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Comparative effectiveness of heel-specific medical devices for the prevention of heel pressure ulcers: A systematic review

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ABSTRACT

Background: Pressure ulcers (PUs) impact on patient's quality of life and are costly for healthcare providers. Heels are a particular concern due to specific risk factors. Relative effectiveness of medical devices, e.g., dressings, off-loading devices, heel cushioning devices, to reduce PU development is unknown.
Methods: Systematic review of the effectiveness of heel-specific medical devices for the prevention of heel PU (HPU)s. Database searches were performed from inception to June 2021 for RCTs. The primary outcome was incidence of new HPUs. Trials were assessed for risk of bias and data analysed with risk ratios, mean difference or hazard ratios as appropriate.
Results: Fifteen RCTs (4724 participants) were identified.
Dressings, as constant low pressure (CLP) devices vs standard care: eight trials (very low quality) showed no-significant difference in effectiveness (RR 0.31, 95%CI 0.10 to 1.01).
Off-loading devices vs standard care: three trials (low quality), showed significant reduction in development of Category≥1 HPUs (RR 0.20, 95%CI 0.05 to 0.80) two trials (medium quality), showed significant reduction in development of Category≥2 HPUs (RR 0.08, 95%CI 0.01 to 0.67).
Comparisons between off-loading devices: two trials (low quality) showed no clear difference in HPU incidence. In a paediatric post-surgical population, one trial of off-loading device and one of a dressing (CLP device), both versus standard care, showed no clear difference in HPU incidence (RR 0.19 95%CI 0.02 to 1.55 and RR 0.89 95%CI 0.56 to 1.42 respectively).
Conclusions: Off-loading devices may reduce HPU incidence, from low-quality evidence. There is insufficient evidence to suggest that dressings reduce HPU incidence.

1. Background

1.1. Description of the condition

Pressure ulcers (PUs) are injuries to the skin and underlying tissues as a result of sustained pressure, which leads to a restriction in the blood flow to that area. PUs primarily affect people with reduced mobility, and those with poor tissue perfusion due to their medical condition [1,2]. Recent guidance also states that individuals with a high potential for friction and shear should be considered as being at risk of developing PUs [3]. PU prevention primarily aims to reduce the intensity and/or duration of pressure and shear.

The most common sites for PUs to develop are the sacrum and heel [4–6]. Whilst the heel has a thick dermis and fatty pad to absorb shock

Abbreviations: CI, Confidence Interval; CLP, Constant Low Pressure; HPU, Heel Pressure Ulcer; HR, Hazard Ratio; ITT, Intention to treat; MD, Mean Difference; NPIAP, National Pressure Injury Advisory panel; NPUAP/EPUAP/PPPIA, National Pressure Ulcer Advisory Panel/ European Pressure Ulcer Advisory Panel/Pan Pacific Pressure Injury Alliance; PAD, Peripheral Arterial Disease; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses; PU, Pressure Ulcer; RCT, Randomised Controlled Trial; RR, Risk Ratio; SMD, Standard Mean Difference.

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from the calcaneum when walking or running, the posterior surface has little subcutaneous tissue for cushioning and has a small surface area. In a supine position high pressures are exerted on the posterior heel, compressing soft tissue overlaying the bone.

Other heel-specific risk factors include:

- sparse blood supply to the skin over the heel [7].
- conditions that affect the circulation to the foot e.g., Peripheral Arterial Disease (PAD), diabetes, hypertension, and smoking [8].
- pedal oedema due to heart failure or chronic venous insufficiency; this impairs supply of oxygen and nutrients and removal of metabolic waste products [9] and increases the weight of the limb and therefore the pressure exerted on the heel
- peripheral neuropathy due to diabetes, neurological conditions e.g., stroke, multiple sclerosis, reduce sensation [10] such that the person does not feel the need to change position
- shear forces and friction due to poor positioning in bed or chair [11,12].

Some patient populations, such as those with hip fractures, with several contributing factors have elevated risk [13–15].

1.2. Description of the intervention

Many interventions seek to reduce either the intensity or the duration of pressure e.g., reduce or completely off-load the pressure at the heel using medical devices, or reduce the friction or sheer forces. Pressure-reducing devices can support the whole body e.g., beds, mattresses, or are heel-specific e.g., heel cups, boots, splints, wedges, troughs, foot protectors and dressings. Heel-specific devices can be categorised as:

a) constant low pressure (CLP) devices e.g., gel or foam heel pad/cup, booties which aim to distribute the pressure over a larger surface area
b) off-loading devices e.g., pillows, wedges or splints which prevent contact between the heel and the bed
c) low friction devices e.g., dressings or booties which reduce friction and sheer when the person moves their foot
d) devices with combinations of functions: e.g., prophylactic dressing or devices that reduce pressure and/or friction and shear e.g., multilayer heel dressings, medical grade sheepskin

1.3. Why it is important to do this review

Heel PUs (HPU)s can have a significant impact upon mobility and quality of life. Given the specific risk factors as described above, the effectiveness of PU preventative interventions may be different for the heels compared to other body sites.

The following reviews of evidence in this field have been identified:

A Cochrane review [16] of the evidence for devices for PU prevention included bed, mattresses, cushions and heel devices, however they did not review the evidence for dressings and made no recommendations about the use of HPU prevention devices.

A Cochrane review [17] investigated dressings and topical agents for the prevention of PUs. This review identified nine trials, however results for HPUs are not presented separately.

A systematic review reporting the use of prophylactic dressings for the prevention of PUs at any site [18] had a limited search strategy and included non-RCT evidence.

Two heel-specific reviews have been identified [19,20] with methodological limitations which may impact their findings.

The EPUAP/NPIAP/PPPIA [3] guidelines acknowledge that the heels have a particular risk of PU and a section is dedicated to HPU evidence and recommendations. Their methodology for evidence appraisal and recommendations is published [21],and the methods were based on Scottish Intercollegiate Guideline Network (SIGN) [22] with limited detail available regarding their search strategies. Their evidence review included only five of the trials analysed in this review [14,23–26], as their search date was to December 2017. Recommendations include off-loading of the heel using a heel suspension device or pillow and using a prophylactic dressing as an adjunct to heel off-loading and other prevention strategies. Both these recommendations are based on low to medium quality evidence and the strength of recommendations are 'expert opinions'.

It therefore remains unclear whether any heel specific devices prevent HPUs. It is also important to understand the cost-effectiveness of these devices as well as any impact on the user e.g., quality of life, mobility or increased pressure damage on other body sites from heel elevation.

Recent guidelines [3,27] recommended more good quality research into the effectiveness of heel-specific devices and prophylactic dressings. This systematic review contributes to the evidence base.

2. Methods

The protocol for the current study has been registered with PROSPERO [28] (CRD42019152949).

2.1. Aim

To determine the relative effectiveness of heel-specific medical devices for the prevention of HPUs.

