S31 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41

S47 S45 NOT S46

S46 MH (human)

S45 S42 OR S43 OR S44

S44 TI (animal model*)

S43 MH (animal studies)

S42 MH animals+

S41 AB (cluster W3 RCT)

S40 MH (crossover design) OR MH (comparative studies)

S39 AB (control W5 group)

S38 PT (randomized controlled trial)

S37 MH (placebos)

S36 MH (sample size) AND AB (assigned OR allocated OR control)

S35 TI (trial)

S34 AB (random*)

S33 TI (randomised OR randomized)

S32 MH cluster sample

S31 MH pretest-posttest design

S30 MH random assignment

S29 MH single-blind studies

S28 MH double-blind studies

S27 MH randomized controlled trials

S26 S20 AND S25

S25 S21 OR S22 OR S23 OR S24

S24 TI decubitus or AB decubitus

S23 TI (bed sore* or bedsore*) or AB (bed sore* or bedsore*)

S22 TI (pressure ulcer* or pressure sore*) or AB (pressure ulcer* or pressure sore*)

S21 (MH "Pressure Ulcer")

S20 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19

S19 TI net bed* or AB net bed*

S18 TI (kinetic therapy or kinetic table*) or AB (kinetic therapy or kinetic table*)

S17 TI (turn* bed* or tilt* bed*) or AB (turn* frame* or tilt* frame*)

S16 TI sheepskin OR AB sheepskin

S15 TI water suspension or AB water suspension

S14 TI air bag* or AB air bag*

S13 TI air suspension or AB air suspension

S12 TI alternat* pressure or AB alternat* pressure

S11 TI static air or AB static air

S10 TI constant N2 pressure or AB constant N2 pressure

S9 TI low pressure N2 support or AB low pressure N2 support

S8 TI low pressure N2 device* or AB low pressure N2 device*

S7 TI pressure alleviat* or AB pressure alleviat*

S6 TI pressure reduc* or AB pressure reduc*

S5 TI pressure relie* or AB pressure relie*

S4 TI (overlay* or pad or pads or gel) or AB (overlay* or pad or pads or gel)

S3 TI (foam or transfoam) or AB (foam or transfoam)

S2 TI mattress* or AB mattress*

S1 (MH "Beds and Mattresses+")

US National Institutes of Health Ongoing Trials Register (ClinicalTrials.gov)

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcer

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Injury

bed OR mattress OR sheepskin OR gel OR pad OR foam OR pressure OR support OR air | Pressure Ulcers buttock

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Ulcer, Pressure

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcer Stage 1

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcers Stage II

bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air | Pressure Ulcers Stage III

World Health Organization International Clinical Trials Registry Platform

pressure ulcer [title] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure ulcer [condition] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure injury [title] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

pressure injury [condition] and bed OR mattress OR sheepskin OR gel OR pad OR foam OR support OR air [intervention]

Appendix 3. Risk of bias

1 'Risk of bias' assessment in individually randomised controlled trials

1. Was the allocation sequence randomly generated?

Low risk of bias

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

High risk of bias

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

Unclear

Insufficient information about the sequence generation process to permit judgement of low or high risk of bias.

2. Was the treatment allocation adequately concealed?

Low risk of bias

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

High risk of bias

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

Unclear

Insufficient information to permit judgement of low or high risk of bias. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement, for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.

3. Blinding: was knowledge of the allocated interventions by participants and personnel adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding.
- Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.

High risk of bias

Any one of the following.

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

Unclear

Any one of the following.

- Insufficient information to permit a judgement of low or high risk of bias.
- The study did not address this outcome.

4. Blinding: was knowledge of the allocated interventions by outcome assessors adequately prevented during the study?

Low risk of bias

Any one of the following.

- No blinding, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding.
- Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.

High risk of bias

Any one of the following.

- No blinding or incomplete blinding, and the outcome measurement is likely to be influenced by lack of blinding.
- Blinding of outcome assessment attempted, but likely that the blinding could have been broken.

Unclear

Any one of the following.

- Insufficient information to permit a judgement of low or high risk of bias.
- The study did not address this outcome.

5. Were incomplete outcome data adequately addressed?

Low risk of bias

Any one of the following.

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

High risk of bias

Any one of the following.

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

Unclear

Any one of the following.

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

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

Low risk of bias

Any of the following.

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

High risk of bias

Any one of the following.

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

Unclear

Insufficient information to permit judgement of low or high risk of bias. It is likely that the majority of studies will fall into this category.

7. Other sources of potential bias

Low risk of bias

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

High risk of bias

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

- had a potential source of bias related to the specific study design used; or
- has been claimed to have been fraudulent; or
- had some other problem.

