An RCT to determine the effect of a heel elevation device in pressure ulcer prevention post-hip fracture

**Objective:** A randomised controlled trial set out to determine whether there are differences between complete offloading and standard care in terms of the number of new pressure ulcers (PUs) developing on the heels of older patients with fractured hips and the number or severity of new PUs on other areas of their bodies.

**Method:** Patients aged over 65 years in a fracture trauma unit with fractured hips were randomly allocated to receive heel elevation (DM Systems, Evanston, Illinois) plus pressure-redistributing support surface or standard care (pressure-redistributing support surface alone). Exclusion criteria included existing heel damage. Patients were assessed on pre- and postoperative days for the occurrence of new pressure damage. Patients completed a satisfaction questionnaire at discharge.

**Results:** 119 patients were recruited into the control group and 120 into the intervention group. Independent t-tests and chi-squared analysis showed both groups were comparable at baseline. Thirty-one subjects (26%) in the control group developed pressure ulcers (PUs) in the intervention group (7%, p < 0.001). No subjects in the intervention group developed a PU on their ankles, feet or heels, whereas 29 subjects in the control group did (p < 0.001). Kaplan-Meier survival curves indicated that subjects in the control group were more likely than those in the intervention group to suffer pressure damage at all timepoints (p = 0.001). A sensitivity analysis showed that when subjects lost to follow-up were assigned the worse outcome (PU positive) those in the intervention group were still less likely to develop PUs than the control group (p = 0.001). The offloading device was rated as comfortable overall by 59% of subjects.

**Conclusion:** The findings suggest that offloading reduces the incidence of heel ulcers.

**Conflict of interest:** None

Patients with fractured hips exemplify those at high risk of pressure ulceration. They tend to be old, frail, have limited mobility and a high proportion has dementia. Unfortunately, the incidence of pressure ulcers (PUs) in this patient population remains high,1–4 and such ulceration has been identified as a measurable indicator of poor quality care.4–7 Furthermore, it has been estimated that failure to implement more effective prevention strategies for these patients may cost the UK NHS at least an extra £24 million per annum in the next 7–10 years.8–10

The heel is a common site for pressure ulceration in patients with a fractured hip.11 Although the precise reason for this is difficult to determine, it may relate to a complex interplay of factors, such as age-related diseases, tissue geometry, the duration of immobility and ineffective pressure relief.

Practitioners use a range of measures, including dressings, splints and pressure-redistributing mattresses, to prevent heel ulceration. No dressing studies have been able to substantiate claims that they prevent pressure ulceration. Two randomised controlled trials,12,13 two controlled clinical trials,14,15 and two quasi-experiments16,17 all had design flaws that left their findings open to question. Five out of these six trials did not perform a sample size calculation or randomly allocate their subjects. Three cast doubt on the reliability of the adhesive dressings in terms of retention.13,15,17 None of the dressings were able to completely eliminate heel ulcers, but two studies did indicate that dressings could potentially protect the heel from friction.12,13

Trials demonstrating that heels subjected to complete offloading did not develop pressure damage,14,18–24 and mattress trials showing that heel ulcers developed on a wide range of support surfaces,25–28 led us to conclude that devices that remove pressure from the heel may be more effective in reducing the incidence of heel PUs than devices that partially redistribute pressure, such as static and dynamic mattresses.

To date, it is not possible to determine which heel suspension device is most effective. This is largely due to the heterogeneity of the trial designs, as well as various methodological limitations, such as lack of a control group,18,21,24 no power analysis,18,21,23 and failure to determine the effect of covariates.18,21,23

Thus, existing literature cannot support the...
Research

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References


Fig 1. Flow diagram of clinical trial process for patients

Selection of candidate by investigator

Invited to participate in trial (verbal and written)

Informed/inclusionary consent

Yes

No

Exclude from trial

Collect baseline data to include:
Gender, age, past medical history, concomitant disease, current health history, accident details, Braden score, Barthel score, Mini-mental score, ASA-PS comorbidity score, baseline skin assessment, Doppler ultrasound

Yes

Complete consent documentation

Assess and document condition of pressure areas daily

Day 1 postop – document details of operation and perioperative period. Update Braden score and ASA-PS score

On postoperative days 1 and 4 complete structured skin assessment documentation

On discharge, complete patient satisfaction questionnaire

Complete adverse event forms
Alert ethics committee if possible, complete patient satisfaction questionnaire

Yes

No

Adverse event

Continue with trial (principle investigator’s decision)

No

Withdraw patient from trial

If possible complete patient satisfaction questionnaire

No

Yes

Pressure damage?