2.2. Types of trials

Randomised controlled trials (RCTs) that compared the effects of medical devices on the incidence of new HPUs were included. RCTs of devices for preventing diabetic foot ulcers and non-heel-specific devices e.g., prophylactic dressings, were included if HPU data could be identified separately.

2.3. Types of participants

Trials that included people of any age in any care setting without pre-existing Category $\geq$2 HPU who were at risk of PUs were included.

2.4. Types of interventions

Any medical device designed to reduce pressure (duration or intensity), sheer, or friction at the heel used as an adjunct to standard care. Interventions were considered if they used one or more approaches. Interventions were grouped as follows:

- Heel-specific CLP devices (Fig. 1)
- Prophylactic dressings (Fig. 2)
- Heel-specific off-loading devices (Fig. 3)
- Heel-specific low friction devices (Fig. 4)

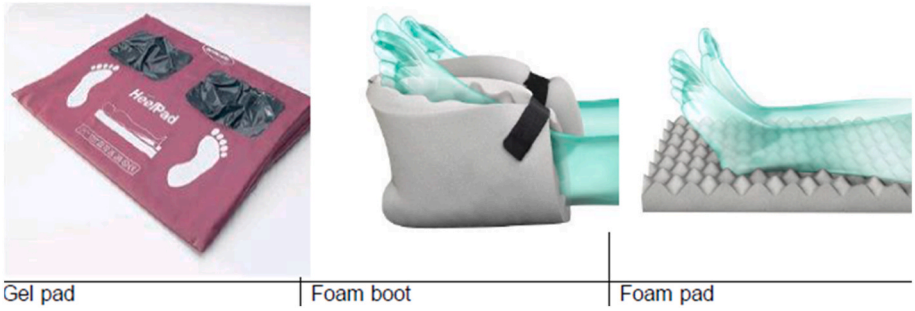

Fig. 1. Examples of heel-specific CLP devices.

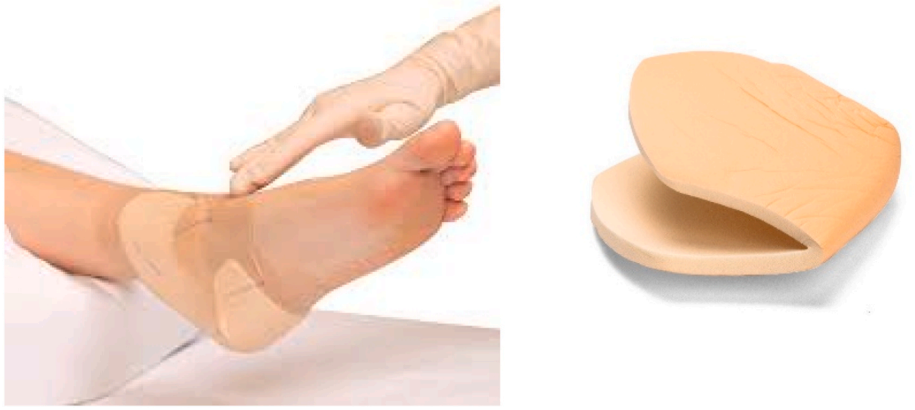

Fig. 2. Examples of prophylactic dressings.

Fig. 3. Examples of heel-specific offloading devices.

Fig. 4. Example of heel-specific low friction device.

2.5. Outcomes

Primary outcome:

Incidence of HPUs of any category i.e., the number of people who developed at least one new HPU or the number of new HPUs that developed, according to the EPUAP/NPIAP/PPPIA grading system [3]. If other grading systems were used, the findings were converted. Where possible results are presented for all HPUs (Category≥1) and for HPUs Category ≥2.

Secondary outcomes:

- Time to development of each HPU
- Cost of intervention
- Acceptability of the intervention e.g., comfort
- Durability of the device e.g., single patient use
- Adverse events e.g., injuries associated with the device, falls, etc.
- PUs at body sites which could be attributable to the device
- Proxy measures e.g., interface pressures, if HPU incidence was the primary outcome

2.6. Search methods for identification of trials

The search strategy, and databases searched are listed in Appendix 1. Citations of potentially relevant publications were retrieved. PU experts and medical device manufacturers (Appendix 2) were contacted for details of potentially relevant trials or data.

2.7. Data collection and analysis

CG and EM independently assessed titles and abstracts against the pre-specified eligibility criteria, retrieved full versions of potentially eligible articles and independently screened against the inclusion criteria. Pre-specified data was independently extracted from the included trials by CG and EM. Any disagreements were resolved through consensus. The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram [29] in Fig. 5 details the process (Figs. 6 and 7).

Risk of bias assessment was performed independently by CG and EM on each included trial according to Higgins and Green [30]. Where appropriate blinding and completeness of outcome data was assessed for each outcome separately. For each meta-analysis of primary outcomes, Grading of Recommendations Assessment, Development and Evaluation (GRADE) [31] was used to assist in grading the strength of recommendations. This incorporated the within trial assessment and an across-trial risk of bias assessment (limitations in trial design and execution or methodological quality), inconsistency (or heterogeneity), indirectness of evidence, imprecision of the effect estimates and risk of publication bias.

Where data were missing or there was unclear risk of bias, we attempted to contact trial authors for clarification. Where data was not forthcoming, we performed sensitivity analysis using best/worst case scenarios for the primary outcomes.

Where possible, outcomes are reported with confidence intervals (CI). Dichotomous outcomes are reported with risk ratios (RR); continuous outcomes with the same measures are reported with mean difference (MD) and standardised mean difference (SMD). Time to event outcomes i.e., time to HPU development, are presented with the appropriate analytical method [32], and hazard ratios (HR), where reported.

It was anticipated that the trial participant was the unit of analysis and that heel-specific interventions would be applied to both feet. Trials might deem the unit of analysis to be the heel, despite randomisation by patient, and if so, then consideration would be given to effect of clustering in the analysis. If it was unclear whether the incidence was reported by patients or heels then authors were contacted for clarification.

