

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

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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 PUs compared with eight 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 time points ($p = 0.001$). 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

randomised controlled trial; pressure ulcers; offloading; heel; high-risk patients

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,¹⁻³ 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-experiments^{16,17} 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,^{18,23,24} no power analysis,^{18,21-23} and failure to determine the effect of covariates.^{18,21-23}

Thus, existing literature cannot support the

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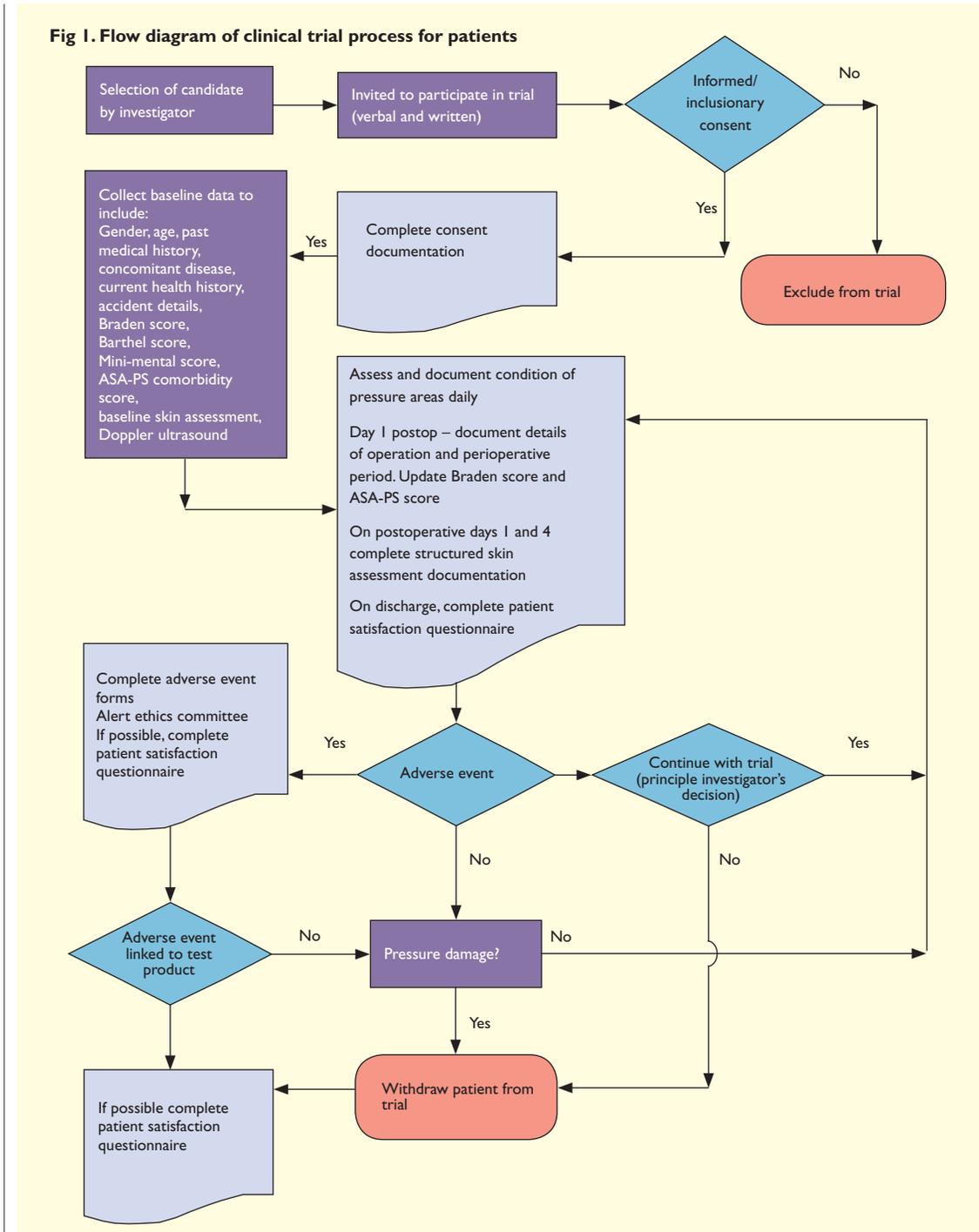
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References

