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Silicone adhesive multilayer foam dressings as adjuvant prophylactic therapy to prevent hospital-acquired pressure ulcers: a pragmatic noncommercial multicentre randomized open-label parallel-group medical device trial

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Summary

Background Silicone adhesive multilayer foam dressings are used as adjuvant therapy to prevent hospital-acquired pressure ulcers (PUs).
Objectives To determine whether silicone foam dressings in addition to standard prevention reduce the incidence of PUs of category 2 or worse compared with standard prevention alone.
Methods This was a multicentre, randomized controlled medical device trial conducted in eight Belgian hospitals. At-risk adult patients were centrally randomized (n = 1633) to study groups based on a 1 : 1 : 1 allocation: experimental groups 1 (n = 542) and 2 (n = 545) – pooled as the treatment group – and the control group (n = 546). The experimental groups received PU prevention according to hospital protocol, and a silicone foam dressing on the relevant body sites. The control group received standard of care. The primary endpoint was the incidence of a new PU of category 2 or worse at the studied body sites.
Results In the intention-to-treat population (n = 1605), PUs of category 2 or worse occurred in 4·0% of patients in the treatment group and 6·3% in the control group [relative risk (RR) 0·64, 95% confidence interval (CI) 0·41–0·99, P = 0·04]. Sacral PUs were observed in 2·8% and 4·8% of the patients in the treatment group and the control group, respectively (RR 0·59, 95% CI 0·35–0·98, P = 0·04). Heel PUs occurred in 1·4% and 1·9% of patients in the treatment and control groups, respectively (RR 0·76, 95% CI 0·34–1·68, P = 0·49).
Conclusions Silicone foam dressings reduce the incidence of PUs of category 2 or worse in hospitalized at-risk patients when used in addition to standard of care. The results show a decrease for the sacrum, but no statistical difference for the heel and trochanter areas.

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Conflicts of interest
The authors declare they have no conflicts of interest.

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What is already known about this topic?

- The incidence of hospital-acquired pressure ulcers (PUs) remains high despite the implementation of best-practice recommendations.
- The concept of using silicone foam dressings as an additional prophylactic strategy in PU prevention has been investigated in previous studies but with some limitations.
- Most RCTs were monocentric studies, restricted to either critically ill or acute care patients and did not observe more than two anatomical at-risk skin sites, which limited the generalizability of the findings.

What does this study add?

- This large pragmatic RCT suggests that it is beneficial to use silicone adhesive multilayer foam dressings on the sacrum, in addition to standard of care, to help prevent hospital-acquired PUs.
- Clinical decision making for heel dressings should be based on the clinical effectiveness of the intervention weighed against the potential risk of falling.

Pressure ulcers (PUs) or pressure injuries are localized injuries to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear.[1] The burden of hospital-acquired PUs (HA-PUs) is high on patients and healthcare systems.[2] A systematic review presented the pooled prevalence of HA-PUs among 1 366 848 patients as 12·8%, a pooled incidence rate of 5·4 per 10 000 patient-days (n = 681 885), and the pooled rate of HA-PUs among 1 893 593 patients as 8·4%.[3] Two large studies determined that most category 2–4 PUs occur in the sacral area (45·0–51·7%) and the heels (26·7–40·7%), followed by the greater trochanter area (1·8–2·6%).[4,5] International guidelines recommend to reduce both the amount and the duration of pressure and shear, by implementing strategies that include regular and comprehensive risk assessment, patient repositioning, skincare, incontinence management, nutritional care, and the use of pressure redistribution surfaces.[1,6]

There is growing international interest in the application of dressings covering areas at risk for PUs, to reduce the mechanical impact on the skin and underlying tissue. The clinical effectiveness has been summarized in five systematic reviews[7–11] – covering six randomized controlled trials (RCTs)[12–17] with a total of 1985 recruited patients – and an additional RCT published recently.[18] The RCTs were mostly monocentric studies and/or restricted to critically ill patients, and observed only one or two body sites (sacrum and/or heels).[12–18] These studies were either funded by industry[13,15,17,18] or funders were not reported.[12,14,16]

Silicone foam dressings, depending on their construction, redistribute pressure over larger areas, mitigate external shearing forces on the skin (multiple layers), and might assist with maintaining the microclimate for the skin to function normally (foam structure or layers and film breathability).[7,8,16,19] Silicone-based adhesives are incorporated into the dressings, which compared with traditional adhesives attach faster to uneven skin surfaces, are gentle to remove, and can be repositioned.[20,21] This allows skin visualization without replacing the dressing after lifting.

