Parafricta bootees compared with standard care to prevent heel pressure ulcers: a multicentre pragmatic randomised controlled trial

KEY WORDS

- Pressure ulcer
- Bootees
- Friction
- Medical device-related pressure ulcers
- Shear

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Background: Parafricta bootees are made of low friction material intended to prevent heel pressure ulcers (PU). **Aims:** To compare, in hospitalised patients, whether the bootees, added to standard care (SC), prevent heel PU compared with SC alone. **Methods**: Patients with Waterlow score ≥20 and no heel PUs at baseline were randomly allocated to either bootees plus SC, or SC alone. Target sample size was 450 patients. Patients' heels were clinically assessed for heel PUs at day 3 and day 14. **Results:** Slow recruitment stopped the study early. In 31 recruited patients there were zero incident heel PUs (intervention group, 0%) versus 1 (SC group, 6%) at day 3 and no new heel pressure ulcers at Day 14. **Conclusion:** This study failed to reach sufficient statistical power to assess the efficacy of the bootees in preventing heel PUs. No adverse events were related to the bootees. Only 1 patient in the SC group developed a heel PU.

Pressure ulcers (PU), that are unpleasant and painful for patients, may delay discharge as well as limit activities and impact on general health. Within acute care in NHS Wales 8.9% of all hospital inpatients were found to have PUs (Clark et al, 2017) with 161/589 (27.3%) PUs with a verified classification presenting at the heels; of these wounds 47 (29.2%) were full-thickness injuries extending beyond the dermis into deeper tissues. The St Helens and Knowsley Teaching Hospitals NHS Trust identified risk factors that predispose to the development of heel PUs including: previous or current heel ulcer, diabetes, stroke/cerebral vascular accident, paralysis, hip fracture, dementia, peripheral vascular disease, Parkinson's disease, agitation, leg oedema and sliding posture in bed/chair (Gleeson, 2016). The mechanism for heel tissue damage is friction and associated shear for some of these factors, rather than direct pressure.

Parafricta bootees are a medical device intended to help prevent skin damage on the heel due to friction and shear. The boots are constructed of a low friction, two-layered material. The intended mechanism of action is that the two layers slide on each other reducing friction and shear on the skin. The bootees do not relieve pressure and are intended for use as an adjunct to standard care (SC) measures intended to protect the patient from pressure-related tissue damage e.g. a mattress or manual repositioning.

The National Institute for Health and Care Excellence (NICE) recommended further research on bootees to be conducted in the hospital setting, comparing the bootees with standard care (SC; NICE, 2014).

Aims

The primary objective of this randomised controlled trial (RCT) was to determine whether in inpatients at very high risk of skin breakdown Parafricta bootees, used as an adjunct to SC (intervention group), reduce the incidence of heel PUs after three days' use (day 3) compared with SC alone (SC group), with the heel PUs determined by assessment of digital images, blind to the allocated treatment. Early assessment at day 3 would ensure that any short-term effects could be recorded. Secondary outcomes included the incidence of heel

PUs at day 14, severity of heel PUs, patient-reported acceptability of bootees and incidence at day 3 and day 14 of heel PUs determined by unblinded clinical examination of the patients' heels at the bedside. Clinical examination is the gold standard method of measuring heel PU incidence. However it was not feasible to introduce a sham medical device as a control, therefore clinical examination was unblinded to allocated treatment.

METHODS

The study was funded by Health and Care Research Wales Research for Patient and Public Benefit Grant 1239 and received a favourable ethical opinion by the Wales Research Ethics Board 7 and is compliant with the Declaration of Helsinki. The investigators were nurse or podiatrist wound healing researchers from a specialist wound research centre. The investigators visited 2 participating hospitals and approached patients with permission granted by the nurse in charge of each clinical area. The investigators screened patients for eligibility, undertook the consent and recruitment process and performed all study assessments with the exception of assessment of digital images, which was performed by expert NHS podiatrists from a separate team. The study was designed to place the minimum burden on clinical areas. Clinical nursing staff were required only to perform SC and apply bootees as advised by the investigators.