- 1 Rademakers, L.M.F., Vainas, T., van Zutphen, S.W.A.M. et al. Pressure ulcers and prolonged hospital stay in hip fracture patients affected by time-to-surgery. *Eur J Trauma Emerg Surg.* 2007; 33: 3, 238–244.
- 2 Heyneman, A., Vanderwee, K., Grypdonck, M., Defloor, T. Effectiveness of two cushions in the prevention of heel pressure ulcers. *Worldviews Evid Based Nurs.* 2009; 6: 2, 114–120.
- 3 Campbell, K.E., Woodbury, M.G., Labate, T. et al. Heel ulcer incidence following orthopedic surgery: a prospective, observational study. *Ostomy Wound Manage.* 2010; 56: 8, 32–39.
- 4 Royal College of Physicians. Fractured neck of femur, prevention and management: summary and recommendations of a report of the Royal College of Physicians. *J R Coll Physicians Lond.* 1989; 23: 1, 8–12.
- 5 Todd, C.J., Freeman, C.J., Camilleri-Ferrante C. et al. Differences in mortality after fracture of the hip: the East Anglian audit. *BMJ.* 1995; 310: 6984, 904–908.
- 6 Audit Commission. United they stand: co-ordinating care for elderly patients with hip fracture. Abingdon: Audit Commission Publications, 1995.
- 7 Scottish Intercollegiate Guidelines Network (SIGN). Number 111. Prevention and Management of Hip Fracture in Older People: A National Clinical Guideline. Edinburgh: Scottish Intercollegiate Guidelines Network, 2009. www.sign.ac.uk/pdf/sign111.pdf.

Fig 1. Flow diagram of clinical trial process for patients



theory that devices designed to remove all pressure from the heel are any more effective than mattresses. This is important since many NHS organisations have invested heavily in pressure-redistributing support surfaces, for example, through total bed management initiatives.²⁹ 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.³⁰ 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.³¹⁻³³ Other exclusion criteria were existing heel pressure damage, as defined by

the NPUAP,³⁴ and/or history of previous pressure ulceration. Patients who the investigator 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,³⁵ a Braden PU risk assessment score,³⁶ and nutritional status, using the Malnutrition Universal Screening Tool.³⁷ The subject's health status was measured using the American Society of Anesthesiologists Physical Status score (ASA-PS).³⁸ 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

8 Johnell, O., Gullberg, B., Allander, J.A., Kanis, J.A. The apparent incidence of hip fracture in Europe: a study of national register sources. MEDOS Study Group. Osteoporos Int. 2002; 2: 6, 298-302.

9 Santy, J.E., Butler, M.K., Whyman, J.D. A comparison study of 6 types of hospital mattress to determine which most effectively reduces the incidence of pressure sores in elderly patients with hip fractures in a District General Hospital. Report to Northern & Yorkshire Regional Health Authority, 1994.

10 Whittington, K., Patrick, M., Roberts, J.L. A national study of pressure ulcer prevalence and incidence in acute care hospitals. J Wound Ostomy Continence Nurs. 2000; 27: 4, 209-215.

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11 Gunningberg, L., Lindholm, C., Carlsson, M., Sjöden, P.O. The development of pressure ulcers in patients with hip fractures: inadequate nursing documentation is still a problem. *J Adv Nurs*. 2000; 31: 5, 1155–1164.

12 Torra i Bou, J.E., Rueda Lopez, J., Camanes, G. et al. Preventing pressure ulcers on heels: comparative study of heel protective bandages and a specially shaped hydrocellular dressing for the heel. *Rev ROL Enf*. 2002; 25: 5, 370–374.

13 Bots, T.C., Apotheke, B.F. The prevention of heel pressure ulcers using a hydropolymer dressing in surgical patients. *J Wound Care*. 2004; 13: 9, 375–378.

14 Cheneworth, C.C., Hagglund, K.H., Valmassoi, B., Brannon, C. Portrait of practice: healing heel ulcers. *Adv Wound Care*. 1994; 7: 2, 44–8.

15 Zernicke, W. Heel pressure relieving devices: how effective are they? *Aust J Adv Nurs*. 1997; 14: 4, 12–19.

16 Kosiak, M. An effective method of preventing decubitus ulcers. *Arch Phys Med Rehabil*. 1966; 47: 11, 724–729.

17 Zernicke, W. Preventing heel pressure sores: a comparison of heel pressure relieving devices. *J Clin Nur*. 1994; 3: 6, 375–380.

18 Cheney, A.M. Portrait of practice: a successful approach to preventing heel pressure ulcers after surgery. *Decubitus*. 1993; 6: 4, 39–40.