The aim of this study was to determine whether silicone adhesive multilayer foam dressings used in combination with standard of care would reduce the incidence of PUs of category 2, 3 or 4; unstageable PUs; and deep tissue injuries (referred to as PU category 2 or worse) on the sacrum, heels and greater trochanters of adult hospitalized patients in intensive care units (ICUs) and non-ICU wards.

Patients and methods

Study design

This was a pragmatic, multicentre, randomized (1 : 1 : 1 allocation), open-label, parallel-group medical device trial performed in eight hospitals (three university or teaching hospitals and five general hospitals) in Belgium, including patients on both ICU and non-ICU wards, with patients in ICU limited to < 25%.

Participants

The sample-size calculation was based on the results of several randomized trials with an incidence of 6% of PU category 2 or worse on the sacrum, greater trochanter and heels in the standard of care (SOC) group,[4] and the treatment group having a 50% reduction in incidence of PUs of category 2 or worse.[2,22] To have 80% power to detect a reduction in PU

incidence from 6% to 3%, data had to be available for 1578 patients in total, of whom 526 had to be allocated to the control group and 1052 to the treatment group. Considering a 5% dropout rate, a total of 1662 patients had to be randomized to ensure enough patients would complete the trial without compromising the statistical power. The study was not powered to analyse subgroups.

Patients aged > 18 years who gave written informed consent (patient or proxy) were included if they were: (i) at risk for PU development based on Braden risk assessment[23] (Braden score < 17); (ii) had been admitted to the hospital within the previous 48 h; (iii) had no PU of category 2 or worse present on the sacrum; and (iv) had no clinically relevant incontinence-associated dermatitis or other skin condition that would be a contraindication for application of the study devices. The Braden scale was applied in all participating sites and in all units (both ICU and non-ICU) because the scale is used nationally to assess risk for PU development (even in the ICU). The study team decided not to change the SOC. Patients could still be included if, at three of the other four sites (heel left/right and trochanter left/right), prevention could be applied or a PU category 2 or worse already existed. Full inclusion and exclusion criteria are available in the clinical study protocol (Appendix S1; see Supporting Information).

Randomization and blinding

Patients were centrally randomized to study groups based on a 1 : 1 : 1 allocation: experimental group 1 (Allevyn® brand), experimental group 2 (Mepilex® brand) and the control group (SOC). Experimental groups 1 and 2 were pooled in the analysis as the treatment group. Randomization was stratified by hospital and ICU vs. non-ICU wards. The randomization was based on a permuted-block randomization with varying block sizes. For each group of wards (ICU vs. non-ICU) the randomization schedule ensured balance of the three study groups at the intended number of randomized patients. Patients, caregivers and study personnel were not blinded to the study procedures as blinding is not possible when using different types of dressings.

Intervention

The study interventions are summarized in Figure 1. Standard hospital protocols for prevention of PUs were used in the SOC and treatment groups, with addition of the silicone foam dressings as the only variable in the treatment group.

Dressings were commercially available, purchased by the sponsor and delivered to the hospitals by the manufacturers. The university-based study team did extensive training with the study sites regarding the PU prevention and study protocols, correct indication, and application of the study devices. In total 1192 nurses across 74 wards were trained during 124 sessions. Dressings were maintained on the treatable skin sites and were changed according to the manufacturer's instructions for use. The study nurse inspected the skin beneath the dressing daily, by lifting the dressing and reapplying (not replacing) it.

If the patient developed a PU of category 2 or worse, or developed incontinence-associated dermatitis, the application of the study device was stopped, and treatment of the PU was started according to the hospital's wound care protocol. Photographs were taken whenever a PU of category 2 or worse developed and were transferred to the chief investigator for blinded central review.

Outcomes

The primary endpoint of this trial was the proportion of patients who developed at least one new PU of category 2 or worse on the sacrum, heels or greater trochanter as judged on site, during the trial period of the patient (maximum 14 days). These proportions were compared between the pooled treatment group and the SOC group as per the randomization scheme. An intention-to-treat (ITT) analysis including all patients randomized, and a per protocol (PP) analysis was performed. Exploratory analyses (ITT and PP) compared new PU incidence between the anatomical sites (sacrum, trochanters and heels) and the experimental investigational devices (experimental groups 1 and 2). Subgroup analyses of the primary endpoint were performed on patient characteristics: age, sex, type of ward, surgery, body mass index (BMI), diabetes and Braden score.

