A clinical evaluation of the Nimbus 3 alternating pressure mattress replacement system

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This study assessed the clinical effectiveness of the Nimbus 3 alternating pressure mattress replacement system (APMRS) on pressure ulcer healing and comfort in subjects ≥65 years, with at least a Grade 2 ulcer and some mobility problems. Twelve patients in a hospital setting were randomly allocated to the Nimbus 3 or another APMRS, and 20 residents in a nursing home setting to the Nimbus 3 or an alternating pressure mattress overlay. Wound surface area (WSA) (cm^2) was recorded twice weekly and comfort once weekly. In the hospital setting, there were no significant differences between groups in the reduction in WSA per day. In the nursing home setting, though subjects on Nimbus 3 had significantly more pressure ulcers at baseline, there were no significant differences between groups in the reduction in WSA per day. Nimbus 3 was statistically more comfortable than control surfaces. The study's sample size has not shown the products were different with regard to clinical effectiveness. However, it might serve as a pilot for a larger, multi-centre RCT aimed at establishing the efficacy of a pressure-relieving (PR) device on pressure ulcer healing.

Pressure ulcers; Alternating pressure; Ulcer healing

Prevention of pressure ulcers is desirable; however, their incidence is likely to increase due to an ageing population.[1] Incidence of 4–10% of patients was found in a UK general hospital,[2] but community incidence is unknown.[3] Treatment can be broken down into:

- Local treatment using wound dressings
- Pressure relief using beds, mattresses or cushions, or repositioning the patient
- Treating concurrent conditions which may delay healing e.g. malnutrition, infection
- Physical therapy e.g. ultrasound, laser therapy.[4]

To establish if any one component of treatment, including pressure relief, is effective, a well-designed randomised controlled trial (RCT) is needed, with clinically important primary outcomes such as rate of change of wound area/volume or time to healing.[5]

Literature review

RCTs provide the most reliable evidence for establishing the efficacy of an intervention.[6] Thirty-seven such trials have been identified investigating pressure-relieving (PR) devices on pressure ulcer prevention and treatment;[3] however, only eight focused on treatment. Many of these trials have been criticised in terms of methodology, and better quality research has been advocated.[3,7,8] This seems pertinent with the increased use of PR devices with ulcers.[9]

Pressure relief provided by alternating pressure devices (APDs) is thought to encourage tissue perfusion by alternately increasing and decreasing pressure under different parts of the body.[10] Some APDs appear to outperform the standard hospital mattress in terms of prevention.[11-13] There is conflicting evidence as to their effectiveness compared with constant-low-pressure devices.[13-20] When compared with each other, large-celled APDs seem to be more effective than small-celled ones at preventing pressure ulcers,[12] and two layers of cells better than one for both prevention and treatment.[20] See Cullum et al[3] for a critique of this evidence.

Only one trial has focused on the effectiveness of APDs on *healing* ulcers in elderly people, comparing the Pegasus Airwave with Nimbus 1. No significant differences were found.[21]

The Nimbus 3 differs from its predecessors in that it has five heel-guard cells that are 'powered down' during deflation. The aim of this study was to evaluate its effectiveness, primarily on healing, compared with alternative PR devices, for elderly subjects; this would be achieved by carrying out a pragmatic trial, in hospital and nursing home settings, following normal practice as closely as possible. Perceived comfort was evaluated as a secondary outcome, as differences have been previously reported in APMRS.[22]

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9. Winman G., Clark M. A random stratified survey of the current use of an alternating pressure air mattress within the NHS. *J Tiss Viabil* 1997; **7:** 84-90.
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Table 1. Baseline comparability of subjects in the hospital setting

Surface	Subject	Age (years)	Gender	Modified APACHE	Waterlow score	No. ulcers at baseline
Experimental						
Nimbus 3	1	68	M	20	20	1
Nimbus 3	2	66	M	22	20	3
Nimbus 3	3	66	M	22	20	3
Nimbus 3	4	68	F	20	20	1
Nimbus 3	5	74	M	27	20	1
Nimbus 3	6	91	F	35	20	2
Nimbus 3	7	80	F	24	20	2
Control						
P.Biwave	1	91	F	33	20	1
P.Airwave	2	78	F	23	20	3
AlphaXcell	3	82	M	23	20	1
P.Cairwave	4	65	F	17	15	1
P.Cairwave	5	69	M	22	15	3
Descriptive statistics	N	Median (range)	Female: Male	Median (range)	High risk (15+) V.high risk (20+)	Median (range)
Expt	7	68 (66–91)	3:4	22 (20–35)	0:7	2 (1–3)
Control	5	78 (65–91)	3:2	23 (17–33)	2:3	1 (1–3)
Inferential statistics						
		[1]p=0.514	[2]p=1.000	[1]p=0.935	[2]p=0.152	[1]p=0.859