19 Tymeck, A.C., Pieper, B., Vollman, K.A. Comparison of two pressure-relieving devices on the prevention of heel pressure ulcers. *Adv Wound Care*. 1997; 10: 1, 39–44.

20 Draper, P., Scott, F. Using traction. *Nurs Times*. 1998; 94: 12, 31–32.

21 Collins, A.S., Todd, R., McCoy, A. et al. Stride right. *Nurs Manage*. 2002; 33: 9, 33–36.

22 Bordner, T. Preventing heel pressure ulcers in hip fracture patients. Thesis submitted for the degree of Masters of Science in Nursing. Gonzaga University: Washington, 2003.

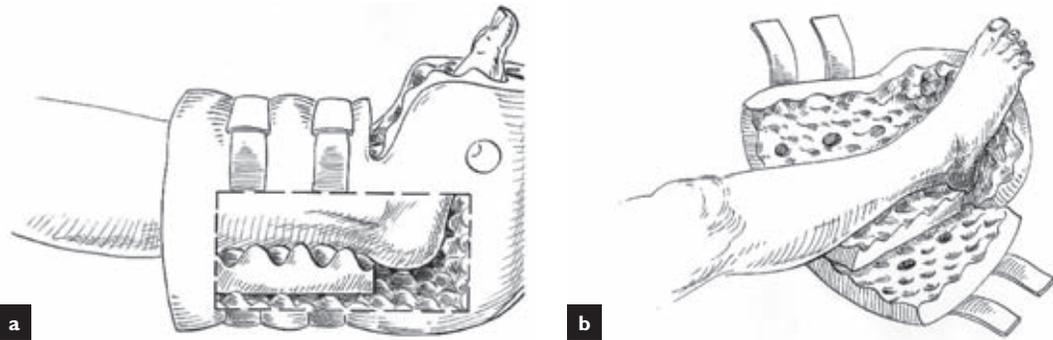


Fig 2. Heelift Suspension Boot, showing heel elevation pad (a) and internal structure (b).

measure of the patient's patho-physiological response to disease burden or alternatively the lack of reserve to a stress because of disease burden...'.³⁹

Interventions

As pillows proved unreliable during a pilot study,⁴⁰ 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-redistributing 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-redistributing support surfaces used within the clinical setting. For pragmatic reasons, mattress type was determined by ward nurses according to perceived need. Their choice, which varied between a cut foam mattress and an alternating mattress, was recorded and analysed as a covariate.

Pressure points were inspected daily for signs of tissue discolouration/ulceration. Complications and treatment details were also recorded. Given that early signs of pressure damage may also be indicated by a change in skin temperature (heat or coolness), tissue consistency (induration or oedema) and/or sensation (pain, itching),⁴¹ these factors were recorded and monitored by the lead author (JD). Lower limb arterial flow was assessed 4–5 days postoperatively.

An experienced tissue viability nurse who was blinded to the subject's history, the investigator's assessment of the skin, and the group to which the subject had been assigned, viewed photographs of suspected pressure damage, as well as intact pressure

points. The nurse was asked to categorise images using the NPUAP scale. Agreement was scored using the kappa statistic.

Outcomes

The primary outcome measure was the presence or absence of a PU (at any site) classified as a NPUAP category I (non-blanching erythema), or above, at the point of censor (hospital discharge, transfer or death).³⁴

In order to prevent any patient receiving an inferior treatment, 'stopping rules' were established *a priori* in collaboration with the study statistician (MS). For example, it was agreed that the first analysis would not be carried out until the study's half-way point (n=240). Second, the statistician would carry out the interim analyses in confidence. The investigators would not be made aware of the results unless they were highly significant (p<0.01). This strategy was adopted to prevent an over-reaction to early suggestions of a possible treatment difference.

