

Pressure relieving devices for preventing heel pressure ulcers (Protocol)

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[Intervention Protocol]

Pressure relieving devices for preventing heel pressure ulcers

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Editorial group: Cochrane Wounds Group.

Publication status and date: Edited (no change to conclusions), published in Issue 3, 2008.

Citation: Donnelly J, Kernohan GW, Witherow A. Pressure relieving devices for preventing heel pressure ulcers. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD007117. DOI: 10.1002/14651858.CD007117.

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To determine whether support surfaces and pressure relieving devices (such as beds, mattress overlays, mattress replacements and heel splints) prevent pressure ulcers on the heels of patients in all care settings.

BACKGROUND

Pressure ulcers (also known as decubitus ulcers, bedsores and pressure sores) may be defined as localised areas of tissue damage, which result from sustained mechanical loading of the skin and its underlying structures (EPUAP 1999; Bouten 2003). They mainly occur over bony prominences on the lower half of the body, with the most commonly affected areas being the base of the spine (the sacrum), the hips and the heel bone (calcaneus) (Barczak 1997; Gunningberg 1999; Gunningberg 2001; Bick 2004). Pressure ulcers vary in size and severity, i.e. from a reddening of intact skin to severe tissue destruction involving skin (epidermis and dermis), subcutaneous fat, tendon, muscle and bone (Witkowski 1982). The depth of pressure damage is often described using a simple 4 or 5-point scale. A score of 0 or 1 usually indicates skin discolouration, whilst a score of 4 or 5 indicates extensive tissue loss with exposed fascia, muscle, tendon or bone. An example of a commonly used grading system the (European Pressure Ulcer Advisory Panel Pressure Ulcer Grading Tool (EPUAP 1999)) is detailed below:

Grade 1 - Persistent discolouration of the skin including non-blanchable erythema; blue/purple/black discolouration.

Grade 2 - Partial thickness skin loss involving epidermis and dermis.

Grade 3 - Full thickness skin loss involving damage or necrosis of subcutaneous tissues but not through the underlying fascia and not extending to the underlying bone, tendon or joint capsule.

Grade 4 - Full thickness skin loss with extensive destruction and tissue necrosis extending to the underlying bone, tendon or joint capsule.

Studies indicate that pressure ulcers are relatively common and that they can affect all age groups (babies, children and adults) in all care settings (hospital and community). However, they are particularly common in critically ill patients (Theaker 2000; Bours 2001); older adults (over 65 years of age), (Barczak 1997; Tourtual 1997; Bergstrom 1998) and people who have reduced sensation or mobility, e.g. patients with spinal injuries or fractures (Fisher 2004; Lindgren 2004).

Pressure ulcers can cause physical, social and psychological suffering. This distress is caused by local factors such as pain, wound exudate and malodour (which may lead to social isolation), delayed rehabilitation (which may result in economic hardship), and serious complications such as cellulitis, osteomyelitis, septicemia, limb amputation and death (Versluysen 1985; Sprigle 1990; Young 1992; Rintala 1995; Tourtual 1997; Morris 2004; Hopkins 2005). It is therefore important that preventive care is based on the best clinical evidence. The goals of pressure ulcer prevention are to protect against the adverse effects of external mechanical forces, through for example the use of specialised mattresses, and to improve tissue tolerance through, for example attention to nutrition. However, a systematic review of the literature indicates that none

of the equipment or strategies currently employed have been reliably evaluated through independent multi-centred randomised controlled trials (Cullum 2004).

A high number of pressure ulcers in one clinical setting, when compared with similar settings may be equated with poor quality care (NICE 2001; NHS 2003). Considered individually as clinical incidents pressure ulcers are recorded in clinical risk registers for many healthcare organisations. Bennett 2004 estimated that the NHS in the UK spends £1.4 to £2.1 billion annually on the treatment of pressure ulcers, with the cost per patient ranging between £1,064 and £10,551. In addition to the direct cost of care there are indirect costs, such as those associated with litigation following pressure ulceration. Up until 1996, settlement figures following successful lawsuits were generally low (approximately £10,000) (Tingle 1997). However, case studies indicate that this figure could be much higher today.