Eligibility

Hospital patients of age ≥18 years were eligible for the study if the following criteria were met:

- Bedbound or unable to walk independently and requiring assistance to transfer to a chair
- 'Very high' risk group for a PU (Waterlow Score of 20 or more)
- No existing heel PUs or any other type of wound on the subject foot
- Patient was not being treated with pressure offloading boots
- Patient was not being treated with a heel cast
- Patient was not a single or double lower limb amputee.

Consent

The study protocol permitted patients with mental capacity to choose themselves whether to join the study. For patients without mental capacity it was permissible to recruit a patient to the study on the advice of a consultee, consistent with the Mental Capacity Act (legislation.gov.uk, 2005).

Sample size and statistical analysis

A target sample was calculated based on work by Smith and Ingram (2010). We required 191 patients per group to detect a 16% difference in heel PU incidence at the 5% significance level with 90% power. Inflating for 15% attrition required a total sample size of 450 patients (225 per group). The study reported the incidence of heel PUs per treatment group (number of patients with a heel PU) by intention-to-treat, and descriptive statistics. For each patient both heels were assessed and heel PU incidence was classified by the number of patients who have one or more heel PUs.

Linear regression models were planned to compare the odds of developing heel PUs between groups (depending on the distribution of this outcome, logistic regressions, Poisson regression or chi-squared may have been used). Survival analysis would explore length of stay outcomes and standard diagnostics would check model fit.

Random allocation

Patients were allocated in 1:1 ratio to intervention group or SC group by telephone call to a central allocation service using a pre-prepared sequence of sealed envelopes.

Treatments

This study did not define SC for the purpose of research. Patients in the SC group received the appropriate SC measures according to local policy e.g. appropriate bed/mattress system, mattress overlay, positional wedges/pillows. Pressure offloading boots could be used on the foot if the need arose during the study period, but were not in use when the patient entered the study.

Patients randomly allocated to the intervention group received the appropriate SC measures according to local policy as above, and were issued with bootees. The patient and clinical staff and the patient's carers were instructed in the use of bootees, that are intended to be worn throughout the day and night and removed only for normal daily washing or examination of the patient's feet. Pressure offloading

boots could be used if deemed clinically necessary during the study, and were to replace the bootee used on that limb. Assessments were made as shown in *Table 1*.

Bedside assessment of skin integrity

The investigators performed clinical examination of patients' heels at the bedside on day 0, day 3 and day 14, to ensure gold standard assessment of skin integrity. This was unblinded to allocated treatment group. Skin was classified by European Pressure Ulcer Advisory Panel (EPUAP)/National Pressure Ulcer Advisory Panel (NPUAP)/Pan-Pacific Pressure Injury Alliance (PPPIA) criteria, described by Edsberg et al (2016). Category 1 or above represents a heel PU.

Photography protocol

Digital photographs were taken by the investigators according to a standardised protocol designed in consultation with a professional medical photographer. Photography used Sony DSC-HX400V bridge cameras pre-set to ISO: 200, exposure duration 1/125 second, F stop 8.0, flash on, white balance: flash, focal length 80mm and image file format: JPEG. For each heel, images were taken from medial, central and lateral perspectives. A Perspex disc was used to photograph blanching or non-blanching erythema.

Assessment of images

For the primary outcome measure an assessment of the digital images taken on day 0, day 3 and day 14 was performed (blinded to allocated treatment) after the study period by two independent podiatrists with disagreement adjudicated by a third senior podiatrist.

RESULTS

A total of 1430 patients were screened for eligibility between October 2017 and April 2018 *(Figure 1)*. The investigators visiting hospitals experienced sustained difficulty in recruiting eligible patients documented as:

- Lack of enthusiasm for the study among patients and relatives because it was a harm prevention study and not a therapeutic study
- A large number of patients who were too ill to be recruited to the study
- Negative perception of random allocation and a belief expressed by some patient's relatives that SC was inferior to the use of bootees
- Clinical staff unwilling to apply the research interventions due to the challenges of delivering routine care, in a hospital environment under high pressure
- Anxiety expressed by clinical staff based on a belief that the bootees may increase the risk of falls.

