

Elevation devices for the prevention of heel pressure ulcers: a review

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Abstract

Aim: The objective of this systematic literature review was to gain insight into the effectiveness of off-loading devices to prevent heel pressure ulcers within the acute hospital setting. **Background:** Heels have been identified as the second most common site for pressure ulcers. Devices which off-load pressure can include pillows, wedges and boots. It is unclear as to which method or device is best at preventing pressure ulcers. **Design and methods:** A systematic review was carried out through the search of electronic databases and bibliographies of relevant publications. Randomised controlled trials (RCTs) and systematic reviews that compared devices which off-load heels to prevent pressure ulcers were identified. **Results:** A total of five studies were included in the review. The methodological quality of the studies was generally poor. The studies reported that heel-boot elevation devices appeared more beneficial. However, poor compliance with wearing the devices was identified, as well as a perceived increased risk of falls. There were little data on cost-effectiveness. **Conclusions:** There is little high-quality trial evidence to support the routine use of heel devices to prevent pressure ulcers. However, they may have a role to play within a multifaceted programme of pressure-ulcer prevention.

Key words: Pressure ulcers ■ Systematic review ■ Prevention ■ Heel off-loading devices

Pressure ulcers, commonly referred to as pressure sores, decubitus ulcers or bed sores, result when damage occurs to the skin, which can extend to underlying structures such as muscle and bone (Lahmann and Kottner, 2011). Pressure ulcers are more likely within high-risk groups such as older people, those with obesity, or those who are malnourished or seriously ill; however, any patient may be at risk. Pressure ulcers can develop in varying degrees of severity and the National Institute for Health and Care Excellence (NICE) (2014) has recommended the use of a classification system such as the European Pressure Ulcer Advisory Panel (EPUAP)-National Pressure Ulcer Advisory Panel (NPUAP) classification system (EPUAP and NPUAP, 2009). This has four levels of injury ranging from grades 1 to 4 based on the degree of damage to the skin and underlying tissues. This has recently been updated and now includes the four categories (1–4), as well

as unstageable and deep-tissue injury (NPUAP et al, 2014).

The financial costs to the NHS are substantial and vary depending on the grade of the ulcer. Using data from 2011, Dealey et al (2012) estimated that the cost of healing an uncomplicated ulcer in the acute setting ranges from £1214 for a grade 1 ulcer to £8783 for a grade 4 ulcer (Dealey et al, 2012). In the UK, the cost of preventing and treating pressure ulcers in a large, 600-bedded general hospital was estimated in 2002 at between £600 000–£3 million per year (Clark et al, 2002). Dealey et al (2012) arrived at a similar figure of £3.36 million as an annual cost to a typical hospital. In many NHS organisations, pressure-ulcer reductions have become a Commissioning for Quality and Innovation (CQUIN) framework target. This makes a proportion of a healthcare provider's income conditional on demonstrating improvements in the quality of the service it provides. In this case, it is the reduction in the number of patients acquiring an avoidable pressure ulcer during their stay in hospital (Newton, 2010).

Pressure ulcers can develop in any area of the body but tend to be over bony prominences, such as the sacrum, heel and elbow (Scheel-Sailer et al, 2013). Heels have been identified as one of the most common sites for the development of pressure ulcers (Vangilder et al, 2008). Heel pressure ulcers differ from those on other parts of the body as the anatomy of the heel makes it vulnerable to pressure. The largest bone of the foot (the calcaneus) has a pointed shape and does not have a cover of subcutaneous fat to act as a cushion, which means that it can be highly susceptible to pressure damage (Mayrovitz et al, 2002). Heel pressure ulcers can be prevented and treated by relieving pressure on the heel through elevation devices which off-load pressure from the heel by supporting the foot or calf (Morton, 2012).