Statistical analysis

The primary analysis of the primary efficacy variable consisted of a superiority analysis that compared the incidence in the pooled treatment group vs. the control group, by means of the Cochran–Mantel–Haenszel (CMH) test controlled for type of ward (ICU or non-ICU) on the ITT population. Superiority was concluded if the estimated impact of the treatment vs. control group was significant, based on a two-sided test at 5% significance level. Patients with missing data were defined as those without any assessment of the primary endpoint after randomization. These patients were excluded from the ITT population.

For exploratory analysis, the primary endpoint was compared firstly between the treatment group and the control group and secondly between experimental group 1 and experimental group 2 (experimental investigational devices) by means of the CMH test, and controlled for type of ward (ICU or non-ICU) in the ITT and PP populations (Appendix S2; see Supporting Information). Logistic regression models were used, adjusted for hospital, age, sex, type of ward and Braden score category (in the ITT and PP populations).

A sensitivity analysis of the primary endpoint of confirmed PU by blinded central review of photographs was conducted in the ITT population. All efficacy (primary and exploratory) analyses were reproduced in the PP population.

Descriptive safety analyses were performed, based on reported adverse device effects (ADEs). An ADE was defined as

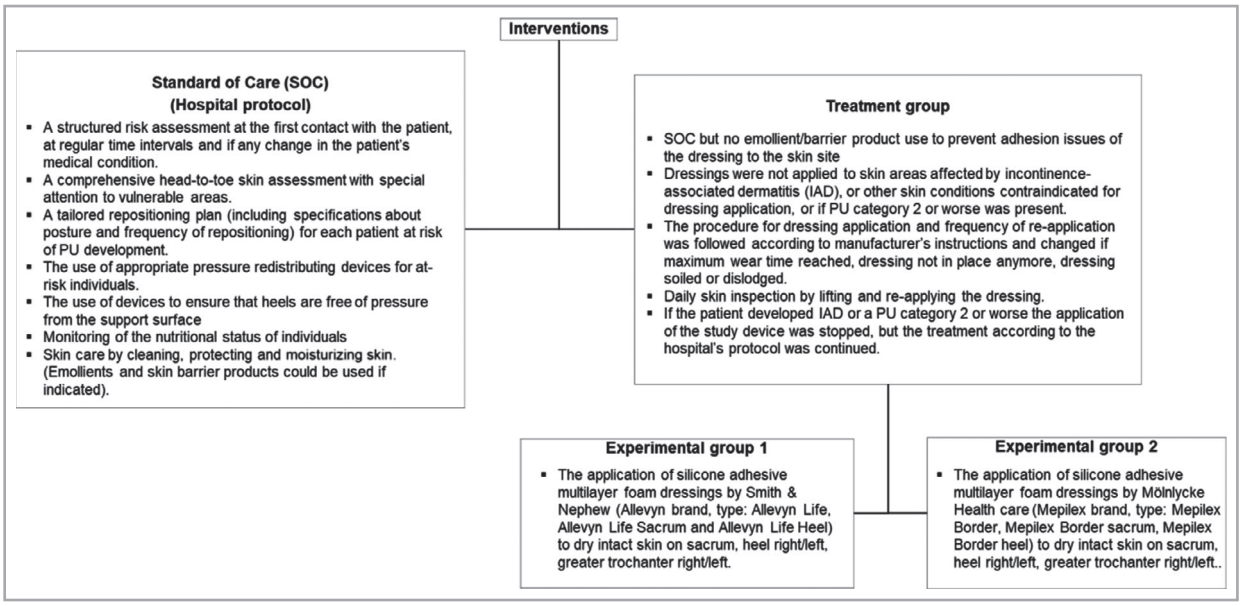

Figure 1 Interventions and procedures. IAD, incontinence-associated dermatitis; PU, pressure ulcer.

any adverse event related to the device used in the trial. Device deficiencies (DDs) were defined as the inadequacy of the study device related to its identity, quality, durability, reliability, safety or performance.

The safety population (n = 1077) was calculated after exclusion of patients in the ITT population who wanted their data excluded (n = 1), were not randomized (n = 46), did not receive at least one dressing (n = 10) or received only SOC (n = 546).