[1] Mann-Whitney U test; [2] Fisher's Exact test * Statistically significant if p=≤0.05

Table 2. Baseline comparability of reference ulcers in the hospital setting

Surface	Subject	Ref ulcer site	Ref ulcer grade	Ref ulcer init size (cm²)
Experimental				
Nimbus 3	1	Heel	3	12.4
Nimbus 3	2	Sacrum	2	3.1
Nimbus 3	3	Sacrum	2	5.8
Nimbus 3	4	Sacrum	2	1.6
Nimbus 3	5	Heel	3	2.2
Nimbus 3	6	Sacrum	3	1.8
Nimbus 3	7	Heel	3	10.4
Control				
P.Biwave	1	Heel	3	5.7
P.Airwave	2	Buttock	2	5.4
AlphaXcell	3	Heel	3	11.5
P.Cairwave	4	Sacrum	3	2.4
P.Cairwave	5	Sacrum	2	11.3
Descriptive statistics	N	Heel:Sacrum: Other	Grade 2: Grade 3	Median (range)
Expt	7	3:4:0	3:4	3.1 (1.6–12.4)
Control	5	2:2:1	2:3	5.7 (2.4–11.5)
Inferential statistics				
			[2]p=1.000	[1]p=0.372

[1] Mann-Whitney U test; [2] Fisher's Exact test; * Statistically significant if p=≤0.05

Method

The study aimed to test two hypotheses:

- The Nimbus 3 heals pressure ulcers at a different rate from alternative PR devices used for elderly subjects with at least a Grade 2 pressure ulcer and some mobility problems
- The Nimbus 3 results in a different perception of comfort compared to alternative PR devices used for elderly subjects with at least a Grade 2 pressure ulcer and mobility problems.

An experimental approach was employed as it comes closest to meeting the criteria for inferring causal relationships.[23] More specifically, a randomised pre-test/post-test two-group experimental design[24] was used in both settings. Ethical approval and informed consent were obtained.

Participants

Subjects were aged ≥65 years with a Grade 3 pressure ulcer, or ≥65 years with a Grade 2 pressure ulcer and one or more of the following:

- Difficulty repositioning in bed and unable to tolerate a 30° tilt
- Unable to move in bed
- In bed for more than 20h in 24h
- Weight ≥108kg (17 stone) and bed bound
- Undergone spinal anaesthetic.

Exclusion criteria were spinal metastases; exudating wounds that may lead to hygiene or infection control problems; weight >250kg (39 stone). Inclusion and exclusion criteria reflected the hospital's criteria for need of an APMRS. The study also took place in a nursing home, as it was anticipated that follow-up would be longer; the same criteria applied.

Baseline assessment

Subjects' age, gender and number of pressure ulcers at baseline were recorded. In addition a modified Acute Physiological, Age, Chronic Health Evaluation (APACHE) score[25] and Waterlow score[26] were calculated. The APACHE III score[27] is a method of assessing illness severity usually used to predict mortality risk. It was anticipated that it would allow comparisons between experimental and control groups, in both settings.

A complete APACHE III score (range 0–299) requires invasive procedures, such as collection of arterial blood. This was considered too invasive, so eight specific variables were identified which could contribute to a reduced score: age, temperature, blood pressure, pulse, respiratory rate, sodium, white blood cell count and creatinine, giving a range of 0–132.

The Waterlow score is a risk assessment; together with clinical judgement it gives an indication of tissue, nutritional, mobility, continence and medication status.[26] The site, grade (using a four-grade system)[3,28] and size of every pressure ulcer at baseline were also recorded.