Off-loading should relieve pressure by completely lifting the heel from the bed. The most common means of achieving this is through the use of pillows placed lengthwise under the calf and boots to elevate the heel. A common method in the past was the use of water-filled gloves; however, these are no longer used as there was little evidence of their effectiveness (Vuolo, 2010). Boot-type devices are commonly used but, along with other heel-protecting devices, the evidence for their effectiveness is still lacking (Junkin and Gray, 2009). However, they are more likely to stay in place, supporting the foot in the right position, which can prevent prolonged plantar flexion compared with pillows or water-filled gloves (Bales, 2012). Boots can be made from a number of different materials including plastic filled with air, foam, fibre or synthetic sheepskin (Langemo et al, 2008).

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Table 1. Summary of Citations Identified from Search Strategy

Source	No. citations
Science Citation Index	428
British Nursing Index	94
CINHAL	101
MEDLINE	216
Total Citations Identified	839
Duplicates	126
Total with duplicates removed	713
Citations eliminated based on review of the abstract	629
Citations obtained for further review	85
Included citations	5

Aim, design and methods

The primary aim of this study was to examine which devices for off-loading the heel most effectively prevent pressure ulceration within secondary care.

A systematic review of the existing published evidence for off-loading devices in the prevention of heel pressure damage was conducted. Articles describing prospective randomised clinical trials conducted in hospital were included if they compared off-loading devices with other interventions for at-risk patients with intact skin within secondary care in order to prevent pressure damage. The primary outcome considered most important for inclusion within the studies was the incidence of heel pressure damage. Secondary outcomes that were included in the review were cost of the device; patient acceptability; and adverse events related to the use of the device. Citations which either included diabetic foot ulcers, were conducted in primary care or did not report the incidence of heel pressure ulcers separately were excluded. Other exclusions were non-comparative trials, methodological descriptions without data, non-systematic review articles and editorials. There was no restriction applied to the searches based on the date of publication or language. However, studies published in any language other than English were only included if there was an English abstract providing sufficient information about the trial design, methods and outcomes.

Searches were conducted up to December 2013 for randomised controlled trials (RCTs) of off-loading devices in the prevention of pressure ulcers on Cumulative Index to Nursing and Allied Health Literature (CINAHL), MEDLINE, Cochrane Library British Nursing Index, Science Citation Index and Google Scholar. No restrictions were placed regarding years. The key words were pressure ulcer*; foot ulcer*; pressure sore; decubitus ulcer; bed sore; foot; heel; and lower limb. Words ending in an asterix/star indicate a search of any terms including the letters before the asterix but with multiple endings, e.g. ulcer would include ulcer, ulcers, ulceration, etc. In addition, keywords from the Cochrane search strategy for clinical trials were included to identify comparative clinical trials (Higgins and, Green 2008).

Decisions regarding inclusion were based on review of the title or abstract and those citations which appeared to compare devices were obtained for more detailed review.

Inclusion or exclusion of articles was decided by the two authors. The quality of the included citations was then assessed against criteria recommended by the Cochrane Collaboration in the Cochrane Handbook of Systematic Reviews (Higgins and Green, 2008).

Results

A detailed breakdown of the search results is shown in *Table 1*. It was not possible to undertake a meta-analysis of the included studies owing to the heterogeneous nature of the studies in terms of location, trial design and outcome assessment.

A total of 80 studies were excluded from the review. There were 19 non-randomised studies, 17 review articles, 36 articles with no off-loading device, 4 in-vitro studies, 2 did not include pressure ulcers and one systematic review that evaluated treatment of existing pressure ulcers rather than prevention. Therefore, after detailed review, only five citations were found to be eligible for inclusion in this review.

Description of studies identified

Article 1: Campbell et al (2010)

Campbell et al (2010) was a randomised evaluation lasting 14 days of three heel off-loading products:

- Repose boot (n=27)
- Wedge (n=23)
- Pillow (n=22).

The patients included were all admitted with an orthopaedic condition or surgery below the waist over a 2-week period. None of the patients developed a pressure ulcer during the trial period. The product with the most positive feedback and fewest complaints was selected to be used in a prevention programme. No cost details of the device were reported.

Article 2: Donnelly (2011)

Donnelly (2011) was an RCT which evaluated the effectiveness of heel elevation (n=120) via a Heel-lift Suspension Boot™ (DMS Systems, USA) compared with standard care (n=119). Both groups were cared for on a pressure-redistribution support surface. A wide variety of support surfaces were used including foam mattress, mattress overlay and dynamic mattress.