Statistical analyses were performed using the SAS statistical package, version 9·4 (IBM, Armonk, NY, USA).

Ethics

Approval was received from both central (Ghent University Hospital) and local ethics committees for the trial protocol, informed consent forms and other relevant documents. The study was registered at ClinicalTrials.gov (NCT03442777).

Results

Between February and December 2018, 1633 patients were centrally randomized to one of the study groups: 542 (33·2%) to experimental group 1, 545 (33·4%) to experimental group 2 and 546 (33·4%) to the SOC group.

Of the 1680 patients screened for eligibility, 46 patients were not randomized and one patient requested to have their data excluded from the analyses. Figure 2 summarizes the participant flow.

Among the 1633 randomized patients, approximately 61·0% were > 80 years old (mean age 79·6 years, SD 12·2, range 28·3–103·7), and the majority were female (57·6%) and from non-ICU wards (87·5%). Patients who were underweight (BMI < 18·5 kg m^{-2}) accounted for 8·3% of the sample (n = 136), 29·7% were overweight (BMI 25·0–30·0 kg m^{-2}) and 16·5% had obesity (BMI > 30 kg m^{-2}). The patient characteristics were equally distributed across the three groups. The baseline demographics are displayed in Table 1.

Of the 1605 patients in the ITT population, 77 (4·8%) developed a PU of category 2 or worse: 4·0% in the treatment group and 6·3% in the SOC control group. The CMH test, controlled for type of ward (ICU or non-ICU), showed a statistically significant reduction of the risk to develop a PU in the treatment group [relative risk (RR) 0·64, 95% confidence interval (CI) 0·41–0·99, P = 0·04], meaning that patients in the treatment group had a 36% risk reduction of developing a new PU compared with those in the SOC group (Table 2). This result was confirmed when using a logistic regression model, adjusted for hospital, age, sex, type of ward (ICU or non-ICU) and Braden score at baseline (P = 0·01). The number needed to treat to prevent one new PU of category 2 or worse from developing was 43.

With exploratory analyses, new PUs on the sacrum were observed in 2·8% and 4·8% of patients in the treatment and SOC groups, respectively. The risk of developing a new PU on the sacrum was statistically significantly reduced by 41% in the treatment group (RR 0·59, 95% CI 0·35–0·98, P = 0·04). The number needed to treat to prevent one new PU of category 2 or worse on the sacrum was 50. PUs on the heels occurred in 1·4% and 1·9% of patients in the treatment and SOC groups, respectively, and no statistical difference was identified (RR 0·76, 95% CI 0·34–1·68, P = 0·49). Only one patient (0·1%), in experimental group 1, developed a PU on the trochanter (Table 2). Exploratory data analyses did not demonstrate any major differences in effectiveness between the two brands, considering that the study was not powered to detect such differences.