In order to gauge the size of the pressure ulcer problem, many organisations carry out prevalence and / or incidence surveys to determine patterns of pressure ulcer distribution (Van Rijswijk 2001). A review of UK, USA and Canadian prevalence and incidence studies by Kaltenthaler 2001 indicated that pressure ulcer prevalence rates within the UK are lowest in community settings - ranging from 2.5 % (Hallett 1996) to 6.8% (Preston 1989) - and highest in palliative care (approximately 37%)(Hatcliffe 1996). A recent study by the European Pressure Ulcer Advisory Panel (EPUAP 2002) indicates that prevalence rates in acute hospitals are approximately 23%.

Heel Pressure Ulcers

Heel pressure ulcers appear to be a significant problem amongst critically ill patients and older people; particularly those who have sustained a fractured hip or who are nursed in long term care facilities (Raghavan 2003; Bours 2001; Gunningberg 2005; Horn 2002). This may be due to a complex interplay of intrinsic and extrinsic factors such as age related disease, tissue geometry, duration of immobility and ineffective pressure relief. Whatever the underlying cause, heel pressure damage may adversely affect mobility and may result in significant disability and morbidity. For example, a heel ulcer may be a determining factor in how quickly an older person with a fractured hip is able to walk independently.

In clinical practice, practitioners attempt to reduce heel pressure in one of two main ways. The first by completely removing pressure (off-loading) from the heel using devices such as carefully positioned pillows or leg splints. The second is to reduce the amount of pressure sustained by the heel through the provision of a conforming support surface. These surfaces increase the area of contact that the body has with the support surface, thus reducing the magnitude of the 'interface' pressure at any single point. The heel is worthy of specific consideration as it is distinct from other bony

prominences and as such may be at increased risk from pressure induced tissue trauma. There are several factors which may place the heel at increased risk from pressure induced tissue trauma:

- the heel area may be subjected to very high interface pressure when a patient is laying down. For example, [Lindan 1965](#) who, using a compressible 'bed of nails', demonstrated that interface pressures are highest over bony prominences, and in particular the heels, where he recorded maximal contact pressures of 50 to 60 mm Hg during recumbence.
- although the heel is designed to withstand high pressure in ambulation, this is not the case when supine, i.e. the natural protection of the heel (the fat pad) is lost as the pressure point moves proximally.
- many neurological and endocrine conditions and life style factors lead to reduced sensation of the feet, for example, diabetes, pernicious anaemia, spina bifida and multiple sclerosis. These conditions may result in a person being unaware of pressure and, therefore, they will not respond to it ([Raney 1989](#)).
- blood flow to the heel may be reduced through, for example, peripheral vascular disease caused by smoking, diabetes and hypertension ([Vogt 1992](#)).
- the heel is predisposed to trauma owing to exposed anatomy.
- given the lack of lymph vessels between adipose cells the fat pad might be at greater risk of cellular damage than other tissue types. If the lymphatic system is damaged the tissue in that region may be compromised and a large necrotic ulcer may develop ([Michel 2005](#)).
- the absence of sebaceous glands may result in a lack of lubrication, which in turn may increase the risk of friction damage.
- oedema - unlike other many other pressure areas, the tissues of the lower leg and foot are often affected by oedema as a result of immobility (dependent oedema) and disease, e.g. cardiac failure and liver disease ([Ciocon 1993](#)). The presence of oedema compromises tissue perfusion and removal of waste products ([Ryan 1969](#)). In addition [Scanlon 2005](#) noted that the weight of the extra fluid in the feet is likely to result in normal resting pressures being exceeded; which may have an impact on tissue tolerance of pressure.
- the Achilles tendon is vulnerable - if the heel is off loaded, pressure may be transferred to the Achilles tendon, which has minimal protection in terms of subcutaneous tissue. Damage to the tendon may result in permanent disability.

The heel is therefore a unique structure that is commonly affected by pressure ulcers. To date, little is known about the clinical and

cost-effectiveness of devices that are designed to protect the heel area. A systematic review of the evidence for the effectiveness of devices and support surfaces that protect the heel will therefore inform practitioners and may improve patient care.

OBJECTIVES

To determine whether support surfaces and pressure relieving devices (such as beds, mattress overlays, mattress replacements and heel splints) prevent pressure ulcers on the heels of patients in all care settings.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs), published or unpublished, if they:

- assess the effect of a support surface or a device used to prevent pressure ulcer development on the heel in any patient group, in any setting;
- report heel pressure ulcer incidence as an objective measure of clinical outcome.

Studies which use only subjective measures of outcome (e.g., skin condition "better" or "worse") will be excluded as will studies which report only proxy measures such as interface pressure. Trilists who have looked at pressure relieving devices for preventing pressure ulcers but have not presented heel data separately will be contacted in an attempt to obtain heel data specifically.