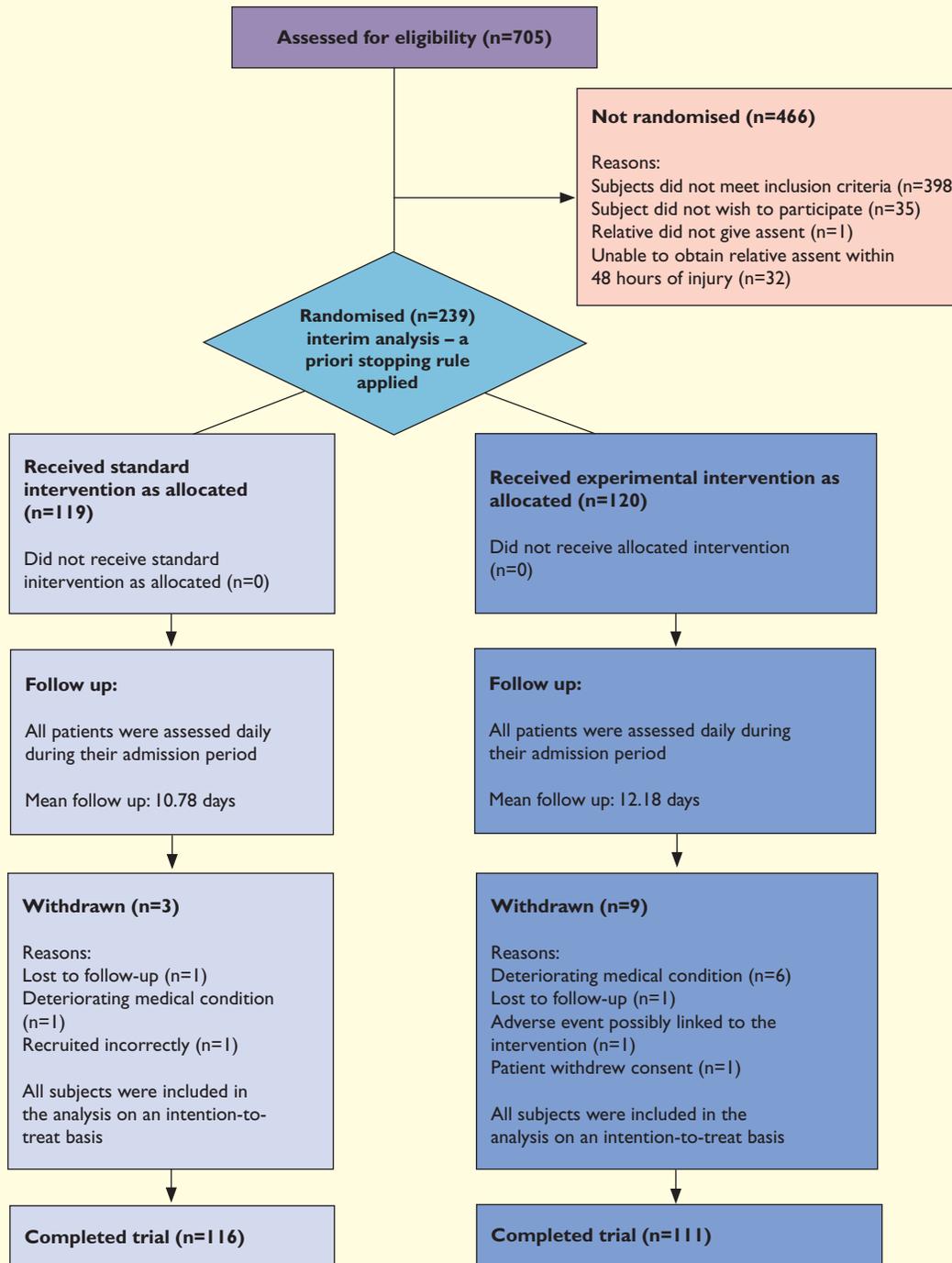
Any departure from the intended treatment or evaluation procedures constituted a protocol deviation. The departure was graded as major (e.g. early patient withdrawal where neither treatment nor evaluation was carried out) or minor (e.g. a lapse from the evaluation schedule), which was unlikely to affect the evaluation of treatment efficacy. An account of protocol violations was kept in order to reduce inflated claims about treatment effect.

Concordance was checked on a daily basis. All eligible patients, regardless of concordance with the protocol, were included in the results using an intention-to-treat analysis.

The secondary outcome was the subjects' opinions of the Heelift Suspension Boots, elicited through a descriptive analysis of a series of structured questions, which were asked at the point of censor. For example, the patient was asked whether the boot was comfortable, acceptable in terms of temperature, interfered with sleep or affected their ability to move while in bed or when transferring from bed to chair.

The study was approved by the University of Ulster's research ethics committee (November 2003, reference no. 03/03).

Fig 3. Flow of participants through each phase of the trial



Statistical analysis

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

23 Wilson, A. Prevention of heel pressure ulcers in an orthopaedic unit. *Nurs Times Plus*. 2002; 98: 25, 53–54.

24 Gilcreast, D.M., Warren, J.B., Yoder, L.H. et al. Research comparing three heel ulcer-prevention devices. *J Wound Ostomy Continence Nurs*. 2005; 32: 2, 112–210.