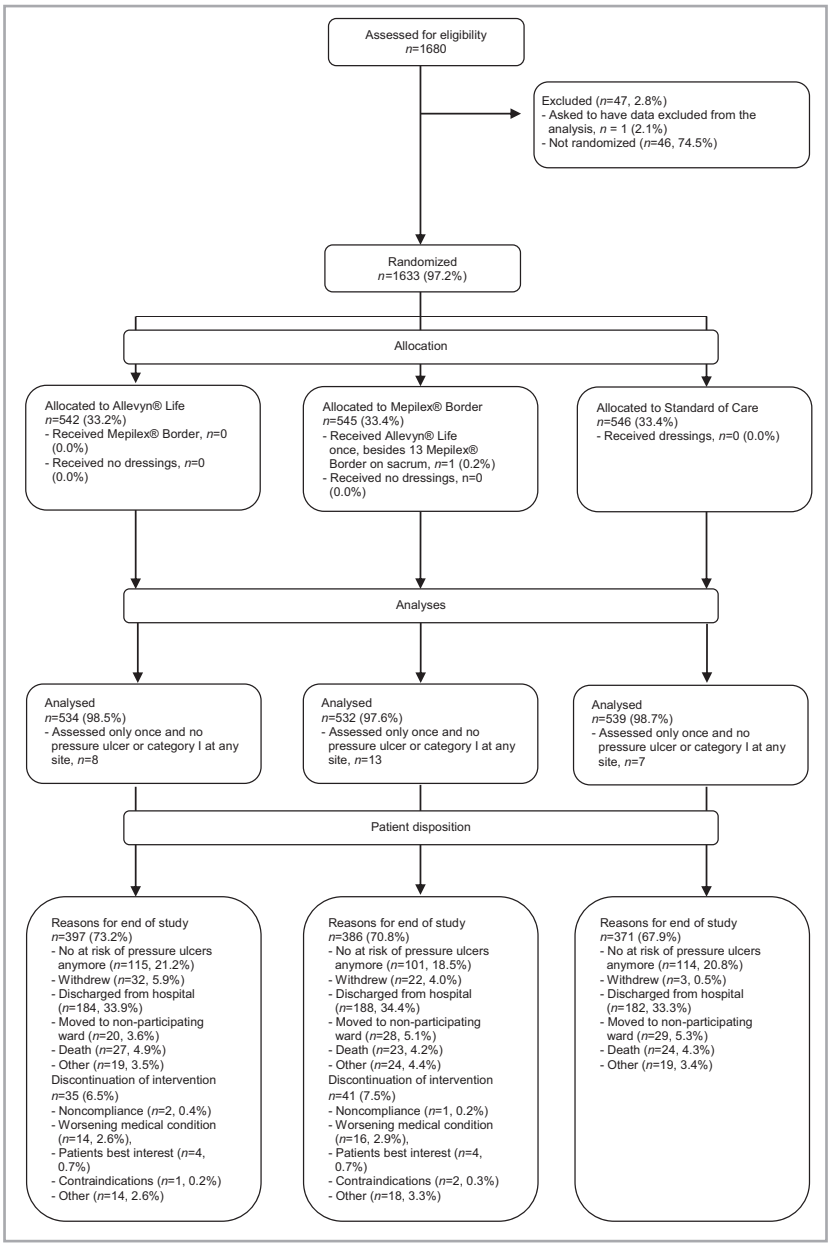

Figure 2 Participant flowchart. PU, pressure ulcer.

The incidence of PUs increased with age (from 0·8% for < 60 years to 5·9% for ≥ 80 years) and was higher among women then among men (5·1% vs. 4·4%). The incidence of PUs decreased across Braden score categories (Table 3), from 6·7% (Braden score ≤ 11) to 4·3% (Braden score 12–16) and 1·6% (Braden score ≥ 17). In the high-risk group (score ≤ 11), the incidence was higher in the experimental group (7·9%) than in the SOC group (4·0%), while it was the inverse in the mild risk category (2·8% in the experimental group vs. 7·3% in the SOC group).

A sensitivity analysis was conducted (ITT population) based on centrally confirmed PUs by blinded review of photographs by the chief investigator. Among the 77 new PUs of category 2 or worse reported by local assessment in the ITT population (n = 1065), 68 had photographs of sufficient quality and were assessed. Of these, 56 (82%) were confirmed as a PU of category 2 or worse by central review. All PP analyses confirmed the ITT analyses, as described in the clinical study report.[24]

No serious ADEs were reported in the safety population (n = 1077) during the study. Thirty-three ADEs were reported in 28 patients. Most of them were mechanical skin injuries (skin tears or skin stripping, n = 11), PU formation (two of PU category 1, one of PU category 2) and blister formation at the edge of or underneath the dressing (n = 3). These injuries were anecdotally attributed to the dressing being 'rolled up', having 'rolled edges' or being 'wrinkled up', alluding to the inability of some of the dressings to stay in place, causing

Table 1 Participants' baseline data (frequencies and descriptive) and total Braden scores at baseline: by randomized arm, intention-to-treat population