Adverse event linked to test product

No

Yes

No

Yes

This is important since many NHS organisations have invested heavily in pressure-reducing support surfaces, for example, through total bed management initiatives. It should also be remembered, though, that practitioners do not look after a single anatomical site: they care for people, not heels.

Therefore, other factors govern equipment selection, such as the effect of the device on other areas of the body, plus patient comfort and acceptability.

The primary objective of this randomised controlled trial was to determine the differences between complete offloading and ‘standard care’ with regards to:

• The number of new PUs on the heels of older patients with fractured hips.
The number or severity of new PUs on other areas of their bodies.

Secondary objectives were to assess patient opinion and concordance with an offloading device and to make recommendations for future clinical practice.

Method

This study was undertaken in the fracture trauma unit of a major tertiary referral centre (Royal Group of Hospitals Trust, Belfast), which treats over 1000 patients per year with fractured hips. Potential participants were identified from the unit’s daily admission list.

Participants

Patients were considered eligible for inclusion if they had suffered a hip fracture, including any bony injury to the femoral head or femoral neck, in the previous 48 hours and were aged ≥ 65 years or older on the day of fracture.

Patients were excluded if they did not give written, informed consent to participate, or indicate their willingness to participate through a process of inclusionary consent. Other exclusion criteria were existing heel pressure damage, as defined by the NPUAP, and/or history of previous pressure ulceration. Patients who investigated or medical/nursing team considered unsuitable were also excluded. The clinical trial process for patients is depicted in Fig 1.

Eligible patients were allocated to either the intervention group (heel elevation) or the control group (standard care), according to a computer-generated block randomisation schedule (in permuted blocks of 20). In order to assure allocation concealment, the randomisation schedule was held and managed by a senior research nurse manager not directly involved in the study.

Baseline data were collected within 48 hours of admission and included concomitant disease, mechanism of injury, fracture classification, a mental state score, a pre-injury Barthel activities of daily living score, and nutritional status, using the Malnutrition Universal Screening Tool. The subject’s health status was measured using the American Society of Anesthesiologists Physical Status score (ASA-PS). The ASA-PS score was recorded on admission by the investigator and immediately before surgery by the anaesthetist.

Kore and Blacklock described this as “…a global

Heelift® Suspension Boot.

Designed for the prevention and treatment of heel pressure ulcers.

- Forefoot support to prevent foot drop
- Three sizes to ensure a proper fit
- Washable/autoclavable

The soft foam design and spare elevation pad make it easy to customize the Heelift to meet a patient’s unique needs.

- Relieve pressure on the Achilles tendon or ankle
- Control hip rotation


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measure of the patient’s patho-physiological response to disease burden or alternatively the lack of reserve to a stress because of disease burden... .

**Interventions**

As pillows proved unreliable during a pilot study, heel elevation was achieved using the commercially available Heelift Suspension Boot (DM Systems Inc., Evanston, Illinois, USA). The boot removes pressure from the heel by lifting it up with an elevation pad and suspending it in a protective space. Pressure is therefore transferred from the heel and dispersed over the lower leg, which is supported on ‘egg-crate’ foam. The device is secured to the lower leg by two Velcro straps (Fig 2). The Heelift Suspension Boot was applied to both lower limbs of each patient within the experimental group. It was not possible to blind either the patient or the investigator as the intervention (Heelift Suspension Boot) was very distinctive.

All patients were nursed on pressure-reducing support surfaces. These included the Pentaflex cut foam mattress, an AlphaXcell mattress overlay, an AutoExcel mattress overlay and the Nimbus 3 alternating mattress (ArjoHuntleigh); all are standard pressure-reducing support surfaces used within the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to the clinical set

![Fig 2. Heelift Suspension Boot, showing heel elevation pad (a) and internal structure (b).](image-url)
Fig 3. Flow of participants through each phase of the trial

Assessed for eligibility (n=705)

Randomised (n=239)

- Received standard intervention as allocated (n=119)
  - Did not receive standard intervention as allocated (n=0)

- Received experimental intervention as allocated (n=120)
  - Did not receive allocated intervention (n=0)

Follow up:

- All patients were assessed daily during their admission period
- Mean follow up: 10.78 days

Withdrawn (n=3)

- Reasons:
  - Lost to follow-up (n=1)
  - Deteriorating medical condition (n=1)
  - Recruited incorrectly (n=1)