The primary outcome was the presence or absence of a pressure ulcer at any site and any grade from 1–4 based on photographs of pressure areas assessed by a tissue viability nurse. An interim analysis was performed when half of the target sample size was reached and it was this analysis that was reported in the article. The trial was stopped early as there appeared to be a clear difference between the intervention and control groups. Those with heel elevators reported fewer pressure ulcers compared with standard care (n=8/120; 7% vs. n=31/119; 26%; $p<0.001$). The benefit of heel elevation was still present after exclusion of grade 1 ulcers and inclusion of those lost to follow-up as having developed an ulcer.

Clinical observations by staff highlighted sleep and restricted movement as issues. There was also poor concordance with wearing of the boots with 88 protocol violations reported based on comments from clinical staff: 42 defined as 'major' and 46 'minor'. No data were reported on costs. A sample size calculation in the article reported that 240 patients were

required in each arm but as this was not achieved, the study was underpowered. This may have meant that the differences found between the groups could have been a result of chance rather than a true difference between the boots and standard care (Halpern et al, 2002).

Article 3: Gilcreast et al (2005)

Gilcreast et al (2005) was an RCT that compared High Cushion Kodel™ heel protector, the Egg Crate Heel lift Positioner™ and the EHOB Foot Waffle Air Cushion™. There were 338 adult patients recruited, although only 240 ended the trial with complete data. This study was conducted at two military tertiary care academic medical centres. A daily skin assessment was performed based on criteria published in the USA by the Agency for Healthcare Research and Quality (AHRQ) (1992). A total of 12 pressure ulcers developed in 240 subjects (5%). There were no statistical differences between the devices with regards to reducing pressure ulcer development. It was stated that a sample size of 6225 would be required to produce a statistically significant difference between the three groups. Compliance with wearing all of the devices was 85% although 39 subjects (16%) were dropped from the analysis as they did not wear the device for at least 48 hours. Anecdotal evidence from patients in the study reported that the devices were uncomfortable.

Article 4: Tymec et al (1997)

Tymec et al (1997) was an RCT comparing the use of pillows with a commercially available foot waffle (i.e. vinyl boot). A total of 52 patients were recruited in an inpatient hospital. All patients had intact skin and were deemed at-risk of pressure ulcer development using the Braden risk-assessment score (Bergstrom et al, 1987). The number of patients developing pressure ulcers was lower using the foot waffle than the pillow (n=3 vs. n=1) but there was no statistically significant difference in the incidence between the two groups based on the Fisher's Exact Test (Fisher, 1935). The study did find that the interface pressure on the Achilles tendon was significantly lower in the pillow group compared with the waffle group ($p<0.01$) and that the waffle group tended to develop pressure ulcers sooner (n=13 days) compared with those in the pillow group (n=10 days). No cost data were reported. One significant issue with the study was that the waffle boot used was redesigned prior to completion of the study. No detail was provided on the changes made.

Article 5: Zernicke (1994)

Zernicke (1994) was an RCT that compared the effectiveness of four pressure-relieving devices: foam splints (n=16), eggshell foam (n=14), duoderm dressing (n=6) and heel protector boots (n=5). Forty one patients admitted to an orthopaedic ward with fracture neck of femur were included and randomly allocated to one of the pressure-relieving devices. The study initially included only three devices but stopped recruiting to the duoderm group and substituted the heel protector boots after 2 months as 2 out of 6 patients in this group developed a blister to their unaffected leg (i.e. leg without the fracture). The inclusion of duoderm as a pressure-relieving device above and beyond its use to reduce

shear and friction (Nakagami et al, 2006) may be surprising but similar dressings have been used this way by some clinicians and researchers (Barberà i Guillem R et al, 2010).