Randomized arm	Allevyn Life (n = 542)	Mepilex Border (n = 545)	Standard of care (n = 546)	Total (n = 1633)
Ward type at start of study				
ICU	65 (12)	67 (12)	71 (13)	203 (12)
Non-ICU	477 (88)	478 (88)	475 (87)	1430 (88)
Age (years)				
< 60	46 (8)	43 (8)	45 (8)	134 (8)
60–69	50 (9)	70 (13)	56 (10)	176 (11)
70–79	106 (20)	107 (20)	117 (22)	330 (20)
≥ 80	340 (63)	325 (59)	328 (60)	993 (61)
Median (IQR)	83·1 (74·7–88·2)	83·1 (72·6–88·3)	82·7 (73·4–87·5)	83·0 (73·7–87·9)
Sex				
Female	320 (59)	302 (55)	319 (58)	941 (58)
Male	222 (41)	243 (45)	227 (42)	692 (42)
BMI (kg m^{-2})				
Underweight (< 18·5)	44 (8)	53 (10)	39 (7)	136 (8)
Normal weight (18·5–25·0)	234 (43)	249 (45)	258 (47)	741 (45)
Overweight (25·0–30·0)	161 (30)	163 (30)	162 (30)	486 (30)
Obesity (≥ 30·0)	103 (19)	80 (15)	87 (16)	270 (17)
Median (IQR)	24·8 (21·8–28·4)	24·2 (21·3–27·6)	24·5 (21·7–27·9)	24·5 (21·5–28·0)
Diabetes				
No	419 (77)	427 (78)	412 (75)	1258 (77)
Yes	123 (23)	118 (22)	134 (25)	375 (23)
Total Braden score				
≤ 11	129 (24)	142 (26)	126 (23)	397 (24)
12–16	392 (72)	376 (69)	403 (74)	1171 (72)
17	21 (4)	27 (5)	17 (3)	65 (4)
Median (IQR) at baseline	13 (12·0–15·0)	14 (11·0–15·0)	13 (12·0–15·0)	13 (12·0–15·0)

The data are presented as n (%) unless indicated otherwise. BMI, body mass index; ICU, intensive care unit; IQR, interquartile range.

Table 2 Estimated relative risks (RRs) and 95% confidence intervals (CIs) for pressure ulcers of category 2 or worse, in the experimental group compared with the standard-of-care group (intention-to-treat analyses)

	Experimental, n/N (%)	Standard of care, n/N (%)	RR[a] (95% CI)	P-value
Overall	43/1066 (4·0)	34/539 (6·3)	0·64 (0·41–0·99)	0·04
Body site				
Sacrum	30/1062 (2·8)	26/539 (4·8)	0·59 (0·35–0·98)	0·04
Any heel	15/1063 (1·4)	10/538 (1·9)	0·76 (0·34–1·68)	0·49
Any trochanter	1/1065 (0·1)	0/539 (0)	n/a	n/a

[a]RR with reference to the standard-of-care group. n/a, not applicable.

tension injuries on the skin. Heel dressings caused two patient falls, without significant harm, when the dressing was in direct contact with the floor (Table 4).

From the DD group in the safety population, 246 DDs were reported in 97 patients. Some of the seven categories identified related to the subsequent ADEs reported, namely poor adhesion or adhesion failure (n = 127), rolled-up edges (n = 44) and dressing causing the floor to be slippery for others (n = 26); in one case of the latter this resulted in a fall, without significant harm. Other DDs noted were dressing layer separation, adhesive residue on the skin, adhesive transfer or poor release of the backing film or liner from the dressing, and footwear obstruction (Table 4).

Discussion

The use of silicone adhesive multilayer foam dressings for PU prevention at the sacrum, heels and trochanters significantly decreased the incidence of PUs of category 2 or worse from 6·3% to 4·0% in hospitalized at-risk patients.

Table 3 Incidence of pressure ulcers of category 2 or worse, by intervention group stratified by patient characteristics (intention-to-treat analyses)