All subjects were included in the analysis on an intention-to-treat basis

Completed trial (n=116)

Not randomised (n=466)

Reasons:

- Subjects did not meet inclusion criteria (n=398)
- Subject did not wish to participate (n=35)
- Relative did not give assent (n=1)
- Unable to obtain relative assent within 48 hours of injury (n=32)

Received standard intervention as allocated (n=119)

- Did not receive standard intervention as allocated (n=0)

Follow up:

- All patients were assessed daily during their admission period
- Mean follow up: 12.18 days

Withdrawn (n=9)

- Reasons:
  - Deteriorating medical condition (n=6)
  - Lost to follow-up (n=1)
  - Adverse event possibly linked to the intervention (n=1)
  - Patient withdrew consent (n=1)

All subjects were included in the analysis on an intention-to-treat basis

Completed trial (n=111)

National and local audits of PU incidence within the fractured hip population were evaluated in order to determine the mean incidence of pressure damage. This exercise did not prove particularly helpful, however, as incidence rates ranged from 8.8% to 55%.42,43 In order to gain a clearer understanding of the local extent of the problem, an audit was carried out over a 2-week period. The results of this audit suggested that the prevalence of PUs (category II and above) was 21.3%.34 This figure was in keeping with that of Guningberg and Rademarkers et al.1,43 It was decided that a 50% decrease in pressure damage (from 20% to 10%) would be clinically
Based on these figures it was calculated that, using a two-sided hypothesis and a 5% significance level, 240 patients per group would give an acceptable level of 87.5% power in order to detect a significant difference in the number of PUs between the two groups.

Prior to statistical analysis, variables were screened for outliers, distributional properties, the number of missing values and obvious mistakes in recording, coding or data entry. This was achieved by visually inspecting the data and performing range checks. The data were described using the central tendency and dispersion, with a standard package used for all statistical analysis (SPSS version 11).

With regards to nominal and categorical baseline characteristics, chance variation was analysed using the Chi-squared test, applying the Fisher’s exact test when appropriate. The means of interval and ratio data (which were normally distributed) were compared using an independent-samples t-test.

The proportions of patients developing one or more PU in each limb of the trial were compared using a Chi-squared test for association. The hypothesis test was two-sided, with a 5% significance level. The Kaplan-Meier survival function was used to estimate the probability of group survival: how many subjects in each group would remain free from pressure damage. The Cox Hazards Regressional Model was used to analyse the potential impact of covariates.

### Results

#### Descriptive statistics

A total of 705 patients were screened over 39 weeks (18/2/04–13/2/05), with 466 patients excluded, as shown in Fig 3. The three main reasons for exclusion related to the time since injury (> 48 hours), difficulties in obtaining relative assent/inclusionary consent, and age (< 65 years of age). Of the remaining 239 subjects, 119 were recruited to the control group and 120 to the intervention group. Of these participants, 184 were female and 55 were male (mean age 81 years, 65–100). This preponderance of female patients is in keeping with national and international figures.

During the study period, 45 adverse events were recorded. These were spread evenly across the two groups, with 20 occurring in the intervention group and 23 in the control group. A Chi-squared test (with continuity correction) indicated that there was no significant association between the groups and adverse events ($\chi^2 = 0.158$, df = 1, $p = 0.691$). Of the 45 adverse events, five resulted in sudden death and were classified as ‘serious’, 21 were thought to be ‘life-threatening’ (e.g. cardiac arrest, pulmonary embolism), nine were considered ‘severe’ (e.g. rectal bleed, tissue trauma), two were graded as ‘moderate’ (e.g. extravasation injury), and eight were considered ‘mild’ (e.g. fall without injury).