The study did not report details of the incidence of pressure ulcers within each intervention group but reported changes to the skin based on a non-validated scoring system of skin change and integrity. Foam splints and eggshell foam were the most effective at relieving pressure on the heel as compared with duoderm and heel protectors. Although two patients complained of discomfort to their Achilles tendon, concordance to all devices was 100%. The study reported costs for the devices but did not provide details of the basis for the costing or how the costs were calculated.

An additional study with implications for the evidence

An additional citation was found, but not included as it was a non-randomised study (Bales, 2012). Nonetheless, it raises an issue with the evidence that is worth visiting within this article. The USA study compared the effectiveness of intravenous (IV) bags and the heel-lift suspension boot in patients admitted to hospital for hip or knee surgery (n=30). Half were non-randomly allocated the IV bag and the other half, the heel-lift suspension boot. The study reported that the pressure-relieving suspension boot was more effective as none of the patients wearing the boot developed signs or symptoms of pressure damage, whereas 6 out of 15 in the IV bag group did. This is not surprising as up-to-date guidelines state that water-filled gloves and IV bags must not be used (NPUAP et al, 2014).

Methodological quality of the included studies

The methodological quality of the included studies assessed against the Cochrane criteria was generally poor (Table 2). There were trial design issues and a high risk of bias within the studies as a result of inadequate reporting of trial design. None of the citations, except for Donnelly et al (2011), provided sufficient detail regarding the efforts made to blind the treatment allocation and the assessment of the interventions. For example, Zernicke (1994) had unbalanced treatment allocation, changed the interventions part-way through the trial and used a non-validated skin assessment tool as the primary outcome.

Discussion

The poor quality of the research within pressure ulcer prevention and the heterogeneous nature of the published studies found within the current review have also been highlighted previously (Reddy et al, 2006; 2008). Despite the poor methodological quality of the identified studies, all of the included trials reported that the use of heel-boot elevation devices appeared more beneficial than using dressings, pillows or IV bags of water.

The recently updated guidelines by NPUAP et al (2014) specifically recommend that IV bags and water-filled gloves are not used. However, these recommendations tended to be based on expert opinion, which is considered low-level evidence in the hierarchy of evidence, as compared with good-quality trials (Centre for Evidence-based Medicine, 2009) to support a specific means of off-loading. This lack of

Table 2. Methodological quality of the included trials based on Cochrane criteria

Study	Was the allocation sequence adequately generated?	Was allocation adequately concealed?	Was knowledge of the allocated intervention adequately prevented during the study?	Were incomplete outcome data adequately assessed?	Are reports of the study free of suggestion of selective outcome reporting?	Was the study apparently free of other problems that could put it at high risk of bias?
Campbell et al (2010)	Yes	Unclear	Unclear	Yes	Unclear	Yes. However, the citation was a product evaluation but was not funded by the manufacturer.
Donnelly et al (2011)	Yes	Yes	Yes	No	Yes	Yes
Gilcreast et al (2005)	Unclear	No	No	No	Yes	Yes
Tymec et al (1997)	Yes	Unclear	Unclear	Yes	Yes	No
Zernicke (1994)	Unclear	Unclear	Unclear	Yes	No	Unclear

Source: Higgins and Green, 2008

high-quality evidence was reflected in the most up-to-date NICE guideline on pressure ulcer prevention which simply recommends that heels are off-loaded without specifying a means (NICE, 2014).

The use of devices that ‘float’ the heels has been recommended in the NPUAP et al (2014) guidance which would implicitly advocate boot-type devices over other means. This was likely owing to the boot devices more easily and effectively off-loading the heels, particularly during patient movement (Junkin and Gray, 2009). However, the data on their use resulting in fewer patients developing pressure ulcers and being cost-effective remains equivocal. One major issue with such devices was the potential for low patient compliance caused by patients finding them uncomfortable, too warm and reducing their mobility (Gilcreast et al, 2005).

The included studies were conducted in a number of different specialties and countries so it was likely that they contained patients with varying comorbidities, ages and other prognostic factors. Two studies (Zernicke, 1994; Donnelly et al, 2011) included only those with fractured hips; one included only orthopaedic surgery patients and those with surgery ‘below the waist’ (Campbell et al, 2010); and two included mostly medical/non-surgical patients (Tymec et al, 1997; Gilcreast et al, 2005). Additionally, the varied populations indicate likely variation in factors which impacted on risk, healing, compliance, staffing and so forth.