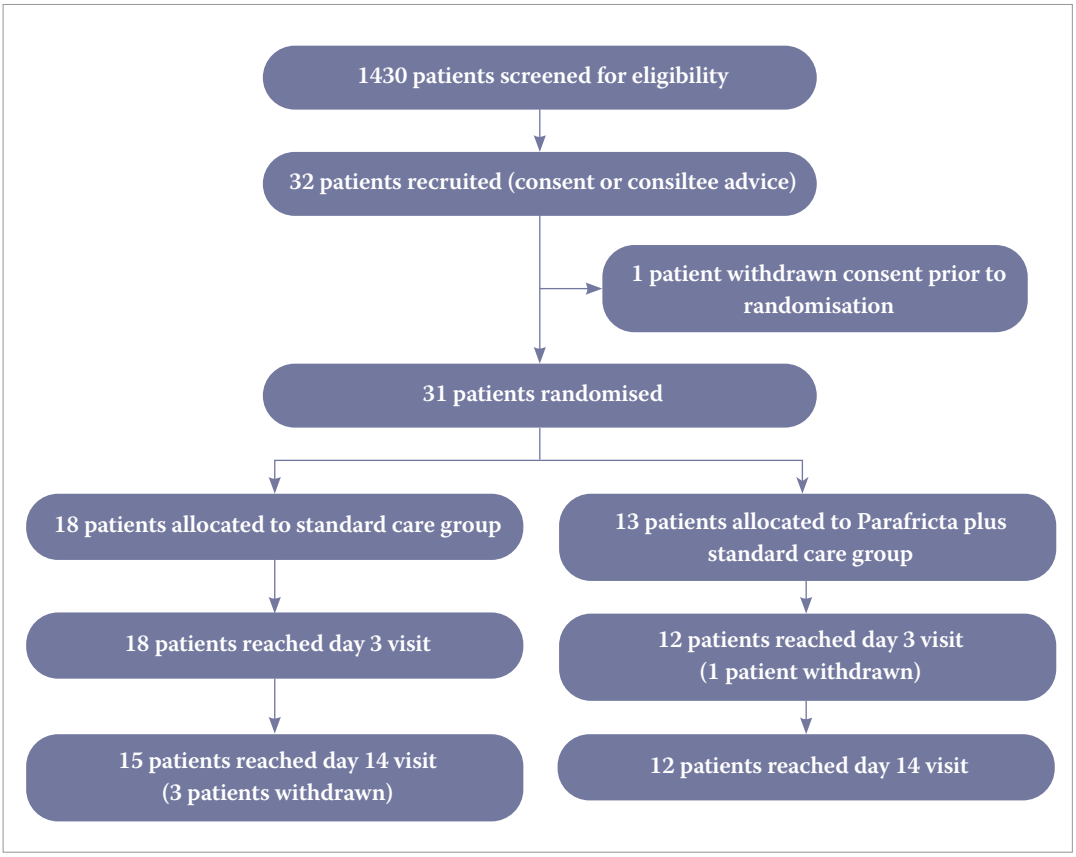
Efforts to recruit patients stopped in April 2018 due to the high screening to recruitment ratio. Nevertheless thirty-two patients met the study eligibility criteria and were recruited into the study. *(Figure 1)*. There were 10 patients who had capacity and provided informed consent, while 21 patients lacked capacity to provide informed consent, and as such the advice of a consultee was followed to recruit into the study. One patient withdrew from the study before randomisation. Of the 31 patients who were randomised; 18 were allocated to the SC group and 13 to the intervention group *(Figure 1)*. At day 3, 18 patients in the SC group remained in the study and 12 patients in the intervention group. At day 14, 15 and 12 patients in each respective

Table 1 Study assessments

Assessment	Day 0 (Baseline)	Day 3	Day 14
Patient medical history and risk factors for heel pressure ulcer	Yes	No	No
Ankle/toe:brachial pressure index *	Yes	No	No
Waterlow score	Yes	Yes	Yes
Unblinded clinical assessment of skin condition on each heel	Yes	Yes	Yes
Digital heel photography	Yes	Yes	Yes
Concomitant medication	Yes	Yes	Yes
Patient acceptability questionnaire (intervention group only)	No	No	Yes

*For anxious or agitated patients this assessment was replaced by Doppler assessment for presence/absence of pedal pulse

Figure 1. Patient flow diagram



group remained in the study. *Table 2* lists patient withdrawals.