		Treatment, n = 1066	Standard of care, n = 539)	Total, n = 1605
	Pressure ulcer			
All	Yes	43 (4·0)	34 (6·3)	77 (4·8)
	No	1023 (96·0)	505 (93·7)	1528 (95·2)
Age (years)				
< 60	Yes	0 (0)	1 (2)	1 (0·8)
	No	81 (100)	44 (98)	125 (99·2)
60–69	Yes	2 (1·7)	2 (4)	4 (2·3)
	No	116 (98·3)	53 (96)	169 (97·7)
70–79	Yes	8 (3·8)	6 (5·2)	14 (4·3)
	No	205 (96·2)	109 (94·8)	314 (95·7)
≥ 80	Yes	33 (5·0)	25 (7·7)	58 (5·9)
	No	621 (95·0)	299 (92·3)	920 (94·1)
Sex				
Female	Yes	27 (4·4)	20 (6·3)	47 (5·1)
	No	581 (95·6)	296 (93·7)	877 (94·9)
Male	Yes	16 (3·5)	14 (6·3)	30 (4·4)
	No	442 (96·5)	209 (93·7)	651 (95·6)
Baseline ward				
ICU	Yes	6 (4·8)	3 (4)	9 (4·6)
	No	118 (95·2)	68 (96)	186 (95·4)
Non-ICU	Yes	37 (3·9)	31 (6·6)	68 (4·8)
	No	905 (96·1)	437 (93·4)	1342 (95·2)
Surgery				
No	Yes	39 (4·1)	30 (6·2)	69 (4·8)
	No	913 (95·9)	454 (93·8)	1367 (95·2)
Yes	Yes	4 (3·5)	4 (7)	8 (4·7)
	No	110 (96·5)	51 (93)	161 (95·3)
BRADEN at baseline				
≤ 11	Yes	21 (7·9)	5 (4·0)	26 (6·7)
	No	244 (92·1)	119 (96·0)	363 (93·3)
12–16	Yes	21 (2·8)	29 (7·3)	50 (4·3)
	No	734 (97·2)	369 (92·7)	1103 (95·7)
17	Yes	1 (2)	0 (0)	1 (2)
	No	45 (98)	17 (100)	62 (98)
BRADEN – Sensory Perception				
Completely limited or very limited	Yes	18 (7·6)	7 (5·8)	25 (7·0)
	No	220 (92·4)	113 (94·2)	333 (93·0)
Slightly limited or no impairment	Yes	25 (3·0)	27 (6·4)	52 (4·2)
	No	803 (97·0)	392 (93·6)	1195 (95·8)
BRADEN – Activity				
Bedfast/chairfast	Yes	42 (4·3)	34 (6·8)	76 (5·2)
	No	928 (95·7)	465 (93·2)	1393 (94·8)
Walks occasionally or walks frequently	Yes	1 (1)	0 (0)	1 (0·7)
	No	95 (99)	40 (100)	135 (99·3)
BRADEN – Mobility				
Completely immobile/very limited	Yes	39 (4·8)	23 (5·5)	62 (5·0)
	No	778 (95·2)	397 (94·5)	1175 (95·0)
Slightly limited/no limitations	Yes	4 (1·6)	11 (9·2)	15 (4·1)
	No	245 (98·4)	108 (90·8)	353 (95·9)
BRADEN – Nutrition				
Very poor/probably inadequate	Yes	34 (4·6)	20 (5·4)	54 (4·8)
	No	709 (95·4)	352 (94·6)	1061 (95·2)
Adequate/excellent	Yes	9 (2·8)	14 (8·4)	23 (4·7)
	No	314 (97·2)	153 (91·6)	467 (95·3)

ICU, intensive care unit.

Exploratory analyses (per anatomical site and between experimental groups) were performed to investigate specific interactions on the primary outcome. Any apparent lack of effect should be regarded with caution as the trial was not specifically powered with interactions in mind. The results show a decrease in PUs of category 2 or worse for the sacrum

Table 4 Number of adverse device effects and device deficiencies, safety population

	Treatment group		
	Allevyn Life, n = 539	Mepilex Border, n = 538	Total, n = 1077
Adverse device effect (33 in 28 patients)			
All	21 (3·9)	12 (2·2)	33 (3·1)
Pressure ulcer development	1 (0·2)	2 (0·4)	3 (0·3)
Erythema	4 (0·7)	4 (0·7)	8 (0·7)
Pruritus	3 (0·6)	1 (0·2)	4 (0·4)
Blister formation	2 (0·4)	1 (0·2)	3 (0·3)
Exacerbates athlete's foot	0 (0)	1 (0·2)	1 (0·1)
Mechanical skin injuries	8 (1·4)	3 (0·6)	11 (1·0)
Patient fall	2 (0·4)	0 (0)	2 (0·2)
Pain at sacrum	1 (0·2)	0 (0)	1 (0·1)
Device deficiency (246 in 97 patients)			
All	168 (31·2)	78 (14·5)	246 (22·9)
Dressing layers separated	20 (3·7)	6 (1·1)	26 (2·4)
Poor adhesion or adhesion failure	75 (13·9)	52 (9·7)	127 (11·8)
Dressing causes floor to be slippery (increased fall risk)	19 (3·5)	7[a] (1·3)	26 (2·4)
Adhesive residue	10 (1·8)	0 (0)	10 (0·9)
Obstructs wearing footwear	1 (0·2)	2 (0·4)	3 (0·4)
Backing film or liner: adhesive transfer or poor release	10 (1·9)	0 (0)	10 (0·9)
Rolled-up edges	33 (6·1)	11 (0·2)	44 (4·1)

The data are presented as n (%). [a]One of these cases resulted in another person falling, without significant harms.