In the absence of significant clinical heterogeneity, data was pooled

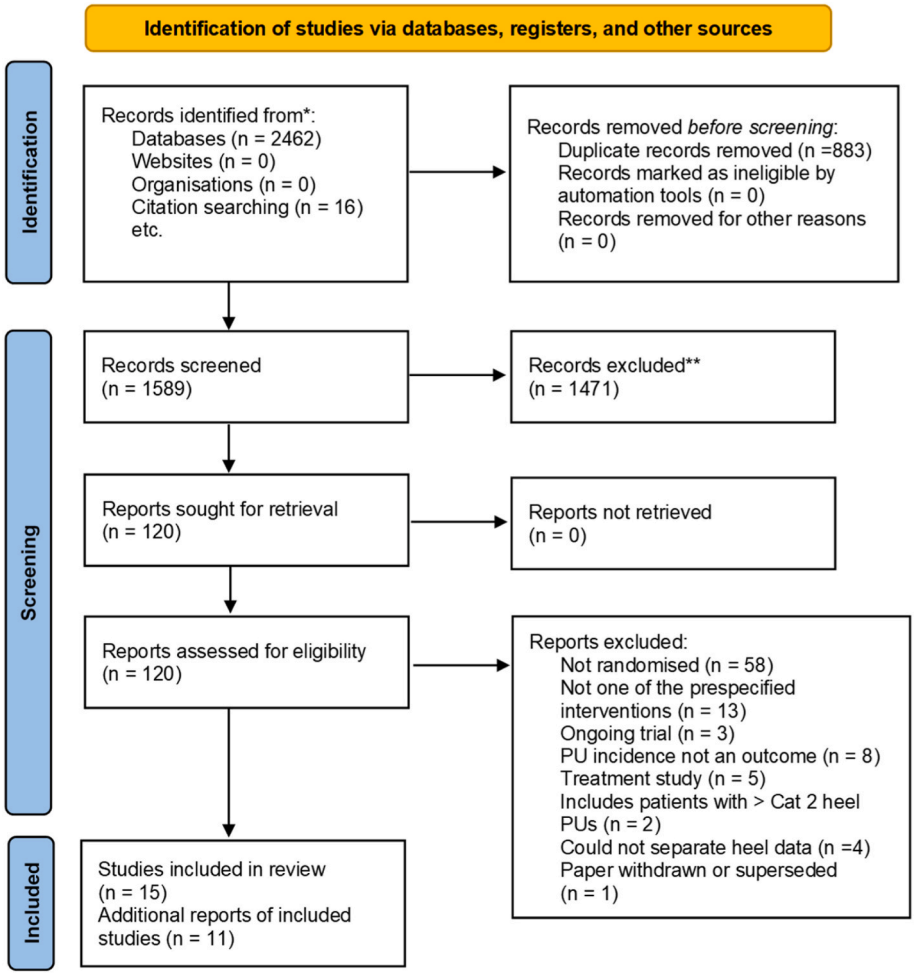

Fig. 5. PRISMA flow chart.

for meta-analysis using Revman 5.2 [36], assessment for statistical heterogeneity using the I^2 test [30] guided use of fixed-effects or a random-effects model.

3. Results

3.1. Results of the search

The comprehensive search identified 2478 records, see PRISMA flow diagram (Fig. 5).

3.2. Included trials

Fifteen randomised controlled trials (4720 Participants) are included in this review. The median sample size was 239 (range 50–1633), eleven trials included an *a priori* sample size estimate (although Veronesi [33] based their calculation on the outcome of pain). Eight trials compared heel dressings to standard care [25,26,34–39], and three trials compared heel-specific off-loading devices to standard care [14,23,24]. Two trials compared heel-specific off-loading devices to other heel-specific devices: one was a three-arm trial comparing two different heel-specific off-loading devices and a CLP device [40], the other compared an off-loading device to a pillow for off-loading [41]. Finally, two trials in paediatric surgical populations: one compared a foam heel dressing prior to application of a lower leg cast versus cast only [42], the other compared a custom splint versus standard off-loading cast following surgery [33]. Standard PU prevention care was either not reported or poorly described in trial manuscripts. Characteristics of included trials, including descriptors of 'standard care' are listed in Table 1.

3.3. Risk of bias in included trials

Risk of bias for each trial was considered using the Cochrane tool for assessing risk of bias [30] summarised in Figure 2 and Figure 3. No studies were excluded due to risk of bias.

All trials had at least one domain assessed as unknown or high risk of bias. These were related to blinding participants, personnel, and outcome assessors when devices were in place. Two trials of patients in ICUs and one trial of patients initially in ambulances [23,25,37] randomised patients then obtained consent later.

3.4. Effects of interventions

How the results are presented and what the terms mean.

The trials have been grouped according to the mode of action of the intervention and whether the comparator is 'standard care' or another device.

Details of primary outcomes are presented in this section.

Secondary outcomes are summarised in Table 2. Seven trials gave time to development as an outcome measure, however different reporting methods were used meaning that meta-analysis was not possible. Only one trial included a validated Quality of Life measure as an outcome assessment [34], however three trials reported pain using visual analogue scales and four trials reported the acceptability of the devices. No trials reported durability of the device.

3.5. Heel-specific constant low pressure (CLP) devices versus standard care

No trials which investigated CLP devices such as bootees or gel pads versus standard care met the inclusion criteria.

3.6. Prophylactic dressings versus standard care

Eight trials[[25,26,34–39] with 3577 participants evaluated heel dressings. Two trials [26,36] compared a polyurethane foam dressing with standard care that included bandaging for the heel. Three trials [25,37,38], compared a multi-layer foam and silicone dressing, and one compared two different brands of multi-layer foam and silicone dressing with standard care alone [34].

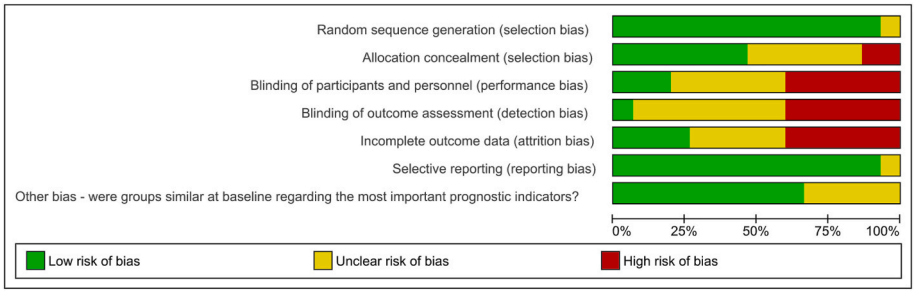

Fig. 6. Risk of bias graph: review authors judgements about each risk of bias item presented as percentages across all included trials.

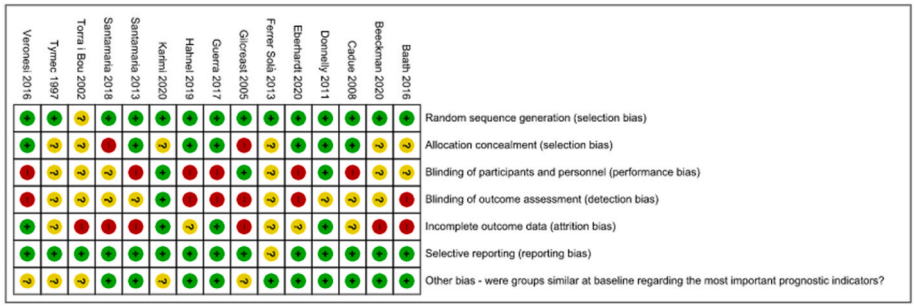

Fig. 7. Risk of bias summary: review authors judgements about each risk of bias item for each.