25 Conine, T.A., Daechsel, D., Lau, M.S. The role of alternating air and silicone overlays in preventing decubitus ulcers. *Int J Rehabil Res*. 1990; 13: 1, 57–65.

26 Ooka, M., Kemp, M.G., McMyn, R., Shott, S. Evaluation of three types of support surfaces for preventing pressure ulcers in patients in a surgical intensive care unit. *J Wound Ostomy Continence Nurs*. 1995; 22: 6, 271–279.

27 Vanderwee, K., Grypdonck, M.H.F., Defloor, T. Effectiveness of an alternating pressure air mattress for the prevention of pressure ulcers. *Age Ageing*. 2005; 34: 3, 261–267.

28 Theaker, C., Kuper, M., Soni, N. Pressure ulcer prevention in intensive care—a randomised control trial of two pressure-relieving devices. *Anaesthesia*. 2005; 60: 4, 395–399.

29 Preece, J. Total bed management: the way forward in pressure sore prevention. *Br J Nurs*. 1999; 8: 22, 1524–1526, 1528–1529.

30 Beringer, T.R.O., Elliott, J.R.M., Durkin, P. Audit of fractures of the proximal femur. Report No. 3. Fracture Outcomes Research Unit audit report. Royal Victoria Hospital, 2001.

31 Dewing, J. From ritual to relationship: a person-centred approach to consent in qualitative research with older people who have a dementia. *Dementia*. 2002; 1: 2, 157–171.

32 Dewing, J. Participatory research: a method for process consent with persons who have dementia. *Dementia*. 2007; 6: 1, 11–25.

33 Donnelly, J. Can adults with cognitive impairment consent to take part in research? *J Wound Care*. 2004; 13: 7, 257–262.

Table 1. Group characteristics at baseline.

Variable		Control group	Intervention group	Total	Significance (2-sided)
Age (mean)		80.82	80.89	N/A	p = 0.94*
Gender	Male	30	25	55	p = 0.52†
	Female	89	95	184	
Smoking	No	73	62	135	p = 0.26‡
	Ex	28	39	67	
	Yes	18	19	37	
Hypertension	No	72	79	151	p = 0.47†
	Yes	47	41	88	
Cardiac problems	No	70	63	133	p = 0.39†
	Yes	49	57	106	
Renal failure	No	117	114	231	p = 0.28§
	Yes	2	6	8	
Confusion	No	93	92	185	p = 0.91†
	Yes	26	28	54	
Mini-mental stage score	0–8.5	46	52	98	p = 0.74†
	9–10	67	67	134	
Steroid medication	No	102	103	205	p = 1.0†
	Yes	17	17	34	
Type 1 diabetes	No	116	117	233	N/A numbers too small
	Yes	3	3	6	
Type 2 diabetes	No	109	105	214	p = 0.41†
	Yes	10	15	25	
Clexane		119	120	239	N/A
PVD	No	114	115	229	p = 1.00§
	Yes	5	5	10	
Risk of malnutrition	Low risk	92	87	179	p = 0.48†
	Med–high	27	33	60	
Hypotension (systolic pressure)	≥90mmHg	107	113	220	p = 0.33§
	<90mmHg	6	3	9	
Lower limb oedema	No	104	108	212	p = 0.67†
	Yes	15	12	27	
Braden score* (mean)		15	14.78	239	p = 0.17*
Barthel score (mean)		17.39	16.43	239	p = 0.080*
Pre-injury mobility	Independent	107	97	204	p = 0.071†
	Dependent	12	23	35	
Urinary incontinence	No	101	99	200	p = 0.75†
	Yes	18	21	39	
Faecal incontinence	No	106	105	211	p = 0.86†
	Yes	13	15	28	
ASA comorbidity score	1–2	30	25	55	p = 0.52†
	3–4	89	95	184	

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.

significant. 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 Regression 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.¹

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 ($\chi^2=0.158$, $df=1$, $p=691$). 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).

Initially, one of the incidents (severe lower limb

Table 2. Injury, periods of immobility and perioperative data characteristics.