Table 3. Primary and secondary outcomes in the hospital setting

Surface	Subject	Days in trial of reference ulcer	Initial size of reference ulcer (cm^2)	Absolute reduction (cm^2)	Absolute reduction (cm^2)/day	Relative reduction (%)/day	Median comfort rating	Reason for withdrawal
Experimental								
Nimbus 3	1	39	12.4	5.7	0.146	1.179	5	discharged
Nimbus 3	2	15	3.1	3.1	0.207	6.667	5	healed
Nimbus 3	3	41	5.8	5.8	0.141	2.439	5	healed
Nimbus 3	4	14	1.6	1.6	0.114	7.143	5	healed
Nimbus 3	5	21	2.2	0.0	0. 000	0.000	5	discharged
Nimbus 3	6	13	1.8	1.6	0.123	6.839	5	developed MRSA
Nimbus 3	7	20	10.4	2.1	0.105	1.010	5	discharged
Control								
P.Biwave	1	34	5.7	2.6	0.076	1.341	4	died
P.Airwave	2	10	5.4	0.6	0.060	1.110	4	died
AlphaXcell	3	37	11.5	5.0	0.135	1.176	4	discharged
P.Cairwave	4	14	2.4	0.6	0.043	1.786	5	discharged
P.Cairwave	5	28	11.3	9.1	0.325	2.875	4	discharged
Descriptive statistics	N	Median (range)	Median (range)		Median (range)	Median (range)	Median (range)	
Expt	7	20 (13-41)	3.1 (1.6-12.4)		0.12 (0.00-0.21)	2.44 (0.00-7.14)	5 (5-5)	
Control	5	28 (10-37)	5.7 (2.4-11.5)		0.08 (0.04-0.33)	1.34 (1.11-2.88)	4 (4-5)	
Inferential statistics								
		$^1p = 0.871$	$^1p = 0.372$		$^1p = 0.570$	$^1p = 0.570$	$^1p = 0.006$*	
Additional statistics					Median (95% CI)	Median (95% CI)		
Expt	7				0.12 (0.00, 0.21)	2.44 (0.00, 7.14)		
Control	5				0.08 (0.04, 0.33)	1.34 (1.11, 2.88)		

^{1} Mann-Whitney U test; * Statistically significant if $p=\leq 0.05$

11. Bliss, M.R., McLaren, R., Exton-Smith, A.N. Mattresses for preventing pressure sores in geriatric patients. *Medical Bulletin of the Ministry of Health* 1966; **25**: 238-267.
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Random allocation

Treatments were randomly allocated to sequentially-labelled sealed envelopes. After baseline assessment, the TVN opened the top envelope that indicated which surface a subject would be nursed on. Random allocation assures, if sample size is large enough, that known and unknown determinants of outcome are evenly distributed.[29] Baseline details ascertained its effectiveness in producing similar experimental and control groups at the start.

Treatment aside from the intervention

Both groups were cared for in a similar manner, except for the PR device used. Nurses followed their organisation's established practice for regular pressure relief. When dressing wounds, they were asked to refer to one specified protocol (provided by one of the hospitals). By keeping conditions constant across groups, differences in healing were unlikely to be due to external determinants such as turning schedules or wound management.

Primary outcome measures

The same TVN assessed and recorded the site, grade and size of all pressure ulcers. The outline of each ulcer was traced twice weekly onto sterile cellophane; using planimetry, the outline of each ulcer was plotted into a computer, and the wound surface area (WSA) calculated. Two research team members, blind to the surface used, carried out the WSA measurements.

Complete healing is seen as the most valuable outcome in studies of wound healing. Where this is not possible, changes in wound size are reported.[5] This can be expressed as an absolute (initial size – final size) or relative (%) change ((initial size – final size) ÷ initial size, then x 100). However, where there is poor comparability at baseline between groups, absolute and relative (%) measures of healing can give different results for relative effectiveness.[5] In this study both absolute and relative (%) reductions were determined on *one* ulcer per subject (reference ulcer). If subjects had more than one ulcer this was the largest with the highest grade. Subjects were