Table 1
Summary of included trials.

Trial[a]	Care setting	Sample Size	Population (mean age, ratio of female to male)	Intervention[b,d]	Comparison[b]	HPU ≥ Category 1 incidence[c]		HPU ≥ Category 2 incidence[c]		Follow up period[d]
						Intervention	Comparison	Intervention	Comparison	
Bååth 2016 [23,43]	Patients in emergency department admitted to 16 different wards, Sweden	N = 405	86.3 114F 63 M	Heelift® suspension boot (off-loading) plus risk assessment and skin assessment (n = 205)	Standard care (support surface, repositioning, risk assessment and skin inspection) (n = 200)	15/103 (14.6%)	24/80 (30%)	0/103 (0%)	1/80 (1.25%)	Until discharge
Beeckman 2020 [34,44,45]	Acute care, Belgium	N = 1633	79.6 941F 692 M	Multi-layered silicone foam plus standard care (n = 1087)	Standard care (support surface, repositioning, heel offloading, risk assessment and skin inspection) (n = 546)	Not reported	Not reported	15/1063 (1.4%)	10/538 (1.9%)	Until not at risk, PU develops or discharge
Cadue 2008 [24]	Intensive care, France	N = 70	62.6 26F 44 M	Foam body heel support (off-loading) plus standard care (n = 35)	Standard care (half-seated position, water mattress, preventive massages 6 times a day) (n = 35)	3/35 (8.6%)	19/35 (54.3%)	Not reported	Not reported	Maximum 30 days
Donnellly 2011 [14]	Fracture trauma centre, UK	N = 239	81 184F 55 M	Heelift® suspension boot (off-loading) plus standard care (n = 120)	Standard care (pressure relieving mattress) (n = 119)	0/120 (0%)	17/119 (14.3%)	0/120 (0%)	9/119 (7.6%)	12 days
Eberhardt 2020 [35,46]	Elective surgery patients, Brazil	N = 154 (308 heels)	59.5 47F 88 M	Multi-layer silicone foam plus standard care (n = 154 heels)	Film dressing plus standard care (heel offloading, daily skin and risk assessment, and 2-hourly repositioning (n = 154 heels)	36/154 (23.4%)	63/154 (40.9%)	3/154 (1.9%)	4/154 (2.6%)	72 h
Ferrer Sola 2013 [36]	Medium-long stay hospital, Spain	N = 409	81 240F 163 M	Allevyn® heel dressing (n = 208)	Classic padded bandage (Standard care not reported) (n = 201)	7/208 (3.4%)	5/201 (2.5%)	5/208 (2.4%)	1/201 (0.5%)	Unknown
Gilcreast 2005 [40]	Military tertiary-care academic medical centres in Texas, USA	N = 240	63.9 77F 87 M	Bunny Boot heel protector plus standard care (n = 77) Egg crate heel lift positioner plus standard care (off-loading) (n = 87)	EHOB (off-loading) (n = 76) plus standard care (Support surfaces included ICU bed, replacement mattress, overlay, or low-air-loss bed).	Bunny boot: 3/77 (3.9%) Egg crate off-loading: 4/87 (4.6%)	EHOB (off-loading): 5/76 (6.6%)	Not reported	Not reported	Until discharge
Guerra 2017 [42]	Paediatric orthopaedic patients, Italy	N = 80	11.71	Polyurethane foam dressing applied beneath leg cast (n = 38)	Standard care (Leg cast only) (n = 42)	17/38 (44.7%)	21/42 (50%)	Not reported	Not reported	Average of 3 days until discharge
Hahnel 2020 [42,54]	Intensive care units, Germany	N = 475	63.5 199F 276 M	Mepilex® border heel dressing plus standard care (n = 238)	Standard care ((i) patient information, (ii) twice daily skin inspection, (iii) mobilization, (iv) use of special support surfaces, (v) repositioning and (vi) heel flotation) (n = 237)	0/212 (0%)	5/210 (2.4%)	0/212 (0%)	3/210 (1.42%)	Till no longer at risk, lost to follow-up, or a HPU developed had healed

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Table 1 (*continued*)

Trial[a]	Care setting	Sample Size	Population (mean age, ratio of female to male)	Intervention[b,d]	Comparison[b]	HPU ≥ Category 1 incidence[c]		HPU ≥ Category 2 incidence[c]		Follow up period[d]
						Intervention	Comparison	Intervention	Comparison	
Karimi 2020 [38]	Intensive care unit, Iran	N = 50	43.2 20F 20 M (10 not accounted for)	Fish oil dressing plus standard care (n = 25)	Olive oil dressing plus standard care (examining the skin at each shift and changing the patient's position based on the patient's need) (n = 25)	0/25 (0%)	0/25 (0%)	0/25 (0%)	0/25 (0%)	Up to 7 days
Santamaria 2013 [25,47,48]	Intensive care unit, Australia	N = 440	55	Mepilex® Border dressing plus standard care (n = 219)	Standard care (low air loss bed, standard PU prevention strategies which included ongoing Braden risk assessment, regular repositioning and skin care. (n = 221)	3/161 (1.9%)	12/152 (7.9%)	Not reported	Not reported	Unknown
Santamaria 2018 [39]	Residential aged care facilities, Australia	N = 305	84 intervention group and 82 in control	Mepilex® border dressing retained with tubular bandage, applied to each heel plus standard care (n = 150)	Standard care (risk assessment, skin inspection, skin care, and pressure area care such as 2-hourly repositioning and the use of alternating air mattresses) (n = 155)	3/138 (2.2%)	5/150 (3.3%)	1/138 (0.7%)	1/150 (0.7%)	4 weeks
Torra I Bou 2002 [26,49–51]	Hospital or home care patients, Spain	N = 111	84.8 94F 36 M	Allevyn® heel dressing (n = 61)	Standard care (includes a protective Bandage, no other care specified) (n = 50)	2/61 (3.3%)	22/50 (44.0%)	Not reported	Not reported	8 weeks
Tymec 1997 [41]	Acute care, USA	N = 52	66.6 23F 29 M	Foot Waffle (off-loading) plus standard care (assumed n = 26)	Hospital pillow (off-loading) plus standard care (mattress depending on unit preference plus repositioning) (assumed n = 26)	0/26 (0%)	1/26 (3.8%)	Not reported	Not reported	14 days
Veronesi [33,52]	Paediatric department, Italy	N = 57	10.5 years 31F 26 M	Custom made splint with off-loading (n = 29)	Standard care (off-loading plaster cast) (n = 28)	1/29 (3.4%)	5/28 (17.6%)	Not reported	Not reported	Until cast removal (approx. 30 days)

[a] All publications are referenced for each study, the first listed is the main clinical results paper.
[b] Numbers given are those randomised to each arm.
[c] Where denominator numbers differ, these are based on numbers analysed.
[d] Descriptors as specified in the original papers.