Unclear

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

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

2 'Risk of bias' assessment in cluster-randomised controlled trials (cluster-RCTs)

1. Recruitment bias

Recruitment bias (or identification bias) is the bias that occurs in cluster-RCTs if the personnel recruiting participants know individuals' allocation, even when the allocation of clusters has been concealed appropriately. The knowledge of the allocation of clusters may lead to bias because the individuals' recruitment in cluster trials is often behind the clusters' allocation to different interventions; and the knowledge of allocation can determine whether individuals are recruited selectively.

This bias can be judged through considering the following questions.

- Were all the individual participants identified/recruited before randomisation of clusters?
- Is it likely that selection of participants was affected by knowledge of the intervention?
- Were there baseline imbalances that suggest differential identification or recruitment of individual participants between arms?

2. Baseline imbalance

Baseline imbalance between intervention groups can occur due to chance, problems with randomisation, or identification/recruitment bias. The issue of recruitment bias has been considered above.

In terms of study design, the risk of chance baseline imbalance can be reduced by the use of stratified or pair-matched randomisation. Minimisation — an equivalent technique to randomisation — can be used to achieve better balance in cluster characteristics between intervention groups if there is a small number of clusters.

Concern about the influence of baseline imbalance can be reduced if trials report the baseline comparability of clusters, or statistical adjustment for baseline characteristics.

3. Loss of clusters

Similar with missing outcome data in individually randomised trials, bias can occur if clusters are completely lost from a cluster trial, and are omitted from the analysis.

The amount of missing data, the reasons for missingness and the way of analysing data given the missingness should be considered in assessing the possibility of bias.

4. Incorrect analysis

Data analyses, which do not take the clustering into account, in cluster trials will be incorrect. Such analyses lead to a "unit of analysis error" and over-precise results (overly small standard error) and overly small P values. Though these analyses will not result in biased estimates of effect, they (if not correctly adjusted) will lead to too much weight allocated to cluster trials in a meta-analysis.

Note that the issue of analysis may not lead to concern any more and will not be considered substantial if approximate methods are used by reviewers to address clustering in data analysis.

5. Comparability with individually randomised trials

In the case that a meta-analysis includes, for example, both cluster-randomised and individually randomised trials, potential differences in the intervention effects between different trial designs should be considered. This is because the "contamination" of intervention effects may occur in cluster-randomised trials, which would lead to underestimates of effect. The contamination could be known as a "herd effect", i.e. within clusters, individuals' compliance with using an intervention may be enhanced, which in return affects the estimation of effect.

Appendix 4. Results of studies that were not analysed

Outcomes	Results
Comparison: Reactive air surfaces compared with undefined surfaces	
Proportion of participants developing a new pressure ulcer (follow-up duration minimum 14 days maximum 60 days)	• Two studies (216 participants) that compared reactive air surfaces with undefined 'standard hospital surfaces' reported inconsistent results: Bennett 1998 (116 participants) suggested no difference in the proportion of participants developing a new ulcer between reactive air surfaces and undefined surfaces (RR 2.00, 95% CI 0.64 to 6.28) whilst Inman 1993 (100 participants) suggested reactive air surfaces reduced the risk of having new pressure ulcers (RR 0.21, 95% CI 0.07 to 0.70). • Vermette 2012 (110 participants) compared reactive air surfaces with alternating pressure (active) air surfaces or RIK® microfluid static overlay (MSO), and reported that: 6 of 55 in MSO or low-air-loss dynamic mattress (LALDM); 2 of 55 in ISO (3.6%) using reactive air surfaces developed a new pressure ulcer and 6 of 55 (10.9%) using undefined reactive surfaces developed new ulcers. The RR is 0.33 (95% CI 0.07 to 1.58).
Support-surface-associated patient comfort (follow-up duration 14 days)	Vermette 2012 (110 participants) compared reactive air surfaces with alternating pressure (active) air surfaces or RIK® microfluid static overlay, and defined this outcome as participants self-rated comfort on a scale of 1 to 5 with 1 indicating very comfortable and 5 indicating not comfortable. In total, 68 participants rated comfort: 27 of 30 participants using undefined reactive surfaces and 29 of 34 using reactive air surfaces responded that they were comfortable or very comfortable.
Cost-effectiveness (follow-up duration 18.8 days)	Only Inman 1993 (100 participants; compared reactive air surfaces with undefined standard hospital surfaces) reported this outcome but did not express it as the incremental cost per health benefit gained. Inman 1993 reported that, when reactive air surfaces were used, the cost saved per 100 patients at risk was 6302.6 Canadian dollars; pressure ulcers prevented per 100 patients at risk were 64; and therefore, reactive air surfaces dominated standard hospital surfaces.