Types of participants

People of any age, in any care setting.

Types of interventions

The support surfaces and devices being evaluated may include:

Limb protectors:

Off loading splints, pads and footwear, e.g. leg 'gutters' to raise heels, rubber gloves filled with water

Low-tech support surfaces:

Standard foam mattresses

Foam mattress replacements or overlays

Gel-filled mattress replacements or overlays

Fibre-filled mattress replacements or overlays

Air filled mattress replacements or overlays

Water-filled mattress replacements or overlays

Bead filled mattress replacements or overlays
 Sheepskins
High-tech support surfaces:
 Alternating pressure mattress replacements or overlays
 Air fluidised beds
 Low air loss beds
Other surfaces:
 Turning beds or frames
 Operating table overlays

Types of outcome measures

Primary outcomes

- Risk of new pressure ulcers

Many evaluations have simply measured the pressure on different parts of the body in contact with the support surface (interface pressure). However, interface pressure is an intermediate or surrogate outcome measure which has serious limitations as a proxy for clinical outcome, since the process which leads to the development of a pressure ulcer almost certainly involves the complex interplay of several factors. Unfortunately, because it is relatively simple, quick and inexpensive to measure, most evaluations only compare interface pressure. In this review we propose to consider trials that report the clinical outcome measure of heel pressure ulcer incidence.

- Grades of new pressure ulcers

As highlighted in the systematic review of support surfaces, studies do not always differentiate between people developing grade 1 ulcers (where the skin is not broken) and those developing more severe ulcers. Ankrom 2005 indicated that there are a number of different pressure ulcer grading tools in use. This means it may be difficult to compare the severity of pressure damage. For the purposes of this review where the studies have not utilised the EPUAP grading tool (EPUAP 1999), the review authors will attribute a EPUAP grade against the descriptors provided in the research article.

- Time to ulceration

Secondary outcomes

The following outcomes will be recorded where available:

- Costs of the devices including consumables and nursing time required applying or changing splints.
 - Patient comfort.
 - Adverse events.
 - Rates of equipment failure.
 - Reliability of the devices.
 - Acceptability of the devices to the patient.

Search methods for identification of studies

Electronic searches

Trials to be considered for this review will be sought through searches of the following databases: Cochrane Wounds Specialised Register; the Cochrane Central Register of Controlled Trials (CENTRAL)(latest issue); Ovid MEDLINE (1950 to present); Ovid CINAHL (1982 to present) and Ovid EMBASE (1980 to present).

The following strategy will be used in CENTRAL and will be modified where appropriate for other databases:

```
#1 MeSH descriptor Beds explode all trees
#2 (bed or beds):ti,ab,kw
#3 (mattress* or cushion* or pillow*):ti,ab,kw
#4 ("foam" or cutfoam or overlay*):ti,ab,kw
#5 ("pad" or "pads" or padding):ti,ab,kw
#6 ("gel" or "gels"):ti,ab,kw
#7 (pressure NEXT relie*):ti,ab,kw
#8 (pressure NEXT device*):ti,ab,kw
#9 (pressure NEXT redistribution*):ti,ab,kw
#10 (low NEXT pressure NEXT support*):ti,ab,kw
#11 ((constant or alternat*) NEXT pressure*):ti,ab,kw
#12 ((air or water) NEXT suspension*):ti,ab,kw
#13 (sheepskin* or (sheep NEXT skin*)):ti,ab,kw
#14 "foot waffle":ti,ab,kw
#15 (air NEXT bag*):ti,ab,kw
#16 (elevat* NEAR/2 device*):ti,ab,kw
#17 "static air":ti,ab,kw
#18 MeSH descriptor Shoes explode all trees
#19 ("shoe" or "shoes" or "boot" or "boots" or booties):ti,ab,kw
#20 (footwear or "foot wear"):ti,ab,kw
#21 MeSH descriptor Orthotic Devices explode all trees
#22 (orthotic NEXT (device* or therapy)):ti,ab,kw
#23 (orthos* or insole*):ti,ab,kw
#24 ((contact or walk*) NEAR/1 ("cast" or "casts")):ti,ab,kw
#25 (aircast or scotchcast):ti,ab,kw
#26 ((foot or feet) NEAR/2 pressure):ti,ab,kw
#27 ((foot or feet) NEAR/2 protect*):ti,ab,kw
#28 ((foot or feet) NEAR/2 device*):ti,ab,kw
#29 (heel* NEAR/2 pressure*):ti,ab,kw
#30 (heel* NEAR/2 protect*):ti,ab,kw
#31 (heel* NEAR/2 device*):ti,ab,kw
#32 (heel* NEAR/2 (lift* or float* or splint* or glove* or suspension or elevat*)):ti,ab,kw
#33 (trough* NEAR/2 (leg* or "foot" or "feet" or heel*)):ti,ab,kw
#34 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33)
#35 MeSH descriptor Pressure Ulcer explode all trees
```