Table 4. Baseline comparability of subjects in the nursing home setting

Surface	Subject	Age (years)	Gender	Modified APACHE	Waterlow score	No. ulcers at baseline
Experimental						
Nimbus 3	1	88	F	31	20	2
Nimbus 3	2	99	F	30	20	1
Nimbus 3	3	91	F	47	20	1
Nimbus 3	4	82	F	28	20	5
Nimbus 3	5	75	F	27	15	5
Nimbus 3	6	71	F	20	20	3
Nimbus 3	7	92	F	33	20	4
Nimbus 3	8	87	F	34	20	3
Nimbus 3	9	81	F	21	20	3
Nimbus 3	10	76	F	24	missing	4
Control						
AlphaXcell	1	72	F	25	20	3
AlphaXcell	2	90	F	26	20	5
Quattro	3	91	F	31	20	3
AlphaXcell	4	94	F	33	20	1
AlphaXcell	5	87	F	26	20	1
AlphaXcell	6	91	F	34	20	1
AlphaXcell	7	92	F	34	20	1
AlphaXcell	8	87	F	30	20	2
AlphaXcell	9	78	F	23	20	1
AlphaXcell	10	76	M	24	missing	2
Descriptive statistics	N	Median (range)	Female: Male	Median (range)	High risk (15+) V.high risk (20+)	Median (range)
Expt	10	84.5 (71–99)	10:0	29 (20–47)	1:8	3 (1–5)
Control	10	88.5 (72–94)	9:1	28 (23–34)	0:9	1 (1–5)
Inferential statistics						
		[1]p=0.595	[2]p=1.000	[1]p=1.000	[2]p=0.100	[1]p=0.045*

[1] Mann-Whitney U test; [2] Fisher's Exact test; * Statistically significant if p=≤0.05

19. Sideranko, S., Quinn, A., Burns, K., Froman, R.D. Effects of position and mattress overlay on sacral and heel pressures in a clinical population. *Res Nurs Health* 1992; **15**: 245-251.
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in the study for differing lengths of time, so absolute and relative (%) reductions in WSA *per day* were calculated. Even when in the study for a short time subjects were included on an intention-to-treat basis. Where appropriate, the status of non-reference ulcers and reasons for withdrawals were recorded.

Secondary outcome measure

Patients indicated the comfort of their mattress weekly using a five-point scale. A mattress may effectively heal ulcers but must also be tolerable to the subject – a subjective measure.

Data analysis

Data were analysed using the Statistical Packages for the Social Sciences (SPSS). The data were categorical e.g. gender; ordinal e.g. comfort rating; or continuous e.g. absolute reduction in WSA per day. Descriptive statistics used to summarise ordinal data sets were medians and ranges. Normality tests (Kolmogorov-Smirnov) on continuous data showed that some sets did not come from normal distributions ($p<0.05$), so descriptive statistics used to summarise continuous data sets were also medians and ranges.[40]

Inferential statistics were used to infer the probability of differences between groups being due to chance. If data were categorical the Fisher's Exact test or a test of proportion (when the Chi square was not possible) was used. If data were ordinal, or continuous but non-normal, the Mann-Whitney U test was used. Differences between groups were considered significant if $p\leq0.05$. All inferential statistical tests were two-tailed. Where possible 95% confidence intervals of the population median were presented for the key estimates (absolute and relative % reductions in WSA per day) to show the range within which the true effect may plausibly lie.[40]

Results: hospital setting

Twelve subjects were recruited; seven randomly allocated to the experimental product, and five to the control products (one each to the Pegasus Airwave, Pegasus Biwave and AlphaXcell, and two to the Pegasus Cairwave).

■ ***Baseline comparability:*** Random allocation produced equivalent groups with regard to age, gender, modified APACHE score, Waterlow score, and number of ulcers (Table 1). They were also equivalent with regard to site, grade and size of reference ulcer (Table 2).

■ ***Primary outcomes*** The median absolute reduction in WSA per day (and range) of reference ulcers of subjects on Nimbus 3 compared to controls was 0.12cm² (0–0.21cm²) versus 0.08cm² (0.04–0.33cm²) (Table 3); this difference was not significant. Median relative reduction in WSA (and range) was 2.44% (0–7.14%) versus 1.34% (1.11–2.88%) (Table 3); again this was not significant.

■ ***Secondary outcomes*** The median comfort score of Nimbus 3 compared to controls was 5 (very comfortable) versus 4 (comfortable); this was statistically significant (p=0.006) (Table 3).

Results: nursing home setting

Twenty subjects were recruited; with ten allocated to the experimental product, and ten to control products (Tables 4, 5, 6).

■ ***Baseline comparability*** Random allocation produced equivalent groups with regard to age, gender, modified APACHE and Waterlow scores (Table 4). Experimental subjects had a median of three ulcers compared to the controls who had a median of one (p=0.045) (Table 4). The groups were equivalent with regard to site, grade and initial size of ulcer (Table 5).