Appendix 5. Sensitivity analyses

Sensitivity analysis	Studies	Participants	Statistical Method	Effect Estimate
Comparison: Reactive air surfaces compared with alternating pressure (active) air surfaces				
Outcome: Proportion of participants developing a new pressure ulcer				
• Complete case analysis for addressing missing data	6	1611	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.35, 1.11]
• Fixed-effect model	6	1648	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.34, 1.00]
• Sensitivity analysis with time to pressure ulcer incidence as the primary outcome	1	308	Hazard Ratio (IV, Random, 95% CI)	0.44 [0.21 to 0.96]

(Continued)

Comparison: Reactive air surfaces compared with foam surfaces				
Outcome: Proportion of participants developing a new pressure ulcer				
• Fixed-effect model	4	229	Risk Ratio (M-H, Fixed, 95% CI)	0.40 [0.23, 0.72]

WHAT'S NEW

Date	Event	Description
18 August 2021	Amended	Minor amendment to include link to overview and network meta-analysis.

HISTORY

Protocol first published: Issue 5, 2020
Review first published: Issue 5, 2021

CONTRIBUTIONS OF AUTHORS

Chunhu Shi: conceived the review; designed the review; coordinated the review; extracted data; analysed or interpreted data; undertook quality assessment; performed statistical analysis; produced the first draft of the review; contributed to writing or editing the review; approved the final review prior to publication; is guarantor of the review.

Jo Dumville: conceived the review; designed the review; coordinated the review; analysed or interpreted data; checked quality of statistical analysis; produced the first draft of the review; contributed to writing or editing the review; advised on the review; secured funding; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Nicky Cullum: conceived the review; designed the review; coordinated the review; checked quality of data extraction; contributed to writing or editing the review; advised on the review; secured funding; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Sarah Rhodes: conceived the review; designed the review; checked quality of statistical analysis; contributed to writing or editing the review; approved the final review prior to publication.

Vannessa Leung: checked quality of data extraction; checked quality assessment; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Elizabeth McInnes: conceived the review; designed the review; coordinated the review; checked quality of data extraction; checked quality assessment; contributed to writing or editing the review; advised on the review; performed previous work that was the foundation of the current review; approved the final review prior to publication.

Contributions of the editorial base

Gill Norman (Editor): edited the protocol; advised on methodology, interpretation and content; approved the final protocol prior to publication.

Gill Rizzello (Managing Editor): coordinated the editorial process; advised on content; edited the protocol and the review.

Sophie Bishop (Information Specialist): designed the search strategy and edited the search methods section.

Tom Patterson (Editorial Assistant): edited the reference sections of the protocol and the review.

DECLARATIONS OF INTEREST

Chunhu Shi: I received research funding from the National Institute for Health Research (NIHR) (Research for Patient Benefit, Evidence synthesis for pressure ulcer prevention and treatment, PB-PG-1217-20006). I received support from the Tissue Viability Society to attend conferences unrelated to this work. The Doctoral Scholar Awards Scholarship and Doctoral Academy Conference Support Fund (University of Manchester) also supported a PhD and conference attendance respectively; both were unrelated to this work.

Jo Dumville: I am Chief Investigator on a National Institute for Health Research grant that funded the conduct of this review (Research for Patient Benefit, Evidence synthesis for pressure ulcer prevention and treatment, PB-PG-1217-20006). This research was co-funded by the National Institute for Health Research Manchester Biomedical Research Centre and partly funded by the National Institute for Health Research Applied Research Collaboration Greater Manchester.

Nicky Cullum: I am Co-investigator on a National Institute for Health Research grant that funded the conduct of this review (Research for Patient Benefit, Evidence synthesis for pressure ulcer prevention and treatment, PB-PG-1217-20006). This research was co-funded by the National Institute for Health Research Manchester Biomedical Research Centre, and partly funded by the National Institute for Health Research Applied Research Collaboration Greater Manchester.

My previous and current employers received research grant funding from the NHS Research and Development programme, and subsequently the NIHR, for previous versions of this review. The funders had no role in the conduct of the review. My previous employer received research grant funding from the NIHR for an RCT comparing different alternating pressure air surfaces for pressure ulcer prevention. This RCT (for which I was the Chief Investigator) was not eligible for inclusion in this review.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

- Two review authors independently assessed the titles and abstracts of the new search results for relevance using Rayyan rather than using Covidence.
- For new included studies, one review author independently extracted data and another review author checked all data, rather two review authors independently carrying out data extraction.
- When a study only had complete case data, we considered complete case data in the related main analysis (i.e. assuming no missing data issue). This was not pre-planned.

- We presented separate 'Summary of findings' tables for four of the five comparisons evaluated in this review. We did not present the table for the comparison between different types of reactive air surfaces.
- Where we did not pool data, we conducted a GRADE assessment and presented these assessments in a narrative format in 'Summary of findings' tables. This was not pre-planned.

INDEX TERMS

Medical Subject Headings (MeSH)

*Air; *Bedding and Linens; *Beds; Bias; *Elasticity; Pressure Ulcer [*prevention & control]; Randomized Controlled Trials as Topic; Viscoelastic Substances; Water

MeSH check words

Aged; Aged, 80 and over; Humans; Middle Aged