#### Table 1. Group characteristics at baseline.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control group</th>
<th>Intervention group</th>
<th>Total</th>
<th>Significance (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>80.82</td>
<td>80.89</td>
<td>N/A</td>
<td>$p = 0.94^*$</td>
</tr>
<tr>
<td>Gender</td>
<td>Male 30</td>
<td>Female 89</td>
<td>55</td>
<td>$p = 0.52^\dagger$</td>
</tr>
<tr>
<td>Smoking</td>
<td>No 73</td>
<td>Ex 28</td>
<td>135</td>
<td>$p = 0.26^\ddagger$</td>
</tr>
<tr>
<td></td>
<td>Yes 18</td>
<td>19</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>No 72</td>
<td>Yes 47</td>
<td>151</td>
<td>$p = 0.47^\dagger$</td>
</tr>
<tr>
<td>Cardiac problems</td>
<td>No 70</td>
<td>Yes 49</td>
<td>133</td>
<td>$p = 0.39^\dagger$</td>
</tr>
<tr>
<td>Renal failure</td>
<td>No 117</td>
<td>Yes 2</td>
<td>231</td>
<td>$p = 0.28^\ddagger$</td>
</tr>
<tr>
<td>Confusion</td>
<td>No 93</td>
<td>Yes 26</td>
<td>185</td>
<td>$p = 0.91^\dagger$</td>
</tr>
<tr>
<td>Mini-mental stage score</td>
<td>0–8.5 46</td>
<td>9–10 67</td>
<td>98</td>
<td>$p = 0.74^\dagger$</td>
</tr>
<tr>
<td>Steroid medication</td>
<td>No 102</td>
<td>Yes 17</td>
<td>205</td>
<td>$p = 1.0^\dagger$</td>
</tr>
<tr>
<td>Type 1 diabetes</td>
<td>No 116</td>
<td>Yes 3</td>
<td>233</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>too small</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>No 109</td>
<td>Yes 15</td>
<td>214</td>
<td>$p = 0.41^\dagger$</td>
</tr>
<tr>
<td>Clecane</td>
<td>No 119</td>
<td>Yes 120</td>
<td>239</td>
<td>N/A</td>
</tr>
<tr>
<td>PVD</td>
<td>No 114</td>
<td>Yes 5</td>
<td>229</td>
<td>$p = 1.00^\ddagger$</td>
</tr>
<tr>
<td>Risk of malnutrition</td>
<td>Low risk 92</td>
<td>Med–high 27</td>
<td>179</td>
<td>$p = 0.48^\dagger$</td>
</tr>
<tr>
<td>Hypotension</td>
<td>$\geq 90\text{mmHg}$ 107</td>
<td>$&lt; 90\text{mmHg}$ 6</td>
<td>220</td>
<td>$p = 0.33^\ddagger$</td>
</tr>
<tr>
<td>Lower limb oedema</td>
<td>No 104</td>
<td>Yes 15</td>
<td>212</td>
<td>$p = 067^\dagger$</td>
</tr>
<tr>
<td>Braden score* (mean)</td>
<td>15</td>
<td></td>
<td>239</td>
<td>$p = 0.17^*$</td>
</tr>
<tr>
<td>Barthel score (mean)</td>
<td>17.39</td>
<td></td>
<td>239</td>
<td>$p = 0.080^*$</td>
</tr>
<tr>
<td>Pre-injury mobility</td>
<td>Independent 107</td>
<td>Dependent 12</td>
<td>204</td>
<td>$p = 0.071^\dagger$</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>No 101</td>
<td>Yes 18</td>
<td>200</td>
<td>$p = 0.75^\dagger$</td>
</tr>
<tr>
<td>Faecal incontinence</td>
<td>No 106</td>
<td>Yes 13</td>
<td>211</td>
<td>$p = 0.86^\ddagger$</td>
</tr>
<tr>
<td>ASA comorbidity score</td>
<td>1–2 30</td>
<td>3–4 89</td>
<td>55</td>
<td>$p = 0.52^\dagger$</td>
</tr>
</tbody>
</table>

Missing data have been excluded from the table. *Independent t-test; †Chi square analysis continuity corrected, computed only for a 2-by-2 table; ‡Pearson’s Chi square analysis; §Fisher’s exact test.
Initially, one of the incidents (severe lower limb bruising) was thought to be related to the Heelift Suspension Boot; however, discussion with the subject’s daughter revealed the patient’s legs had been bound tightly together by paramedics, in order to immobilise her fracture, prior to transfer. The pattern of bruising was not evident on admission but was consistent with this story. However, as the link with the boot could not be entirely ruled out, the boot was removed and appropriate authorities informed.

Tables 1 and 2 show that the group characteristics were comparable at baseline, in terms of comorbidities and the length of time spent lying on a hard surface prior to study enrolment. Subjects in the intervention group had a shorter wait from injury to theatre (χ² = 6.86, df = 1, p = 0.009) but spent a longer period of time in theatre than those in the control group (χ² = 11.82, df = 3, p = 0.004).