■ ***Primary outcomes*** Despite subjects on the Nimbus 3 having more ulcers at baseline,

Table 5. Baseline comparability of reference ulcers in the nursing home setting

Surface	Subject	Reference ulcer site	Reference ulcer grade	Initial size of (cm^2) reference ulcer
Experimental				
Nimbus 3	1	Heel	3	21.0
Nimbus 3	2	Heel	3	3.5
Nimbus 3	3	Sacrum	4	19.2
Nimbus 3	4	Heel	3	6.6
Nimbus 3	5	Heel	3	5.3
Nimbus 3	6	Sacrum	2	9.9
Nimbus 3	7	Malleolus	3	2.2
Nimbus 3	8	Buttock	4	17.1
Nimbus 3	9	Heel	3	7.2
Nimbus 3	10	Heel	3	2.7
Control				
AlphaXcell	1	Sacrum	4	37.4
AlphaXcell	2	Sacrum	2	3.0
Quattro	3	Sacrum	4	7.8
AlphaXcell	4	Sacrum	2	0.1
AlphaXcell	5	Heel	3	12.2
AlphaXcell	6	Malleolus	3	1.5
AlphaXcell	7	Heel	3	6.8
AlphaXcell	8	Heel	4	5.8
AlphaXcell	9	Sacrum	3	1.9
AlphaXcell	10	Heel	4	19.0
Descriptive statistics	N	Heel:Sacrum: Other	Grade 2: Grade 3: Grade 4	Median (range)
Expt	10	6:2:2	1:7:2	6.9 (2.2–21.0)
Control	10	4:5:1	2:4:4	6.3 (0.1–37.4)
Inferential statistics				
				[1]p=0.545

[1] Mann-Whitney U test; * Statistically significant if p=≤0.05

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their median absolute reduction in WSA per day (and range) was 0.11cm^2 (0.04–0.41cm^2) versus 0.05cm^2 (0–0.48cm^2) (Table 6); this difference was not significant. Median relative reduction in WSA per day (and range) of subjects nursed on Nimbus 3 was 1.57% (0.45–5.00%) versus 0.99% (0–2.54%) (Table 6); again this difference was not significant.

■ ***Secondary outcomes*** The median comfort score of the Nimbus 3 was 5 (very comfortable) versus 4 (comfortable); this difference was statistically significant (p=0.002) (Table 6).

Discussion

Most hospital subjects were in their sixties or seventies, male or female, with high Waterlow scores, one or more ulcers at baseline, and reference ulcers mainly on the heel or sacrum and graded as 2 or 3. Because patients were often discharged before the reference ulcer had completely healed, changes in size were recorded but no significant differences in healing rates between groups were found. These findings complement another small RCT comparing Nimbus I with Pegasus Airwave.[21] In the present study, where subjects had more than one ulcer, the most severe was analysed based on the assumption that if this did well, the less severe ulcers were likely to do well too. This was supported because where the reference ulcer improved the less severe ulcers also improved or healed.

Most nursing home subjects were in their eighties or nineties, predominantly female, with high Waterlow scores, one or more ulcers at baseline, and reference ulcers mainly on the heel or sacrum, graded predominantly as 3 or 4. Some were not followed to complete healing of reference ulcer, because they did not survive the study period. Instead changes in ulcer size were recorded. Despite those on the Nimbus 3 having more ulcers at baseline, no significant differences in healing rates were found. As in the hospital setting, one reference ulcer per resident, the largest and highest graded, was analysed. In most cases if this ulcer improved the less severe ones also improved or healed.

Because there were no statistically significant differences of primary outcomes between groups, these findings do not prove the products were the same, they simply have not proved different. Because the sample size was very small the study's power to show a difference, if one existed, was very small.

A secondary objective was to evaluate perceived comfort of the Nimbus 3, compared with other PR. Although all surfaces were comfortable, the Nimbus 3 was perceived as statistically more comfortable than the controls. Similar findings were reported when evaluating the Nimbus 2.[22]

Limitations

The features of a well-constructed clinical trial were included[6,7,29] but the small sample size achieved within the constraints of the study increased the risk of a Type 2 error.