There were also problems related to the validity of the data-collection methods and assessment in some of the studies. One study (Zernicke, 1994) did not classify ‘redness’ as skin damage despite being classed as a Grade 1 pressure ulcer in NPUAP et al (2014) guidance; this was likely owing to the fact that it predated any such guidance.

The sample sizes of the included studies did not appear to have any statistical basis. Only one of the studies (Donnelly

et al, 2011) performed a sample size calculation to estimate the necessary sample to detect a difference between the interventions in term of the incidence of pressure ulcers. However, it did not reach the specified numbers and, so, the study could potentially have made a type 1 error, i.e. there is no difference between the groups but the study reports that there is a difference. There was also significant heterogeneity in terms of the length of the studies and the time period of data collection and assessment. The majority of the studies had limited follow-up of 12–14 days. There were also issues with how results were reported. The majority of studies in this review reported simple proportions and did not seek to undertake any sophisticated analysis to allow for confounders or differences in time to pressure ulcer development, such as regression or Kaplan-Meier survival analysis. Tymec et al (1997) did perform a more sophisticated analysis but this was poorly reported. One example was their use of the Fisher Exact test which did not specify if this was based on a one- or two-tailed analysis, which could potentially influence the significance of the results (McKinney et al, 1989).

Within the clinical setting, adhoc devices such as pillows can routinely be used. However, these are often ineffective as heel elevation devices as they tend to remain in place for only brief periods of time. Heels tend to rapidly slip off the pillow onto the bed or the lower extremities move so that the heels rest directly on the pillow, which paradoxically increases tissue-interface pressure, rather than relieving it (Junkin and Gray, 2009). Another issue in relation to pillows may be that there is an increased risk for foot-drop (Tymec et al, 1997). Nevertheless, they may be useful as a short-term aid in areas such as accident and emergency.

The evidence for the effectiveness of current off-loading devices was found to be disappointingly sparse while that for their cost-effectiveness was almost completely absent. The

need for detailed data on cost-effectiveness is particularly important as the cost of the devices may be considerable. Patient compliance with wearing the boot device may also be a problem and was reported in Gilcreast et al (2005). It became more of a problem as patients' mobility improved. There may also be added challenges of patients disliking wearing the boot devices and a perceived higher risk of falls; although these devices are designed for use in bed, patients may still attempt to mobilise while wearing them therefore increasing their risk of falls.

In considering the best device for off-loading the heel and preventing pressure ulcers, clinical staff are left with their clinical judgement and an assessment of each individual device in terms of its ability to effectively off-load the heel. Consideration should also be given to the device's comfort, ability to prevent foot-drop, whether it restricts mobility and whether it can remain in place without resulting in additional pressure to other areas (Junkin and Gray, 2009).

Conclusion

There are a many off-loading device choices and the client group requiring them can be extremely varied. Some devices are expensive and there may be issues regarding patient comfort and therefore compliance. The clinician therefore needs to carefully consider patient comorbidities and suitability. Healthcare providers with tight budgets will need clearer guidance on the cost-effectiveness of these products and be reassured of patient compliance in order to use them for the prevention of heel pressure ulcers.

Despite recent guidance advocating that heels are off-loaded, there was a lack of evidence for the use of any one identified elevation device over the other in terms of its ability to prevent heel pressure ulcers, reduce shear and friction and prevent foot-drop. More research is needed regarding the comparative effectiveness of heel-elevation devices in terms of cost, outcomes, and potential adverse events. An ideal device to prevent heel pressure ulcers should be lightweight, comfortable, and easily to apply and remove so that practitioners can check pressure areas. BJN

Conflict of interest: none

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KEY POINTS

- Heels are the second most common site for pressure ulcers
- This review found little evidence for the best methods for preventing heel pressure ulcers
- Off-loading boots may be more effective than pillows but they were associated with poor patient compliance
- Wearing boots may increase the risk of falls

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