

The summary of the clinical stay report will be replaced by the full clinical study report when the publication is accepted for publication and no later than 1/09/2020

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Summary:

Study Title	The use of a silicone adhesive multilayer foam dressing as an adjuvant prophylactic therapy to prevent hospital acquired pressure ulcers: a multicentre randomised open label parallel group medical device trial.
Internal ref. no. and short title	KCE-16012: Silicone adhesive multilayer foam dressings to prevent pressure ulcers.
Introduction	Pressure ulcers are localised injuries to the skin and/or underlying tissue, caused by pressure, or pressure in combination with shear. Pressure ulcers may affect all body locations covering a bony prominence, although mostly occur at the sacral/ischial tuberosity/coccyx area, the heels and the greater trochanter. Clinical practice guidelines recommend reducing the amount and duration of pressure and shear to prevent pressure ulcers. This includes the application of appropriate support surfaces combined with regular patient repositioning. Interest is growing in the application of multilayer foam dressings as an adjuvant prophylactic therapy. Foam dressings may further reduce the amount of pressure and shear and additionally act on the skin's microclimate.
Purpose	The purpose of this trial was to determine if silicone adhesive multilayer foam dressings applied to the sacrum, heels and greater trochanter in addition to standard prevention reduce pressure ulcer incidence category 2, 3, 4, Unstageable, and Deep Tissue Injury (DTI) compared to standard pressure ulcer prevention alone in at risk hospitalised patients. Medical device related and mucosal pressure ulcers were out of the scope of this trial.
Primary endpoint	The primary endpoint of this trial was the incidence rate during the trial period of the patient (during maximum 14 days) of at least one new pressure ulcer category 2, 3, 4, Unstageable, Deep Tissue Injury (DTI) (briefly referred to as pressure ulcers category 2 or worse) on sacrum, heels and greater trochanter as judged on site compared between the pooled treatment groups and the standard of care group as per randomisation scheme.
Study Design	A multicentre, randomised controlled, open label, parallel group medical device trial was performed in 8 hospitals in Belgium. Patients were randomly allocated to three study arms based on a 1:1:1 allocation.
Treatment	<p>Experimental groups:</p> <ul style="list-style-type: none"> • Patients in the experimental group: <ul style="list-style-type: none"> - were cared for on the available support surfaces of the hospital (mattresses, cushions) for the duration of their hospital stay. - received standard pressure ulcer prevention strategies (as described in the hospital protocol) which included ongoing risk assessment, regular repositioning and skin care. • Silicone adhesive multilayer foam dressings were applied on dry intact skin on sacrum, heel right/left, greater trochanter right/left, in addition to standard pressure ulcer prevention. • The maximum treatment duration was 14 days. <p>Control group:</p> <ul style="list-style-type: none"> • Patients in the control group: <ul style="list-style-type: none"> - were cared for on the available support surfaces of the hospital (mattresses, cushions) for the duration of their hospital admission. - received standard pressure ulcer prevention strategies (as described in the hospital protocol) which included ongoing risk assessment, regular repositioning, and skin care. • No silicone adhesive multilayer foam dressing was applied on any skin sites to prevent pressure ulcer development.