Variable		Control	Intervention	Total	Significance (2-sided)
Injury	Right hip	52	59	111	p=0.47†
	Left hip	67	61	128	
Aetiology of injury	Low impact fall	116	120	236	Numbers too small for computation
	Other	3	0	3	
Time from injury to arrival of ambulance	≤ 15 minutes	56	59	115	p=1.00†
	> 15 minutes	36	37	73	
Time from ambulance arrival to hospital arrival	≤ 15 minutes	62	66	128	p=0.91†
	> 15 minutes	25	29	54	
Time taken to transfer from local hospital to research centre (if applicable)	Within 25 hours	52	49	101	p=0.93†
	25–48 hours	9	7	16	
Time lying in A&E department	≤ 2 hours	28	23	51	p=0.14†
	> 2 hours	32	48	80	
Time from injury to operation	≤ 72 hours	34	54	88	p=0.0009†
	> 72 hours	83	62	145	
ASA score on day of operation – recorded by anaesthetist	1–2	34	23	57	p=0.29†
	3–4	65	65	130	
Type of operation	Hemiarthroplasty	50	56	106	p=0.38*
	Dynamic hip screw	55	45	100	
	Other	11	15	26	
Type of anaesthetic	Spinal	100	102	202	p=0.85†
	GA	16	14	30	
Duration of surgery	≤ 2 hours	95	81	176	p=0.034†
	> 2 hours	20	35	55	

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

34 National Pressure Ulcer Advisory Panel (NPUAP) Stage I assessment in darkly pigmented skin, Reston, VA: NPUAP, 1998. Available from: <http://www.npuap.org>. (Accessed 20th June 2011).

35 Mahoney, F.I., Barthel, D.W.. Functional Evaluation: The Barthel Index. *Md State Med J*. 1965; 14: 61–65.

36 Bergstrom, N., Braden, B.J., Laguzza, A., Holman, V. The Braden Scale for predicting pressure sore risk. *Nurs Res*. 1987; 36: 4, 205–210.

37 Malnutrition Advisory Group (MAG) Malnutrition universal screening tool. MAG, a Standing Committee of BAPEN, 2003.

38 Hodkinson, H.M., American Society of Anesthesiologists (ASA) Evaluation of a mental test score for assessment of mental impairment in the elderly. *Age Ageing*. 1972; 1: 4, 233–238.

39 Kore, R.N. Blacklock, A.R.E. American Society of Anaesthesiologist Physical Status (ASA-PS): a predictor of treatment outcome of transurethral resection of the prostate (TURP). *J R Coll Surg Edinb*. 2000; 45: 1, 25–28.

40 Donnelly, J. Randomised Controlled Trial of Pressure Ulcers: Concurrent Session. Integrated Musculoskeletal Trauma Conference. Waterfront Hall, 2005.

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.

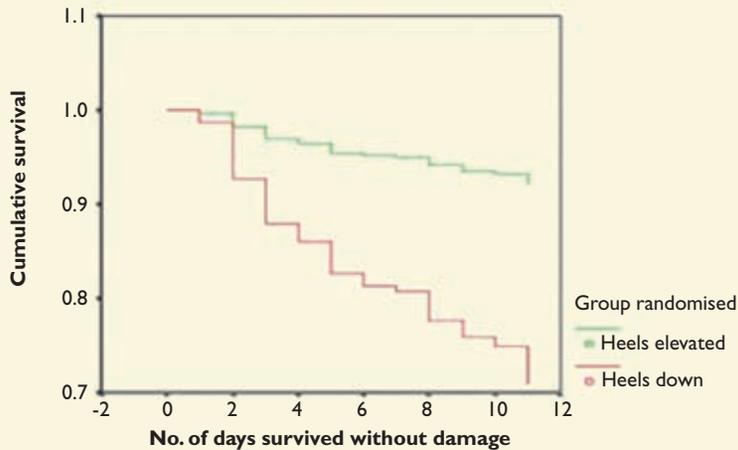
Tables 1 and 2 show that the group characteristics were comparable at baseline, in terms of comorbidities and the length of time spent lying on a hard surface prior to study enrolment. Subjects in the intervention group had a shorter wait from injury to theatre ($\chi^2=6.86$, $df=1$, $p=0.009$) but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

There were 88 protocol violations: 46 minor and 42 major. These were themed according to subjects' comments, as well as clinical observations, and consisted primarily of hindered independent move-

Table 3. Pressure damage by group and area affected.

Area affected	Control group			Intervention	
	Category I	Category II	Ungraded	Category II	Ungraded
Sacrum	1	6	2	3	2
Buttocks				1	1
Heels	8	7	2		
Lateral malleolus	8	3			
Achilles region			1		
Knees					2
Toes	1				
Totals	18	16	5	4	5

Fig 4. Kaplan-Meier survival curves used to estimate the probability of group survival.