Baseline characteristics

Baseline demographics and clinical characteristics of the 31 randomised patients were similar between the two groups *(Table 3)*. Mean Waterlow score was 25 (SC) and 26 (intervention). In the recruited sample mean age was 77 years, and patients had a median of 7 (mean 6.6; SD 2.7) prior medical conditions and a median of 11 (mean 11.9, SD 4.8) concomitant medications. All patients had at least one risk factor for heel PUs defined by the St Helens and Knowsley criteria (Gleeson, 2016), the commonest factors being 'sliding down bed or chair' (n=20), 'stroke/CVA' (n=13) and 'agitated' (n=10). All patients had a pulse present in both feet and no HPUs were present at baseline by bedside clinical examination (category 0). The most commonly used SC methods in the whole recruited sample were alternating pressure mattress (84% of all patients, *Table 4*).

Table 2. Patients withdrawn from study

Point of withdrawal	Reason for withdrawal	
Before randomisation	1 patient withdrew consent during vascular assessment	
After randomisation	**SC group**	**Intervention group**
	3 patients were withdrawn (1 patient died (SAE) following a fall and UTI, 1 patient died (SAE) following aspiration pneumonia and cerebrovascular accident, 1 patient developed a category 1 HPU)	1 patient was withdrawn (safety concerns because patient lacked capacity and was at risk of slipping in bootees)

Abbreviations: BMI: body mass index; EPUAP: European Pressure Ulcer Advisory Panel; IQR: interquartile range; SC: standard care; SD: standard deviation.

Table 3. Baseline demographics and follow-up of recruited patients

Baseline demographics	Total (n=31)	SC group (n=18)	Intervention group (n=13)
Male (total male and female n=31)	18 (58%)	10 (56%)	8 (62%)
Mean BMI (n=31)	22.0 (Range: 15.8-35.0, SD 4.5)	22.1 (Range: 15.8–35.0; SD: 4.6)	21.8 (Range: 17.0–30.4; SD: 4.6)
Mean age (n=31)	77 (Range: 37–94, SD 14)	78 (Range: 62–93; SD: 9)	75 (Range: 37–94; SD 20)
Median Waterlow score at day 0 (n=31)	25 (IQR: 23–28)	25 (IQR: 23–28)	26 (IQR 23–29)
Mean Waterlow score at day 0 (n=31)	26 (SD: 4)	25 (SD: 3)	26 (SD 5)
Median number of concomitant medications at day 0 (n=31)	11 (IQR: 9–14)	12 (IQR: 9–13)	11 (IQR 9–14)
Median number of relevant prior medical conditions at day 0 (n=31)	7 (IQR: 5–9)	7 (IQR: 6–9)	7 (IQR 3–9)
Median number of risk factors at day 0 (min 0 max 11) (n=31)	3 (IQR: 2–3)	3 (IQR: 2–4)	3 (IQR 2–3)
Mean number of risk factors at day 0 (min 0 max 11) (n=31)	3 (SD: 1)	3 (SD: 1)	2 (SD 1)
List of risk factors at day 0			
Previous heel ulcer (either foot) or current heel ulcer (contralateral)	6 (19%)	3 (17%)	3 (23%)
Diabetes	6 (19%)	5 (28%)	1 (8%)
Stroke/cerebral vascular accident	13 (42%)	10 (56%)	3 (23%)
Paralysis	6 (19%)	4 (22%)	2 (15%)
Hip fracture	3 (10%)	2 (11%)	1 (8%)
Dementia or cognitive impairment	9 (29%)	5 (28%)	4 (31%)
Peripheral vascular disease	0	0	0
Leg spasms/ Parkinson's / tremors	5 (16%)	2 (11%)	3 (23%)
Agitated	10 (32%)	6 (33%)	4 (31%)
Leg oedema	6 (19%)	4 (22%)	2 (15%)
Frequently slides down bed or chair	20 (65%)	13 (72%)	7 (54%)
Bilateral pulse present in feet (n=30)	All	All	All
EPUAP category at day 0 (Left) unblinded observation (n=31)	Category 0 =31 (100%)	Category 0 =31 (100%)	Category 0 =31 (100%)
EPUAP category at day 0 (Right) unblinded observation (n=31)	Category 0 =31 (100%)	Category 0 =31 (100%)	Category 0 =31 (100%)
Day 3			
Median Waterlow score at day 3 (n=31)	25 (IQR: 22–28)	25 (IQR: 23–28)	25 (IQR: 22–29)
Mean Waterlow score at day 3 (n=31)	25 (SD 4)	25 (SD 3)	26 (SD 5)
Compliance with wearing bootees since day 0			
0–24%	-	-	0
25–49%	-	-	0
50–74%	-	-	0
75–100%	-	-	12 (92%)
Unknown	-	-	1 (8%) patient withdrawn
Day 14			
Median Waterlow score at day 14 (n=27)	24 (IQR: 22.5–28)	24 (IQR: 24–27.5)	25 (IQR: 22–29.5)
Compliance with wearing bootees since day 14			
0–24%	-	-	1 (8%)
25–49%	-	-	0
50–74%	-	-	1 (8%)
75–100%	-	-	10 (83%)
Unknown	-	-	0