One trial was a cluster randomised trial, with the unit of analysis being the residential care facility [39]. It is not clear in their report how clustering was accounted for in the sample size calculation, baseline comparability, blinding of staff at the facility or the analysis. No response has been received to our queries. Follow-up ranged from 3.5 days [25] to eight weeks [26].

Karimi [38] compared a fish oil dressing with an olive oil dressing, therefore was not included in the meta-analysis as both arms had interventions and were not comparable. Patients were followed up for 7 days and no HPUs developed in either arm.

Eberhardt [35] compared multi-layer foam and silicone dressing with standard care that included a film dressing and was not included in

Table 2
Summary of Secondary Outcomes (as per original trial reports).

Trial	Time to development	Costs	Acceptability of the intervention	Device related adverse events
Bååth 2016 [23]	Not reported	Not reported	Using a validated pain scale (0–10) found HPU related pain in the off-loading group to range between 0 and 4 and between 0 and 7 in the control group. Patients' perception of the intervention: •9 (39%) respondents felt it caused friction, •14 (48%) respondents said it was comfortable when lying down •7 (25%) comfortable when side lying •15 (63%) ok to have on when sleeping, •19 (76%) said it was ugly, •3 (12%) said it was stylish/worth price, •7 (30%) said it was itchy.	One patient experienced blistering from the device straps
Beeckman 2020 [34]	Does not report time to HPU development separately	"Health utility state at baseline was 0.28 (SD 0.28) in the treatment group and 0.29 (SD 0.28) in the standard of care group. At the end of the study a health utility state of 0.41 (0.27) was reported in the treatment group and 0.44 (SD 0.27) in the standard of care group. Analyses from both value sets showed similar results "	Not reported	Nil reported related to heel dressings
Cadue 2008 [24]	Mean for Category≥1 HPUs of 5.6 days in the off-loading group vs 2.8 days in the standard care group. HPU free days in the off-loading group 8.7 days vs 2.8 days in the standard care group.	Not reported		Four events of reversible red areas to the calves of patients in the intervention group
Donnelly 2011 [14]	Kaplan-Meier survival function found significant difference in time to development in favour of the off-loading group	Not reported	Several protocol violations attributable to the intervention due to hindrance of independent movement, unacceptably warm, pain or discomfort and problems with application or removal of the device.	One incident of lower leg bruising on a patient in the intervention group, however it was unclear whether this was attributable to the device.
Eberhardt 2020 [35]	Kaplan- Meyer test (survival analysis) 43.9 h (95% CI 38.5–49.4) in the film group compared to 57.5 h (95% CI 53.0–62.0) in the multi-layer foam group	Not reported	Not reported	Not reported
Ferrer Sola 2013 [36]	Days to HPU development for 12 participants: mean time 19.3 days polyurethane foam group compared to 22.6 days in control group	Not reported	Not reported	Not reported
Gilcreast 2005 [40]	Not reported	The CLP device was reported as significantly cheaper than the other interventions. However, this was based only on the cost of the device and pillows and no account was made for other resources or relative cost benefits.	•CLP devices did not stay in place, were sometimes lost and new devices purchased. •Compliance in wearing devices was approximately 85% •39 subjects were withdrawn from the trial as they did not wear the device for at least 48 h. •36(15%) subjects requested device cessation after 48 h, mainly due the device being 'hot and bothersome', however type of device is not reported. •As subjects became more alert, the less compliant they were with a device.	
Guerra 2017 [42]	Not reported	Not reported	Pain (score 〉 3 in a 0–10 scale) 68.4% with the intervention and 59.5% with the control.	Not reported
Hahnel 2020 [37]	Does not differentiate between sacrum and heel	The incremental cost-effectiveness ratio was €8144.72 for each HPU prevented in the intervention group. They concluded that prophylactic dressings to the heel are only marginally cost-effective in critically ill patients(47).	Not reported	Not reported
	Not reported	Not reported	Not reported	Not reported

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Table 2 (*continued*)

Trial	Time to development	Costs	Acceptability of the intervention	Device related adverse events
Karimi 2020 [38]				
Santamaria 2013 [25]	Does not differentiate between sacrum and heel	Average costs per group $55.84 per patient for intervention and $137.94 for control [48].	Not reported	Not reported
Santamaria 2018 [39]	Does not differentiate between sacrum and heel	Not reported	Not reported	Not reported
Torra I Bou 2002 [26]	Not reported	Costs of the device plus nursing time over eight-weeks in favour of the foam heel dressing when compared with the standard care (SMD -0.46, 95% CI -0.81 to −0.11)[58]	Not reported	Not reported
Tymec 1997 [41]	Mean time-to-development in favour of the control group; 10 days for the off-loading device group compared with 13 days in the control group.	Not reported	Not reported	Reported higher mean interface pressures to the Achilles tendon of 31.2 mmHg (SD 15.6 mmHg) in the off-loading device group compared with 14.2 mmHg (SD 15.6 mmHg) when using a pillow to off-load the heel. Patients using the off-loading device developed six additional PUs in the lower limb compared to only one in the pillow group.
Veronesi 2016 [33]	Not reported	Not reported	Reported pain, caregiver interventions and comfort, there were no significant differences between the two interventions.	Not reported

the meta-analysis as randomisation was by heel not patient. They reported significantly fewer Category 1 HPUs developed in the multi-layered foam group (23.4%) compared to the film dressing group (40.9%), although there was no statistical difference for Category≥2 HPUs.

3.6.1. Primary outcome: incidence of HPUs Category≥ 1

Of the eight trials only two presented data for all the patients who had been randomised to their study [35,36], therefore an available case analysis was undertaken. Data for five trials were pooled using a random-effects model due to statistical heterogeneity, with 1543 participants: n = 15/780 (1.9%) dressing versus n = 49/736 (6.4%) standard care. We are uncertain whether foam heel dressings prevent HPUs as the certainty of the evidence according to GRADE [31] has been assessed as very low (RR 0.31, 95% CI 0.10 to 1.01) (Fig. 8).

Sensitivity analysis to assess the impact of missing patients on the individual trials was performed using best-case and worst-case scenarios. One trial found to have no effect on the direction of the effect [26]. For three trials the worst-case scenario changed the direction of the effect towards the control group [25,37,39].

3.6.2. Primary outcome: incidence of HPUs Category≥2

Of the eight trials, five presented data separately for Category≥2. Eberdhardt was not included in the meta-analysis due to heterogeneity [35]. The available case data for these four trials were pooled with 2720 participants using a random-effects model. Dressings may make little or no difference to the prevention of Category≥2 HPUs compared to standard care, (GRADE assessment: low quality evidence) dressing group (n = 21/1621, 1.3%) compared with standard care (n = 15/1099, 1.4%) (RR 0.94, 95% CI 0.32 to 2.76) (Fig. 9).