#36 pressure NEXT (ulcer* or sore*):ti,ab,kw
#37 decubitus NEXT (ulcer* or sore*):ti,ab,kw
#38(bed NEXT sore*) or bedsore:ti,ab,kw
#39(#35 OR #36 OR #37 OR #38)
#40(#34 AND #39)

The Ovid MEDLINE search will be combined with the Cochrane highly sensitive search strategy for identifying reports of randomised controlled trials which appears in Cochrane Handbook of Systematic Reviews of Interventions (Higgins 2006). The EMBASE and CINAHL searches will be combined with the trial filters developed by the Scottish Intercollegiate Guidelines Network (SIGN).

Searching other resources

We will handsearch conference proceedings from the European Pressure Ulcer Advisory Panel, European Wound Management Association and the Tissue Viability Society for all available years. Publications will not be limited by date of publication or language. Bibliographies and citations from retrieved articles will be searched for additional studies. Relevant equipment manufacturers and professional organisations will be contacted for details of unpublished and on-going studies. Where multiple publications from one study are identified, all citations will be referenced with the primary source identified.

Data collection and analysis

Selection of studies

Two authors will independently read the titles or abstracts resulting from the search process and eliminate any clearly ineligible studies. Another author will check the rejected articles. We will retrieve in full the remaining studies classified as clearly relevant or unclear. We will undertake further independent assessment of these full study papers, those meeting the exclusion criteria will be included in the review, those not meeting the inclusion criteria will be excluded from the review and will be added to the Table of Excluded studies with reasons given for their exclusion. If there is insufficient information to make a decision, we will contact the study authors for further information to aid the decision process. We will resolve differences in opinion by consensus with a third author acting as arbitrator in case of disagreement.

Data extraction and management

Two authors will independently extract and summarise details from studies using a standardised data extraction sheet. Where a study reports data on a variety of devices we will attempt to separate the data into device types for the purpose of the analysis. If data are missing from reports then we will attempt to contact the

authors to obtain missing information. We will contact manufacturers to obtain complementary information. Data from studies that had been published more than once will be included only once, however, we will extract the relevant data from all publications.

The following data will be collected:

- Author
- Title
- Source of reference
- Health care setting and country of study
- Use of clear inclusion and exclusion criteria
- Number and description of participants, e.g. age, sex, concurrent disease
- Presence of existing pressure ulcers on entering the study (site, number, grade and size of ulcer)
- Description of intervention and comparison
- Statistical power - if stated and for what difference
- Study design
- Method of random sequence generation
- Method of allocation and adequacy of concealment at the point of randomisation
- Outcomes and method of measurement, i.e. incidence of new ulcers including grade, size and location
- Description of concurrent interventions by treatment arm
- Duration of intervention period and follow-up
- Baseline comparability
- Use of intention to treat analysis
- Number and description of withdrawals from study
- Blinded outcome assessment.
- Evaluation of cost
- Adverse events
- Quality of life data
- Patient acceptability data
- Pain, discomfort
- Verification of delivery of intervention
- Training and experience of practitioners delivering the intervention
- Source of funding
- Date of the study

Where necessary, additional primary data will be obtained from the original authors.

Assessment of risk of bias in included studies

Two authors will independently assess the quality of studies without blinding to journal or authorship using the checklist below. We will resolve discrepancies by discussion.

Each item will be assessed separately rather than combined in a scoring system

1. Adequacy of the randomisation process:

Trials will be awarded the following grades for adequacy of the randomisation process:

A = Adequate - sequence generation is reported using random number tables, computer random number generation, coin tossing, or shuffling.

B = Did not specify one of the adequate reported methods in (A) but mentioned randomisation method.

C = Using a system involving dates, names, or admittance numbers for the allocation of patients. These studies are known as quasi-randomised and will be excluded from the review.