Abbreviations: BMI = body mass index; EPUAP = European Pressure Ulcer Advisory Panel; IQR = interquartile range; SC = standard care; SD = standard deviation

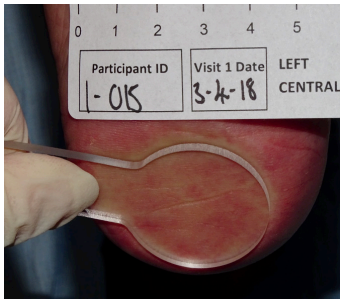


Figure 2. Digital image erroneously suggestive of nonblanching erythema, Participant 1-015, left heel, central aspect, day 0 (baseline) visit

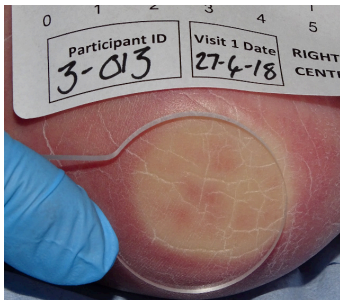


Figure 3. Digital image erroneously suggestive of nonblanching erythema, Participant 3-013, right heel, central aspect, day 0 (baseline) visit

Digital images

More of the patients were judged to have a PU from blinded assessment of digital images than from unblinded clinical examination *(Figures 2 and 3)*. The reason for the discrepancy between the heel images and direct skin observation remains unclear and will form the subject of a second publication. This publication reports heel PU incidence by gold standard clinical examination.

Heel PU incidence by gold standard clinical examination

By bedside clinical examination there were zero Heel PUs at baseline. At day 3 one patient (6%) of 18 in the SC group developed a category 1 heel PU. This patient was subsequently withdrawn from the study. No patients developed a heel PU of any category at day 3 in the intervention group. No patients in either group developed a new heel PU of any category at day 14 *(Table 5)*.

Compliance with treatment and patient satisfaction

Compliance with wearing the bootees was fairly high among patients in the intervention group with the majority wearing the bootees 75–100% of the time at day 3 (92%) and day 14 (83%) *(Table 3)*. There were 7 patients completed the non-validated patient satisfaction survey (5 in the SC group and 2 in the intervention group). No problems were reported from the 2 patients allocated to the intervention group.

Adverse events

There were no adverse events related to the bootees *(Table 6)*.

DISCUSSION

This study compared Parafricta bootees plus SC versus SC alone in an elderly, hospitalised patient sample with significant morbidity and high risk for heel PUs. Due to difficulty recruiting eligible patients

Table 4. Measures taken to protect skin integrity at day 0

	Total (n=31)	SC group (n=18)	Intervention group(n=13)
Alternating pressure mattress	26 (84%)	14 (78%)	12 (92%)
Hybrid mattress	0	0	0
Foam mattress	5 (16%)	4 (22%)	1 (8%)
Mattress overlay	0	0	0
Support pillows	4 (13%)	2 (11%)	2 (15%)
Wedge	0	0	0
Transferred to chair	7 (23%)	4 (22%)	3 (23%)
Other intervention (pressure redistribution cushion or boot, tilt and space chair, intermittent pneumatic compression, turns)	9 (30%)	5 (28%)	4 (31%)