3.6.3. Subgroup analysis: multilayer silicone foam dressings

3.7.1 and 3.7.2 included all dressing types for the prevention of HPUs. A subgroup analysis, using available case data, was performed for multilayer foam dressings.

Four trials were included. Prophylactic multilayer foam dressings may prevent Category≥1 HPUs (n = 6/511, 1.2%) versus standard care, (n = 22/512, 4.3%) (RR 0.29, 95% CI 0.12 to 0.68) (GRADE assessment: low quality evidence) (Fig. 10). However, when the Beeckman trial [34] was included, there is probably no difference in the prevention of Category≥2 HPUs between the dressing (n = 16/141, 31.1%) compared with standard care (n = 14/898, 1.6%) (RR 0.65, 95% CI 0.32 to 1.35) (GRADE assessment: moderate quality evidence) (Fig. 11).

3.7. Comparison between heel-specific off-loading devices and standard care

Three trials [14,23,24] with 492 participants, compared a foam device which offloaded the heel to standard care. Two trials used a Heelift® suspension boot[[14,23], and one did not specify a proprietary name [24]. Bååth [23] randomised 405 patients in the ambulance but only 183 were analysed as consent was taken later and not all patients were admitted to hospital and followed-up. Follow-up ranged from 8 days [23] to 30 days [24].

3.7.1. Primary outcome: incidence of HPUs Category≥1

HPU incidence was pooled for three trials, with 492 participants (available cases), using a random-effects model due to statistical heterogeneity. Heel offloading devices may prevent more Category≥1 HPUs (n = 18/258, 7.0%) (RR 0.20, 95% CI 0.05 to 0.80) compared to standard care (n = 60/234, 25.6%) (GRADE assessment: low quality evidence) (Fig. 12).

3.7.2. Primary outcome: incidence of HPUs Category≥2

Two trials [14,23] reported Category≥2 HPUs with a total of 422 participants. Pooling this data, using a fixed-effects model it was found that heel-offloading devices (n = 0/223, 0%) probably prevent more Category≥2 HPUs compared to the standard care group (n = 10/199, 5.0%) compared with the off-loading group: (RR 0.08, 95% CI 0.01 to 0.67) (GRADE assessment: moderate quality evidence) (Fig. 13).

3.8. Comparison of heel-specific off-loading devices versus other heel-specific off-loading devices or CLP devices

Two trials compared heel-specific off-loading devices to other devices [40,41]. One trial [40] compared three different devices: an egg-crate foam off-loading device (no proprietary name), an inflatable off-loading device (EHOB Foot Waffle Air Cushion), and a CLP device (bunny boot – High-Cushion Kodel Heel Protector). Double counting was avoided by numbers in the control group (CLP device) being halved

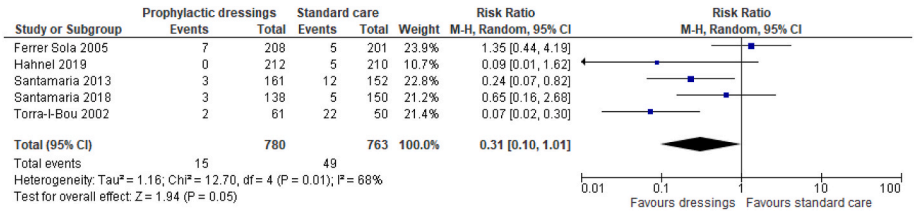

Fig. 8. Comparison of foam heel dressing versus standard care. Outcome: number of patients with Category≥1 HPUs.

Fig. 9. Comparison of foam heel dressing versus standard care. Outcome: number of patients with Category≥2 HPUs.

for the analysis. This trial also lost patients for follow-up (388 participants randomised but 240 analysed), therefore the data analysed uses available cases. It was not possible to perform a sensitivity analysis as it was not reported which arm those lost to follow up had been randomised. A second trial compares an inflatable off-loading device (EHOB Foot Waffle Air Cushion) with a pillow positioned under the calves, as an off-loading device [41]. Results have not been pooled as numbers of participants in each arm were not specified.

3.8.1. *Primary outcome: incidence of HPUs Category≥ 1*

Data was pooled using a fixed-effect model [40]. We are uncertain whether heel offloading device (n = 9/163, 5.5%) prevent more Category≥1 HPUs compared with CLP device (n = 3/77, 3.9%) as the certainty of the evidence has been assessed as very low (RR 1.42, 95% CI 0.4 to 5.07) (Fig. 14).

Tymec [41] reported no HPUs in intervention arm and one patient developed a HPU in the control arm.

3.8.2. *Primary outcome: incidence of HPUs Category≥ 2*

Neither trial reported Category≥ 2 outcomes.

3.9. *Trials of post-surgical paediatric populations*

Two trials [33,42] were carried out in children who underwent orthopaedic surgery of the lower limb and required a plaster cast splint post-surgery (137 participants). They were led by the same investigator at the same site. Due to the clinical heterogeneity (patient population) it was decided to present these trials separately. This is a post-protocol change for this review. Veronesi [33]compared a custom-made splint with off-loading at the heel to a standard splint (which required pillows under the calf to achieve off-loading), their primary outcome was pain with a secondary outcome of HPUs. Guerra [42] compared the use of a polyurethane foam dressing (CLP device) applied to the heel prior to the application of a Walker splint, to standard care (no dressing) and a Walker splint for post-surgery for 'flat foot' prior to discharge. Data collection was daily for three days prior to discharge.

3.9.1. *Primary outcome: incidence of HPUs Category≥ 1*

We are uncertain if either intervention prevented HPU development due to the very low-quality evidence. Veronesi [33] had 57 participants, 1/29 (3.4%) developed a HPU in the treatment group and 5/28 (17.9%) in the control group. Using a fixed-effects model there was no clear difference between the two interventions (RR 0.19, 95% CI 0.02 to 1.55). Guerra [42] had 80 participants, 17/38 (44.7%) developed a HPU in the treatment group and 21/42 (50%) in the control group. Using a fixed-effects model there was no clear difference between the two interventions (RR 0.89, 95% CI 0.56 to 1.42).

3.9.2. *Primary outcome: incidence of HPUs Category≥2*

Neither trial specified the severity of the ulcers.

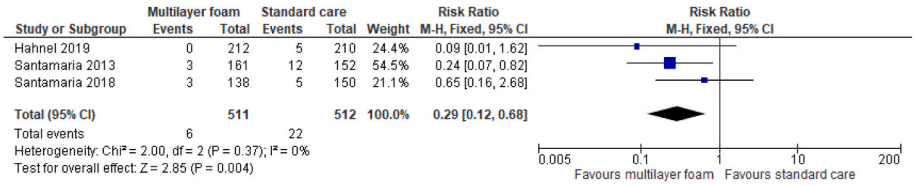

Fig. 10. Comparison of multi-layer silicone foam versus standard care. Outcome: number of patients with Category≥1 HPUs.