There were 88 protocol violations: 46 minor and 42 major. These were themed according to subjects’ comments, as well as clinical observations, and

<table>
<thead>
<tr>
<th>Variable</th>
<th>Control</th>
<th>Intervention</th>
<th>Total</th>
<th>Significance (2-sided)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Injury</td>
<td>Right hip</td>
<td>52</td>
<td>59</td>
<td>111</td>
</tr>
<tr>
<td></td>
<td>Left hip</td>
<td>67</td>
<td>61</td>
<td>128</td>
</tr>
<tr>
<td>Aetiology of injury</td>
<td>Low impact fall</td>
<td>116</td>
<td>120</td>
<td>236</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Time from injury to arrival of ambulance</td>
<td>≤ 15 minutes</td>
<td>56</td>
<td>59</td>
<td>115</td>
</tr>
<tr>
<td></td>
<td>&gt; 15 minutes</td>
<td>36</td>
<td>37</td>
<td>73</td>
</tr>
<tr>
<td>Time from ambulance arrival to hospital arrival</td>
<td>≤ 15 minutes</td>
<td>62</td>
<td>66</td>
<td>128</td>
</tr>
<tr>
<td></td>
<td>&gt; 15 minutes</td>
<td>25</td>
<td>29</td>
<td>54</td>
</tr>
<tr>
<td>Time taken to transfer from local hospital to research centre (if applicable)</td>
<td>Within 25 hours</td>
<td>52</td>
<td>49</td>
<td>101</td>
</tr>
<tr>
<td></td>
<td>25–48 hours</td>
<td>9</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>Time lying in A&amp;E department</td>
<td>≤ 2 hours</td>
<td>28</td>
<td>23</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>&gt; 2 hours</td>
<td>32</td>
<td>48</td>
<td>80</td>
</tr>
<tr>
<td>Time from injury to operation</td>
<td>≤ 72 hours</td>
<td>34</td>
<td>54</td>
<td>88</td>
</tr>
<tr>
<td></td>
<td>&gt; 72 hours</td>
<td>83</td>
<td>62</td>
<td>145</td>
</tr>
<tr>
<td>ASA score on day of operation — recorded by anaesthetist</td>
<td>1–2</td>
<td>34</td>
<td>23</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>3–4</td>
<td>65</td>
<td>65</td>
<td>130</td>
</tr>
<tr>
<td>Type of operation</td>
<td>Hemiarthroplasty</td>
<td>50</td>
<td>56</td>
<td>106</td>
</tr>
<tr>
<td></td>
<td>Dynamic hip screw</td>
<td>55</td>
<td>45</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td>11</td>
<td>15</td>
<td>26</td>
</tr>
<tr>
<td>Type of anaesthetic</td>
<td>Spinal</td>
<td>100</td>
<td>102</td>
<td>202</td>
</tr>
<tr>
<td></td>
<td>GA</td>
<td>16</td>
<td>14</td>
<td>30</td>
</tr>
<tr>
<td>Duration of surgery</td>
<td>≤ 2 hours</td>
<td>95</td>
<td>81</td>
<td>176</td>
</tr>
<tr>
<td></td>
<td>&gt; 2 hours</td>
<td>20</td>
<td>35</td>
<td>55</td>
</tr>
</tbody>
</table>

Missing data have been excluded from the table
*Chi square analysis continuity corrected, computed only for a 2-by-2 table; †Pearson’s Chi square analysis

Table 3. Pressure damage by group and area affected.

<table>
<thead>
<tr>
<th>Area affected</th>
<th>Control group</th>
<th>Category I</th>
<th>Category II</th>
<th>Ungraded Category II</th>
<th>Ungraded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sacrum</td>
<td>1</td>
<td>6</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Buttocks</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Heels</td>
<td>8</td>
<td>7</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral malleolus</td>
<td>8</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Achilles region</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Knees</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Toes</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Totals</td>
<td>18</td>
<td>16</td>
<td>5</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>


Discussion

The main finding of this study was that older people with fractured hips are less likely to develop PUs on their heels, if their heels are elevated off the mattress during the acute phase of treatment. This finding is valuable to practice because PUs impact negatively on quality of life and are expensive to treat in terms of time, staffing and resources. Our results are also supported by a recent study, which found that, in the hip fracture group only, the use of heel pressure-relieving measures was associated with no PUs at discharge.5

Generalisability

The trial exercised good practice in sample size estimation, case randomisation with allocation concealment, intention-to-treat analysis, engagement of an independent statistician, a priori stopping rules and, where possible, blinding. The above results are reported in an open and transparent manner, with issues such as loss to follow-up and protocol deviations described.