It was not possible to measure statistically if medication and medical diagnosis were equivalent between groups. If the samples had been large enough, random allocation would have left it to chance that such variables would have been equivalent. The modified APACHE and Waterlow scores may partially address these issues; however, the utility of the modified APACHE score must be examined.

It may have been useful to classify wounds as sloughy or necrotic. Again if the sample size had been big enough, random allocation would have left it to chance that such characteristics were equivalent between groups. However, wound appearance was taken into account when selecting dressings.

Table 6. Primary and secondary outcomes of subjects in the nursing home setting

Surface	Subject	Days in trial of reference ulcer	Initial size of reference ulcer (cm^2)	Absolute reduction (cm^2)	Absolute reduction (cm^2) per day	Relative reduction (%) per day	Median comfort rating	Reason for withdrawal
Experimental								
Nimbus 3	1	8	21.0	3.3	0.413	1.964	5	died
Nimbus 3	2	60	3.5	2.1	0.035	1.000	5	died
Nimbus 3	3	25	19.2	3.3	0.132	0.688	5	died
Nimbus 3	4	60	6.6	6.2	0.103	1.566	5	died
Nimbus 3	5	7	5.3	1.8	0.257	4.852	5	died
Nimbus 3	6	25	9.9	1.3	0.052	0.525	5	died
Nimbus 3	7	41	2.2	1.5	0.037	1.663	5	died
Nimbus 3	8	217	17.1	16.6	0.076	0.447	5	completed
Nimbus 3	9	59	7.2	6.7	0.114	1.577	5	completed
Nimbus 3	10	20	2.7	2.7	0.135	5.000	3	completed
Control								
AlphaXcell	1	467	37.4	29.8	0.064	0.171	4	hospitalised
AlphaXcell	2	12	3.0	0.4	0.033	1.111	2	disliked surface
Quattro	3	222	7.8	7.8	0.035	0.450	5	healed
AlphaXcell	4	4	0.1	0.0	0.000	0.000	4	died
AlphaXcell	5	90	12.2	12.2	0.136	1.111	5	healed
AlphaXcell	6	279	1.5	0.5	0.002	0.119	4	completed
AlphaXcell	7	84	6.8	6.8	0.081	1.190	4	healed
AlphaXcell	8	114	5.8	5.8	0.051	0.877	3	healed
AlphaXcell	9	48	1.9	1.9	0.040	2.083	4	healed
AlphaXcell	10	6	19.0	2.9	0.483	2.544	3	hospitalised
Descriptive statistics	N	Median (range)	Median (range)	Median (range)		Median (range)	Median (range)	
Expt	10	33 (7–217)	6.9 (2.2–21.0)		0.11 (0.04–0.41)	1.57 (0.45–5.00)	5 (3–5)	
Control	10	87 (4–467)	6.3 (0.1–37.4)		0.05 (0.00–0.48)	0.99 (0.00–2.54)	4 (2–5)	
Inferential statistics								
		[1]p=0.256	[1]p=0.545		[1]p=0.131	[1]p=0.173	[1]p=0.002*	
Additional statistics					Median (95% CI)	Median (95% CI)		
Expt	10				0.11 (0.04, 0.26)	1.57 (0.53, 4.85)		
Control	10				0.05 (0.00, 0.14)	0.99 (0.12, 2.08)		

[1] Mann-Whitney U test; * Statistically significant if p=≤0.05

It was not possible to control for all external influences on healing, such as how long subjects sat in a chair during the day,[30] though staff were asked to use their institute's policy for regular pressure relief.

Wound healing was defined as a reduction in WSA over time;[31] it is also a reduction in volume.[32] Computerised image analysis may be useful to assess volume.[5]

It was impossible to blind subjects and the TVN to the surface used. However, the data analysts were blind to the surface used when measuring WSA.

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Conclusion and recommendations

- It is inconclusive whether the products are the same with regard to clinical effectiveness on pressure ulcer healing. With the sample size achieved the study has simply not demonstrated they were different.
- Although all products used were considered comfortable, the Nimbus 3 was statistically more comfortable; however these findings must be treated with caution considering the simplicity and subjectivity of the measure used.
- This study might serve as a pilot to those able to carry out larger, multi-centre RCTs.
- Larger, multi-centre RCTs are needed in order to obtain a sufficient sample to effectively compare different PR devices.
- A single agreed procedure for documenting wound healing is desirable so comparisons across different RCTs can be made. ■