Abbreviations: SC = standard care

Table 5 Summary of pressure ulcer categories (pressure ulcer did not contribute to 'new ulcer'/incident counts if they were present at baseline or preceding visit)

	EPUAP pressure injury grading by clinical examination			
	SC group (n=18)		Intervention group (n=13)	
	Left	Right	Left	Right
Day 0	Category 0 =18 (100%)	Category 0=18 (100%)	Category 0=13 (100%)	Category 0=13 (100%)
Day 3	Category 0=17 (94%) Category 1=1 (6%)	Category 0=18 (100%)	Category 0=12 (100%) NR=1	Category 0=12 (100%) NR=1
Day 14	Category 0=15 (100%) NR=3	Category 0=15 (100%) NR=3	Category 0=12 (100%) NR=1	Category 0=12 (100%) NR=1

Abbreviations: EPUAP = European Pressure Ulcer Advisory Panel; NR = not reported; SC = standard care

to the study, the sample size of 31 is too small to have adequate statistical power to draw a conclusion on the efficacy of the bootees in preventing heel PUs. However, the study did highlight practical difficulties in recruitment and provides valuable lessons about how RCTs of devices in vulnerable groups should be conducted, and the importance of engaging patients and relatives.

All recruited patients were free of heel PUs at baseline as a study inclusion criterion, assessed by gold standard clinical examination. This method revealed that at day 3 there was a single incidence of heel PU (category 1) in a patient in the SC group, versus zero incidence of heel PU in the intervention group. By clinical examination there were no new heel PUs at day 14. There was one patient withdrew from the study before day 3 and a further three were withdrawn before day 14. Had these patients remained in the study the incidence of heel PUs may have been higher.

The observation that a standardised photography protocol appeared to overestimate the redness of intact heel skin was unexpected and will be explored further to identify whether photography of intact heel skin may provide artifacts that could mislead blinded assessment.

The difficulty experienced in recruiting patients to this study highlights the importance of engaging hospital teams to enable research to be conducted. This is a challenge when hospital teams are under immense pressure to meet ever increasing demands. It also highlights the importance of information given to potential research participants, particularly those with a cognitive impairment while in hospital. Our study used a robust informed consent process with recourse to consultees where appropriate and in accordance with the Mental Capacity Act (legislation.gov.uk, 2005). Our patient information leaflets were available in a variety of formats to assist understanding and the investigators paid careful attention to face-to-face communication. Nevertheless our experience suggests that patients and their families perceptions of aspects of our study including harm prevention, random allocation, equipoise between interventions and safety were barriers to recruitment.

Table 5. Adverse events

		Total	SC group (n=18)	Intervention group (n=13)
Number of patients with	0 adverse events (%)	19 (61%)	8 (44%)	11 (85%)
	1 adverse event (%)	9 (29%)	7 (39%)	2 (15%)
	2 adverse events (%)	3 (10%)	3 (17%)	0 (0%)
Total number of adverse events		15	13	2
Adverse events severity				
	Mild	8	8	0
	Moderate	6	4	2
	Severe	1	1	0
Total number of SAEs		2	2*	0
Categories of adverse events				
	Lower limb and foot	6	5	1
	UTI	3	2	1
	Gastrointestinal event	2	2	0
	Fall	1	1	0
	Abnormal blood results	1	1	0
	Stroke/CVA	1	1	0
	Respiratory event	1	1	0
Number of events related intervention group (possible, probable, definite)		2	2†	0

*patient died following UTI and fall; patient died following aspiration pneumonia and CVA.
† blanchable red mark on foot; category 1 heel PU.

Abbreviations: CVA = cerebral vascular accident; SC = standard care; SAE = serious adverse event; UTI = urinary tract infection.

CONCLUSIONS

This study lacked statistical power to conclude on the efficacy of bootees as an adjunct to SC in preventing heel PUs in high risk patients.

We observed no heel PUs in patients treated with bootees by clinical examination and no cases of harm arising from use of bootees. There were no objections to use of bootees recorded in patient questionnaires. WUK

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CONFLICT OF INTEREST STATEMENT

The company APA Parafricta Ltd provided the Parafricta® bootees at no cost to the study but did not have any involvement in the design and conduct of the study.