(from 4·8% to 2·8%), but no statistically significant effect for the heels (decrease from 1·9% to 1·4%). The incidence of PUs on trochanters was too low to identify any effect. These results are consistent with those from previous trials using silicone foam dressings.[7–11,18] This study further expands the generalizability of the results as more than one dressing type was used, the study was performed in different disciplines, and multiple anatomical sites were included. There were no statistical differences between experimental groups 1 and 2 (detailed in the clinical study report).[24]

While no serious adverse events were reported, 33 ADEs in 28 patients, and 246 DDs in 97 patients were reported – including two incidents of patient falling, due to heel dressings being slippery on the floor. The surface of the dressing is designed to minimize friction (be slippery) and therefore advice was provided that the dressings should not be placed directly on the floor, and that shoes or antislip stockings should be worn, although three patients reported that their footwear did not fit over the bulk of the dressing. For both brands there were also reports that placing feet covered by heel dressings directly on the floor made the floors slippery and risked staff or other people slipping. In one case this resulted in a nonstudy individual falling, without significant harms. This observation appeared to be made more frequently when the ambient temperature was above 30 °C.

As the trial results showed no clear effect on the heels, a risk–benefit analysis should be considered when applying prophylactic dressings on the heels to determine whether any potential benefits of protecting the heels outweigh the reported risk of falls. The product specifications highlight differences in construction and adhesive properties between the two study dressings. This may explain the differences in the ADEs and DDs (Table 4). No known standards exist for this product class despite their widespread and growing use. This conclusion feeds the discussion about the need for performance standards for prophylactic dressings. In November 2020, the European Pressure Ulcer Advisory Panel and the National Pressure Injury Advisory Panel announced the establishment of an international task force to develop such performance standards (https://www.epuap.org/prophylactic-dressing). These standards will generate critical information to guide (i) effective clinical product selection and practice, (ii) benchmarks for development purposes and (iii) reimbursement policies.

It should be reiterated that the use of silicone adhesive multilayer foam dressings might be an *additional* intervention to obtain adequate PU prevention, and that the current standard guidelines for PU prevention still remain the cornerstone of prevention.[1] The risk exists that applying a prophylactic dressing on an at-risk patient will create a false sense of security for the clinician, leading to the remaining 'standard of care' of PU prevention being ignored; however, there was no suggestion of this happening in this study. If prophylactic dressings are added to PU prevention strategies, the protocols should stress the importance of education, daily skin assessment underneath the dressing, and monitoring of the adherence to the protocol.

There were some limitations to this study. Performance and detection bias may have occurred because patients, caregivers and study personnel could not be blinded to the study procedures and devices. However, the results were consistent when based on confirmed PUs by review of photographs, all study

nurses were trained, and for most hospitals their wound care teams were involved when a PU occurred, further strengthening the correct identification of skin injuries. As the organization of care and staff characteristics is setting specific, generalizability to other hospitals in other regions might be limited. However, there was a range of hospital types (university and general hospitals), the hospital standard prevention protocols corresponded to the international state-of-the-art recommendations, and the treatment effect is consistent with the results of previous RCTs.

Strengths of this noncommercial study are firstly, its large size and the pragmatic nature of the trial setup and performance. Pragmatic studies can measure realistic treatment effects in daily clinical routines compared with highly standardized RCTs. Secondly, the effect estimate is based on category 2 or worse PUs. As category 1 PUs are not wounds, the clinical relevance of this outcome is questionable, and the measurement error of this outcome is high. Thirdly, the quality of data collection and high-level education provided by the study team to the sites are a strength.

Future academic research priorities could include evaluating the cost and benefit of using prophylactic dressing to reduce HA-PUs, and if prophylactic dressings are included within SOC for PU prevention, evaluating the adherence level to a newly implemented PU protocol.

In conclusion, our study confirmed previous reports from predominantly small single-centre studies that multilayer dressings reduce the incidence of sacral PUs in addition to SOC, both in ICUs and in other wards. Given that on average 50 qualifying hospitalized patients would need to be treated with supplemental dressings in order to prevent one patient from developing a PU of category 2 or worse on the sacral area, a health-economic analysis would be informative before such intervention is routinely implemented in hospitals.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website:

Appendix S1. Clinical study protocol.

Appendix S2. Statistical analysis plan.