41 National Pressure Ulcer Advisory Panel (NPUAP) In: Cuddigan, J., Ayello, E.A., Sussman, C. (eds). Pressure Ulcers in America: Prevalence, Incidence, and Implications for the Future. Reston, VA: NPUAP, 2001.

42 Baumgarten, M., Margolis, D., Berlin, J.A. et al. Risk factors for pressure ulcers among elderly hip fracture patients. *Wound Repair Regen.* 2003; 11: 2, 96–103.

43 Gunningberg, L., Lindholm, C., Carlsson, M., Sjöden, P.O. Reduced incidence of pressure ulcers in patients with hip fractures: a 2-year follow-up of quality indicators. *Int J Qual Health Care.* 2001; 13: 5, 399–407.

44 Swain, I., Bader, D. The measurement of interface pressure and its role in soft tissue breakdown. In: Clarke, M. (ed). *Pressure Ulcers: Recent advances in tissue viability.* Cromwell Press, Quay Books, 2004.

45 Allman, R.M., Goode, P.S., Patrick, M.M. et al. Pressure ulcer risk factors among hospitalised patients with activity limitation. *JAMA.* 1995; 273: 11, 865–870.

46 Nixon, J., Cranny, G., Bond, S. Skin alterations of intact skin and risk factors associated with pressure ulcer development in surgical patients: a cohort study. *Int J Nurs Stud.* 2007; 44: 5, 655–663.

ment (15 major, 8 minor), unacceptably warm, particularly at night, (13, 9) and pain or discomfort (10, 3), while problems concerning the application/removal of the boot also contributed significantly towards the minor violations (3, 24).

Main findings

The primary outcome measure (number of new PUs) was checked through an analysis of the sample means at the halfway point (n=240). These interim findings indicated an association between the groups and the intervention; the null hypothesis was rejected (early) using a predetermined stopping rule. This decision was agreed by all members of the research team.

PUs occurred in both groups. Thirty-one out of 119 subjects (26%) in the control group developed PUs (total number of PUs 39), whereas eight out of 120 subjects (7%) in the intervention group developed PUs (total number of PUs 9) ($\chi^2=15.05$, $df=1$, $p<0.001$, with continuity correction). No subjects in the intervention group developed a PU on their ankles, feet or heels, whereas 29 subjects in the control group developed PUs in these areas.

Kaplan-Meier survival curves indicated that subjects in the control group were more likely to suffer pressure damage at all points in time than those in the intervention group (log rank, $p=0.001$) (Fig 4).

A sensitivity analysis showed that when subjects who were lost to follow-up were assigned the worst outcome (PU positive), those in the intervention group were still less likely to develop pressure damage than those in the control group ($p=0.001$). The main study finding was unchanged when category I PUs were excluded from the analysis.

The combined effect of covariates was assessed using a backward stepwise regression model. The

clinical and pathological variables considered for prognostic effect were chosen in response to findings from other studies or theoretical assumptions suggesting that they were specific risk factors for pressure ulceration. The analysis indicated that when the effect of all of these factors were taken into consideration, the group to which the subjects were randomised remained significant, namely, the treatment group were five times less likely to develop pressure damage (hazard ratio=0.21, CI=0.08–0.54) than the control group (hazard ratio=1.00).

A themed analysis of the participants opinions indicated that, although 32% of subjects felt that boots interfered with sleep and 41% felt that they adversely affected movement in bed, 59% rated them as comfortable overall. Subjects' reasons for poor concordance were the weight and bulk of the boot (36%), heat (particularly at night) (31%) and discomfort (24%).

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.³

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,³¹ 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.⁴⁵⁻⁴⁸ 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'.⁴⁹ 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.⁵⁰ 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.⁵¹ 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.⁵² 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. ■

47 Reed, R.L., Hepburn, K., Adelson, R. et al. Low serum albumin levels, confusion, and fecal incontinence: are these risk factors for pressure ulcers in mobility-impaired hospitalized adults? *Gerontology*. 2003; 49: 4, 255-259.

48 Nixon, J., Cranny, G., Iglesias, C. et al. Randomised, controlled trial of alternating pressure mattresses compared with alternating pressure overlays for the prevention of pressure ulcers: PRESSURE (pressure relieving support surfaces) trial. *BMJ*. 2006; 332: 7555,1413.