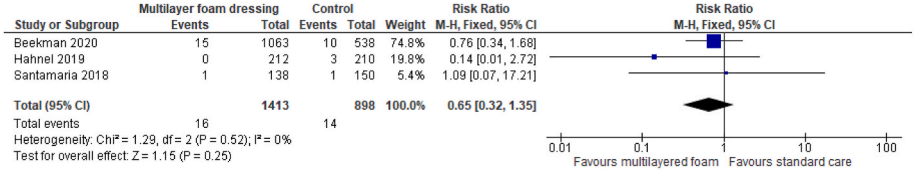

Fig. 11. Comparison of multi-layer silicone foam versus standard care. Outcome: number of patients with Category≥2 HPUs.

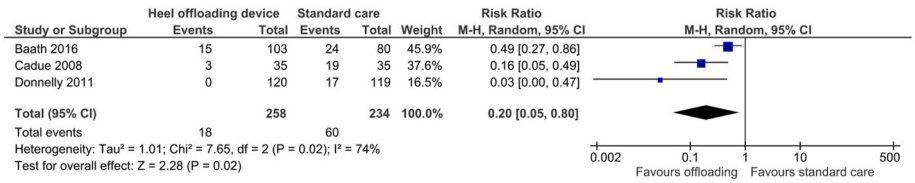

Fig. 12. Comparison of heel off-loading devices versus standard care. Outcome: number of patients with Category≥1 HPUs.

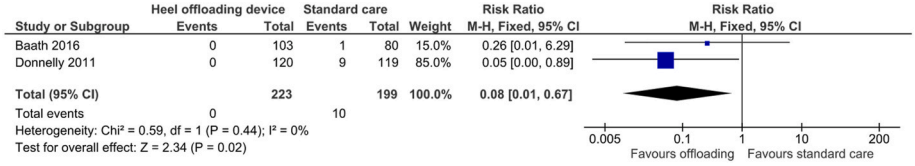

Fig. 13. Comparison of heel off-loading devices versus standard care. Outcome: number of patients with Category≥2 HPUs.

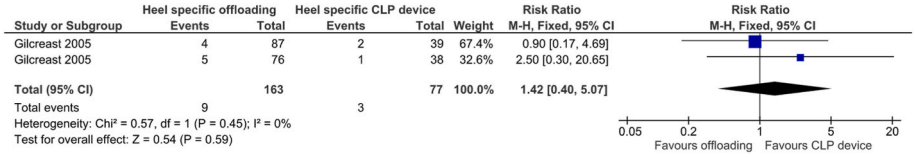

Fig. 14. Comparison of heel off-loading devices versus CLP devices. Outcome: number of patients with Category≥1 HPU.

4. Discussion

4.1. Summary of the results

4.1.1. Prophylactic dressings versus standard care

A difference was only detected when Category 1 HPUs were included, however the trials were at high risk of bias and overall quality was very low making the results uncertain [25,26,36,37,39]. The overall number of events is very low for each trial. Three trials reported details of costs [25,26,37] and found these to be lower for the intervention. None of the trials reported any adverse events, issues with compliance, quality of life, or acceptability of the devices.

4.1.2. Offloading versus standard care

Comparisons between heel-specific off-loading devices and standard care found a significant benefit of the device for all Categories of HPU [14,23,24]. While the quality of evidence was low according to GRADE, reducing the certainty of the results. When one of the trials was excluded [24] the evidence was assessed as moderate quality. Time to development was also longer in the intervention group. None of the trials reported costs. The trials reported issues with adverse events, compliance, quality of life and acceptability of the devices.

4.1.3. Offloading versus CLP

Two trials that compared off-loading devices or CLP with other off-loading devices [40,41] did not find a significant difference between interventions. The time to development of a HPU was found to be in favour of the control (pillow) in one trial [41]. One trial reported that the costs of the control devices were less than the off-loading device but did not include an economic evaluation [41]. Both trials commented on issues with adverse events, compliance, factors that could affect quality of life and acceptability of the off-loading device.

4.1.4. CLP versus standard care

The two paediatric trials did not find any clear difference between the interventions although the number of participants in both were small. There were no significant differences in the acceptability of the intervention reported by Veronesi [33], but the pain scores were higher with the intervention in Guerra [42].

4.2. Quality of the trials

Due to the nature of the interventions, it is difficult to blind either the participants or the researchers. Trials could have been deemed at low risk of performance and detection bias if they had attempted to minimise this bias e.g., using photographs independently assessed by someone blinded to the intervention. Evidence suggests that this could be a method to minimise this source of bias [53].

There is a potential for publication bias: trials of pressure relieving devices are often sponsored by the manufacturers so results may not be published if they show no evidence of benefit or difference. Attempts were made to overcome this by contacting manufacturers for unpublished data and grey literature searching but this did not produce any additional information.

As the patient populations were all assessed as 'at risk' of PU development, it would have been unethical for any trial not to include PU prevention interventions in standard care. Standard care (e.g., repositioning, skin inspection, mattresses, etc.) was not routinely reported in the included trials (Table 1). Donnelly [14] noted that patients were nursed on different types of pressure relieving mattresses chosen by the ward nurses, however this was recorded and analysed as a covariate. They reported that this did not affect the significance of the effect of the intervention. Given that RCTs that compare PU prevention mattress have found very little difference in effectiveness [15,54], this is not unexpected. Hahnel [37] and Santamaria [39] reported the type of PU prevention mattresses used, these were mostly balanced across both groups. Standard care in several trials was reported to include off-loading or 'floating' the heels. If this had occurred for every control arm patient then none of these patients should have had any pressure on the heels.

A consideration may have been patients' baseline status of PAD. It is known that PAD is a prognostic factor for PU development [1] and healing [55]. Although Ferrer Sola [36] reported Ankle Brachial Pressure Index and Donnelly [14] reported PAD status, these were balanced

across both groups. None of the other included trials reported PAD status.

Reporting of outcome measures differed in many of the trials, making comparisons difficult. Methods for reporting time to development differed, and many of the trials included Category 1 HPUs in their outcomes. The identification of Category 1 PUs has a degree of controversy due to potential misdiagnosis and limited duration [56,57]. The potentially transient nature of Category 1 PUs suggests that their inclusion as an event may result in a higher event rate if outcome assessments are frequent. Category 1 PUs are also a prognostic factor for more severe PU development [1,15]. The inclusion of Category 1 PUs as an endpoint may result in better recruitment, however work is still needed to establish the reliability of Category 1 PUs as endpoints.