2. Adequacy of allocation concealment

Trials will be awarded the following grades for allocation concealment:

A = Adequate: a randomisation method described that would not allow an investigator/participant to know or influence an intervention group before an eligible participant entered the study, such as central randomisation; serially numbered, opaque, sealed envelopes.

B = Unclear: trial states that it is 'randomised', but no information on the method used is reported or a method is reported that was not clearly adequate.

C = Inadequate: inadequate method of randomization used, such as alternate medical record numbers or unsealed envelopes; or any information in the study that indicated that investigators or participants could influence the intervention group.

3. Blinding

The following points will be graded as 'A' for blinding undertaken, 'B' when the relevant information is not stated in the trial report and 'C' for no blinding:

(i) Blinding of investigators.

(ii) Blinding of participants.

(iii) Blinding of outcome assessor.

(iv) Blinding of data analysis.

4. Intention-to-treat analysis

A = Yes: If specifically reported by authors that ITT was undertaken and this was confirmed on study assessment, or not stated but evident from study assessment that ITT was undertaken

B = Unclear. Described as ITT analysis, but unable to confirm on study assessment, or not reported and unable to confirm by study assessment.

C = No: Lack of ITT confirmed on study assessment (Patients who were randomised were not included in the analysis because they did not receive the study intervention, they withdrew from the study or were not included because of protocol violation) regardless of whether analysis described as ITT.

5. Withdrawals - reported by treatment group with reasons

A = Adequate, if the numbers and reasons for dropouts and withdrawals in all intervention groups were described or if it was specified that there were no dropouts or withdrawals.

B = Unclear, if the report gave the impression that there had been no dropouts or withdrawals, but this was not specifically stated.

C = Inadequate, if the number or reasons for dropouts and withdrawals were not described.

6. Completeness of follow-up

Percentage of participants for whom data was complete at defined study end-point. Adequate follow is achieved when 80% of people initially randomised to the trial were included at the final outcome measurement.

7. Comparability at baseline

Were the groups similar at baseline in terms of prognostic factors? If there were differences, were these adjusted for in the analysis?

A = Yes; B = Unclear; C = No

Data synthesis

Data will be entered into and analysed using Cochrane RevMan software. Results will be presented with 95% confidence intervals. Estimates for dichotomous outcomes (e.g. occurrence of ulcers) will be reported as relative risk. Continuous data will be converted to the standardised mean difference (or a weighted mean difference, when plausible) and overall effect size (with 95% confidence intervals) will be calculated. Methods of synthesising the studies will depend on its quality, design and heterogeneity. Both clinical (age, co-morbidities, risk-at-onset, and setting) and statistical heterogeneity will be explored. If primary studies appear similar in terms of trial design and patient group then the degree of inconsistency between study results will be assessed using the I^2 statistic (Higgins 2003). This examines the percentage of total variation across studies due to heterogeneity rather than to chance. Where there is very little clinical and statistical heterogeneity and where I^2 is less than 25% a fixed effect model will be applied to pool data. Values of I^2 between 25% to 75% indicate the existence of heterogeneity and a random effects model will be applied for meta-analysis. Values of I^2 over 75% indicate a high level of heterogeneity and it is likely that pooling would be inappropriate (Higgins 2003). Where synthesis is inappropriate we will undertake a narrative overview.

ACKNOWLEDGEMENTS

We would like to thank the peer referees (Duncan Chambers, Carol Dealey, Susan Hunter and Stephanie Kondos) and the Wounds Group Editors (Gill Cranny, Nicky Cullum and Andrea Nelson) who refereed the protocol. We would like to acknowledge the contribution of Ali Baba Akbari Sari who helped develop the initial search strategy, Ruth Foxlee who contributed to the development of the current search strategy and who conducted the searches and Sally Bell-Syer provided advice on protocol writing, document review, data extraction and edited the protocol.

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- * Indicates the major publication for the study

WHAT'S NEW

22 April 2008	Amended	Converted to new review format.
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HISTORY

Protocol first published: Issue 2, 2008

1 February 2008	New citation required and major changes	Substantive amendment
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CONTRIBUTIONS OF AUTHORS

Donnelly, Jeannie (JD) planned, developed, wrote and edited the protocol and designed the search strategy.

Kernohan, George (GK) planned, developed, wrote and edited the protocol and designed the search strategy.

Witherow, Anne (AW) planned, developed, wrote and edited the protocol and designed the search strategy.

DECLARATIONS OF INTEREST

Jeannie Donnelly completed a heel ulcer prevention trial as part of a PhD study. Professor George Kernohan supervised this study.