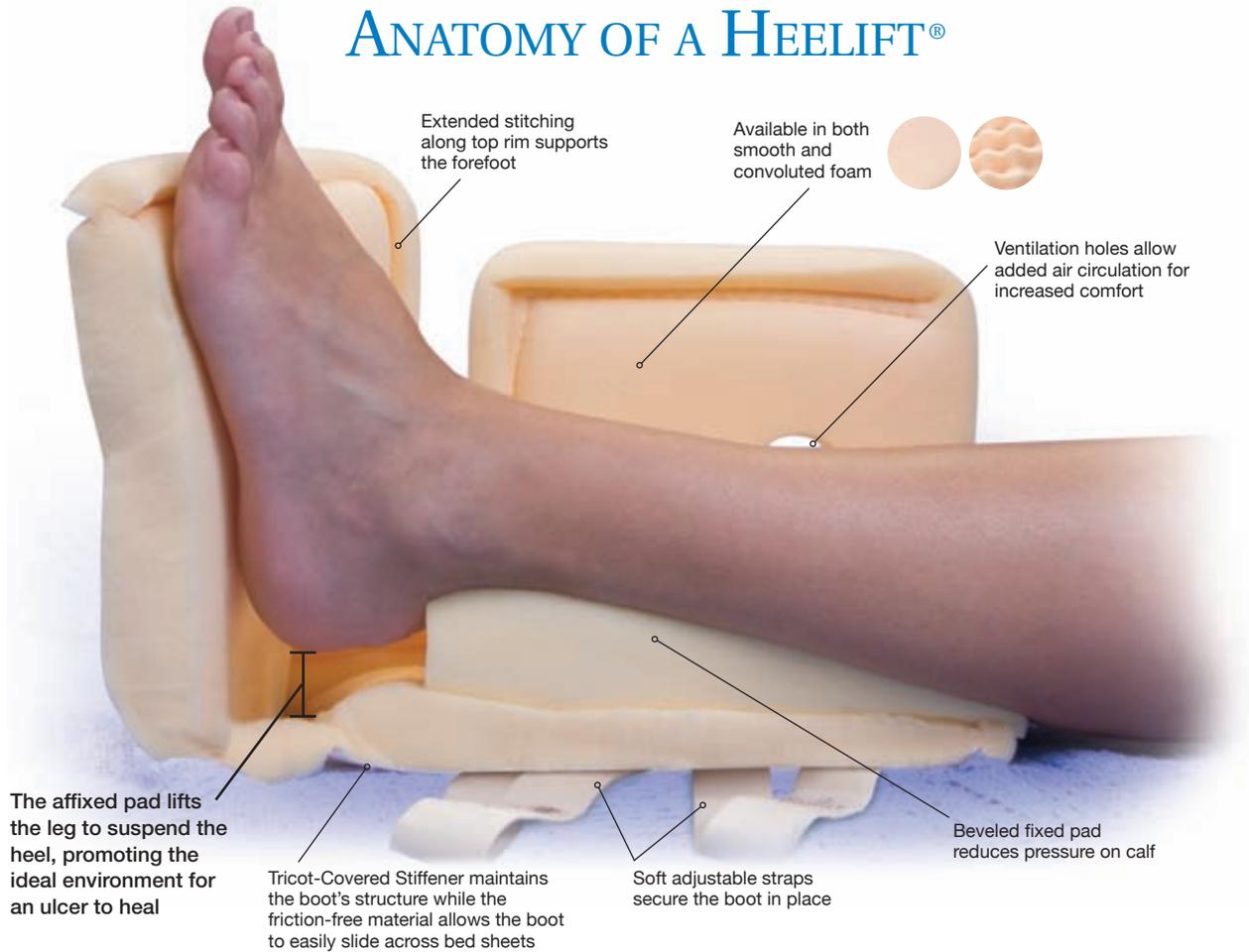
49 Royal College of Nursing (RCN) The management of pressure ulcers in primary and secondary care. NICE, 2005. Available at www.nice.org.uk (Accessed 20th June 2011).

50 McInnes, E., Jammali-Blasi, A., Bell-Syer, S.E.M. et al. Support surfaces for pressure ulcer prevention. *Cochrane Database Syst Rev*. 2011; 13: 4, CD001735.

51 Rycroft-Malone, J., Harvey, G., Seers, K. et al. An exploration of the factors that influence the implementation of evidence into practice. *J Clin Nurs*. 2004; 13: 8, 913-924.

52 Herman, J. The randomised controlled trial: limits and alternatives. Paper presented at the 13th International Conference of the International Society for Quality in Health Care, Jerusalem, 1996.

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