One of the main strengths of this study is that the participants were drawn from a population who are at risk of developing PUs. This included people who would normally be excluded from research due to a cognitive impairment. This is important because it is difficult to generalise findings from, for example, young healthy volunteers to frail older people. This is largely due to differences in the anatomy and physiology of the tissues, such as loss of muscle tone and a reduction in skin strength as well as the effects of chronic disease.44

Furthermore, all subjects, including those with a cognitive impairment, were recruited in a way that valued their wishes and beliefs. The recruitment process was underpinned by Dewing’s Model of...
Inclusionary Consent, which essentially enabled one to respect people for the choices they could and could not make, and to ‘hear’ what patients were saying through their verbal, non-verbal and behavioural cues. It should be noted that the recruitment process was time consuming.

Study limitations

It is accepted that the study was subject to potential observer bias due to non-blinding of the outcome assessor, although this was not practically possible. This was controlled to some extent by ward staff, who continued routine, independent monitoring, reporting on skin condition twice daily. Ward staff findings were checked by the investigator on a daily basis.

Category I PUs were viewed as a negative outcome as they are a main predictor of category II pressure damage. This view is supported by a systematic review that stated: ‘The identification of a grade 1 pressure ulcer is a significant risk factor for the development of a more severe ulcer and therefore an open wound’. It could therefore be argued that a failure to act on the signs of a category I ulcer is a serious omission of duty of care, particularly as these measures might improve clinical outcomes.

However, it has been noted that studies using the incidence of category I PUs as the primary outcome measure are less reliable. This may be due to difficulties in assessment and interpretation of category I lesions. The scientific concerns relating to this reliability issue were managed in two ways. First, areas of erythema were compressed using a magnifying glass and photographed. This allowed the independent assessor to determine if the erythema was blanching or non-blanching. This worked to good effect in all but two cases, where the independent assessor was not convinced that the area of redness was shown to be non-blanching. Second, statistical tests were rerun with category I PUs (non-blanching erythema) viewed as normal skin. The main result was unaffected.

Half of the subjects in the study (n=110) had their support surface upgraded by nursing staff, from a cut-foam mattress to an alternating pressure-redistributing mattress, based on perceived need. This would suggest that nurses were using their professional knowledge (which is often implicit and intuitive) to protect vulnerable subjects. Rycroft-Malone et al. suggest that this knowledge is generated from four different types of evidence: research, clinical experience, the patients and their carers, and knowledge from local context and environment, such as the culture of the organisation or feedback from audit. It would therefore be useful in the future to explore the various factors that influenced the decision to upgrade, and whether these factors were scientifically robust.

It is appreciated that the conclusions drawn are based on treatment being applied under ideal circumstances in a homogeneous patient population. In this instance, the investigator closely monitored patients and minor protocol violations were quickly corrected, like the boots being reapplied. This may not happen in routine practice. Also, the participants of a trial may be more interested in their own health, compared with those who refuse to take part. Therefore, patient concordance may be higher than in the routine practice. This comment is of concern given the poor concordance already noted in this trial.

Conclusions

The data presented here indicate that older people with fractured hips should have their heels elevated during the acute phase of injury/treatment to reduce the incidence of heel PU. This conclusion is based on an inclusive RCT design, which could be used to determine the effectiveness of other PU devices.

Although the Heelift Boot successfully prevented heel and ankle pressure damage, it did not meet the needs of all patients in terms of comfort, which ultimately affected concordance. More research is required to identify or further develop a heel elevation device that is cost-effective, comfortable and acceptable to all patients. This device should be lightweight so that it does not hinder independent movement, maintain an acceptable skin temperature, and be easily applied and removed so that practitioners can carry out routine pressure area checks. Moreover, it should be designed in such a way that other areas of the foot and leg, such as the tibial crest, are not at risk of tissue damage. Further development work should include user experience and opinions.

Given the problems relating to the reliability of non-blanching erythema as a primary outcome measure, and the ethical dilemma of allowing potentially viable tissue to breakdown, it is important that lead organisations collaborate in order to develop a scientifically acceptable outcome measure, which will also allow one to intervene at the earliest opportunity to protect patients from avoidable harm. This may require further research to link pathophysiological events to the clinical manifestations of pressure assault and subsequent PU development.

Relevance to clinical practice

Older, acutely ill, immobile patients should have their heels elevated off support surfaces from the moment of hospital admission until they are independently and effectively able to reposition their lower limbs in response to pressure related discomfort. Heel pressure relief must be viewed as part of a wider strategy, which aims to prevent all PUs. This strategy must include pressure-redistributing support surfaces, as patients who were nursed in this way consistently developed less pressure damage than those who were not.