Secondary outcomes were rarely reported, and when they were different methods were used to report costs and time to event, meaning that none could be included in a comparison. Where costs were reported [39], intention to treat (ITT), there appears to have been no adjustment to account for potential patient differences or PU severity. There is a potential risk of bias as it is not known whether the costs of treating a PU would be the same for both arms.

Five trials analysed the data for all patients randomised [14,24,33,36,42] (ITT), the rest reported outcomes for participants who remained in the trial. This results in potential selection bias as those lost to follow-up were not reported by intervention group.

As stated, most of the trials only reported data on patients followed-up, while reasons are given for loss of follow-up, it is not always clear whether these are random across both arms or free from any other biases. Sensitivity analyses of best case/worst case scenarios when performed, changed the direction of effect for all but one trial, this supports the findings that their primary analyses were not robust. It is possible to calculating Information Missingness Odds Ratios (IMORs), however IMORs are beyond the scope of this review.

It is noted that the results of one trial [36] were in favour of the control group. The trial authors concluded that this was due to multiple preventative interventions and the low event rate.

This review did not include patients with existing HPUs Category$\geq$2, this decision was taken as previous experience found that separating out new incidence and healing in a report can be difficult and the presence of a PU is a risk factor for developing a new one [1].

The method followed for our review was based on the Cochrane Handbook version 5.1.0 [30] and used review software RevMan. An updated handbook is available online, version 6 with new guidance on dealing with lack of follow up, and lack of blinding due to impracticality, both of which have been identified in this review. It is possible that updated assessment of bias may have made a small change to the results and the interpretation of the findings but given the multiple domains of quality and risk of bias which remain unchanged between version 5 and 6 of the Handbook, we do not consider that the level of evidence would have altered significantly.

5. Conclusions

The findings suggest that heel off-loading devices may be effective at reducing the incidence of HPUs, however there are problems of patient acceptability and compliance with these devices, and the evidence is not of high quality. Due the quality of the trials, there was insufficient evidence for the use of prophylactic dressings for prevention of HPUs.

Given the level of documented withdrawals, loss to follow-up, protocol violations, device related adverse events, patient compliance and effect on quality of life such as being 'uncomfortable, hot, sweaty', there is a need for further research to better inform the design of devices, their practical use, effectiveness, and iatrogenic effects. Patient reported outcomes should be included in the design of future RCTs to inform both efficacy and effectiveness. We would also recommend that future trials include full descriptions of 'standard care' and ensure patients are included in protocol development and evaluation to increase compliance and ensure devices are used appropriately. Validated Quality of Life measures should be included, and cost effectiveness considered.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files].

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Authors contributions

CG conceived the idea for the review and wrote the protocol. CG and EM conducted the review (searched the literature, selected, assessed the quality and data extracted the trials for inclusion, interpreted the findings and drafted the manuscript). EAN, JN and AVP provided scientific and methodological oversite of the review. All authors contributed to and approved the final manuscript.

Declaration of competing interest

The authors declare that they have no competing interests.

Acknowledgements

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Appendix A. Search methods for identification of trials

Electronic searches

A search of the following electronic databases was performed on September 19, 2019 to find reports of relevant RCTs:

- The Cochrane Wounds Group Specialised Register
- The Cochrane Central Register of Controlled Trials (CENTRAL) (latest issue)
- Ovid MEDLINE (1946 to present)
- Ovid EMBASE (1974 to present)
- EBSCO CINAHL (1982 to present)

The following search strategy was used in CENTRAL:

#1 (pressure NEXT relie*) ti, ab, kw

#2 (pressure NEXT reduc*) ti, ab, kw
#3 (pressure NEXT (distribut* or redistribute*)) ti,ab, kw
#4 (pressure NEXT device*) ti, ab, kw
#5 (medical NEXT device*) ti, ab, kw
#6 (low NEXT pressure) ti, ab, kw
#7 (constant NEXT low NEXT pressure) ti, ab, kw
#8 (off-loading NEXT device*) ti, ab, kw
#9 (low NEXT friction NEXT device*) ti, ab, kw
#10 (reduc* near friction) ti, ab, kw
#11 (reduc* near sheer) ti, ab, kw
#12 (elevat* NEXT device*) ti, ab, kw
#13 (elevat* near/2 device*) ti, ab, kw
#14 (heel near/2 (elevat* or suspen*)) ti, ab, kw
#15 (foot near/2 (elevat* or suspen*)) ti, ab, kw
#16 ((foot or feet or heel) near/2 lift*) ti, ab, kw
#17 ((foot or feet or heel) near/2 protect*) ti, ab, kw
#18 ((foot or feet or heel) near/2 pressure) ti, ab, kw
#19 ((foot or feet or heel) near/2 device) ti, ab, kw
#20 foam: ti, ab, kw
#21 pad* ti, ab, kw
#22 gel* ti, ab, kw
#23 dressing ti, ab, kw
#24 bandage ti, ab, kw
#25 (sheepskin* or (sheep NEXT skin*)) ti, ab, kw
#26 ((air or water) NEXT suspen*) ti, ab, kw
#27 foot waffle ti, ab, kw
#28 (air NEXT bag*) ti, ab, kw
#29 static air ti, ab, kw
#30 pillow* ti, ab, kw
#31 wedge* ti, ab, kw
#32 trough*: ti, ab, kw
#33 MeSH descriptor [Shoes] explode all trees
#34 (shoe* or boot* or cup*) ti, ab, kw
#35 (footwear or foot wear) ti, ab, kw
#36 MeSH descriptor [Foot orthothses] explode all trees
#37 (orthotic NEXT (device* or therapy)) ti, ab, kw
#38 orthos* ti, ab, kw
#39 (cast*) ti, ab, kw
#40 ((contact or walk*) near/1 ('cast or casts')) ti, ab, kw
#341 (aircast or scotchcast) ti, ab, kw
#42 splint* ti, ab, kw
#43 (#1 OR through to #42)
#44 MeSH descriptor [Pressure Ulcer] explode all trees
#45 pressure NEXT (ulcer* or sore* or injur*) ti, ab, kw
#46 decubitus NEXT (ulcer* or sore* or injur*) ti, ab, kw
#47 (bed NEXT sore*) or bedsore ti, ab, kw
#48 (#44 or #45 or #46 or #47)
#49 (#43 and #48)

This search strategy was adapted accordingly for Ovid MEDLINE, Ovid EMBASE and EBSCO CiNAHL. We also searched the following clinical trials registries:

- EU Clinical Trials Register (http://www.clinicaltrialsregister.eu/index.html)
- ClinicalTrials.gov (http://www.clinicaltrials.gov)
- WHO International Clinical Trials Registry Platform (ICTRP) (http://www.who.int/ictrp/en/)

Appendix B. List of manufacturers contacted

We contacted the manufacturers of devices used in the prevention of HPUs and asked for information relevant to this review: Frontier Medical Group, DM Systems, Posey, Coviden, Sundance Solutions, Smith & Nephew, Spenco.

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