Study Devices	<ul style="list-style-type: none"> The maximum observation period was 14 days. Silicone adhesive multilayer foam dressings by Smith & Nephew (Allevyn® brand, type: Allevyn® Life, Allevyn® Life Sacrum and Allevyn® Life Heel) Silicone adhesive multilayer foam dressings by Mölnlycke Health care (Mepilex® brand, type: Mepilex® Border, Mepilex® Border Sacrum, Mepilex® Border Heel)
Clinical study population	<p>The study population included hospitalised patients at risk for pressure ulcer development in university/teaching and general hospitals. Hospitals were eligible to participate if dressings were not used as standard of care to prevent pressure ulcers.</p> <p>Patient inclusion criteria:</p> <ol style="list-style-type: none"> At risk for pressure ulcer development based on Braden risk assessment (Braden score ≤ 17). Admitted to hospital within the previous 48 hours. <i>Note: Not more than 25% of patients per site from ICU wards.</i> Skin at sacrum was assessable and there was no clinically relevant incontinence-associated dermatitis (IAD) or another skin condition that could have been a contra-indication for the application of the devices under study, and there was no pressure ulcer category 2 or worse present. Clinically relevant IAD was defined as any of the 4 categories included in the Ghent Global IAD Categorisation Tool (GLOBIAD) (Beekman et al., 2018). For at least 3 of the following 4 skin sites (heel left, heel right, greater trochanter left, greater trochanter right) one of the following two conditions had to be applicable: <ul style="list-style-type: none"> A study dressing could have been applied as prevention of a pressure ulcer category 2 or worse at that skin site (there is no contra-indication) <p>OR</p> <ul style="list-style-type: none"> There was already a pressure ulcer category 2 or worse at 3 of the 4 sites. Written informed consent by the patient or his/her legal representative. <p>Patient exclusion criteria:</p> <ol style="list-style-type: none"> Aged < 18 years. The length of stay counting from first day of admission in one or (if the patient is transferred to another ward) more participating wards was < 7 days. Both heels amputated. Previously known/documentated allergy for substances used in the devices under study. A clinical condition not allowing participation in a clinical trial. Participation in another interventional clinical trial. Patients who exceptionally received or were planned to receive a dressing for the prevention of pressure ulcers at sacrum, heels and trochanters based on best medical judgment and outside of the surgery setting.
Results	<ul style="list-style-type: none"> Randomisation: From February 2018 until December 2018, 1633 patients were randomised to one of the study arms; 542 (33.2%) to the Allevyn® Life group (experimental group 1), 545 (33.4%) to the Mepilex® Border group (experimental group 2) and 546 (33.4%) to the standard of care group (control group). In the ITT population 12.4% of patients were in the ICU and 87.5% in non-ICUs. Baseline characteristics: Among the 1633 patients, the mean age was 80 years old (SD=12) and the majority (57.6%) were female. ICU patients counted for 12.4% and 39.1% of the patients had their consent signed by a legal representative. Patients being underweight (BMI <18.5) counted for 8.3% of the sample, versus 29.7% for overweight and 16.5% for obesities (BMI >30). About 22.9% of the patients had diabetes and 10.6% had a surgery since admission. Patient characteristics were equally distributed across the 3 study groups. Primary endpoint: Of the 1605 participants in the intention-to-treat population, 77 (4.8%) developed a PU category 2 or worse (sacrum, trochanters or heels); 4.0% in the treatment group and 6.3% in the standard of care (SOC) control group. The Cochran-Mantel-Haenszel test, controlled for type of ward (ICU/Non-ICU), revealed a statistically significant reduction of the risk to develop a PU in the treatment group

	<p>(RR=0.64, 95% 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 to those in the SOC group. This result was further confirmed using a logistic regression model, adjusted for hospital, age, gender, type of ward and Braden score at baseline (p=0.01).</p> <ul style="list-style-type: none"> • Exploratory analyses: (all exploratory analyses presented were pre-planned in the statistical analysis plan): PUs on the sacrum were observed in 2.8% and 4.8% of the patients in the treatment group and the SOC group, respectively. The risk to develop 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). PUs on the heels occurred in 1.4% and 1.9% of patients in the treatment and SOC group respectively, and no statistical difference was identified (p=0.49). Only one patient (0.1%) developed a PU on the trochanter. Exploratory data analyses did not demonstrate any major differences in effectiveness between the 2 brands, considering that the study was not powered to detect such differences. • Subgroup analyses: The incidence of PUs increased with age (from 0.8% for <60 years old to 5.9% for ≥80 years old) and was higher among women (5.1% vs 4.4% among males). While the incidence of PUs was similar in ICU and non-ICU wards, the difference between the treatment group and the SOC incidences was higher in non-ICU wards (3.9% and 6.6% respectively in non-ICU vs. 4.8% and 5.6% in ICU wards). The incidence of PU decreased across Braden score categories, from 6.7% (Braden score ≤11) to 4.3% (Braden score 12-16) and 1.6% (Braden score ≥ 17). • Sensitivity analyses: Results were consistent when based on confirmed PUs by blinded review of photographs, as well as when performed on the Per Protocol Population, although the number of events was insufficient to show a statistically significant effect in these analyses. • Safety report: While no serious adverse device effects were reported during the study, 33 adverse device effects (ADEs) were reported from 28 patients of the safety population (n=1077). Most common ADEs reported were classified as “mechanical skin injury” (n=11), ‘erythema’ (n=8), ‘pruritus’ (n=4) or ‘PU development’ (n=3). Also, 246 device deficiencies (DDs) were reported in 97 patients. Most DDs were related to poor adhesion / adhesion failure, rolled-up edges, dressing layers separation, dressing causing floor to be slippery and increased risk of falling. Heel dressings (of both brands) caused a couple of falls (n=2) when the dressing was in direct contact with the floor. In some cases, it was reported (n=26) that heel dressings made the floor slippery for others and in 1 case this resulted in a fall without significant harms. • Quality of life data: was reported at baseline, day 3 and day 14 or end of study. Descriptive analysis showed similar results between the groups.
<p>Conclusion</p>	<p>The use of multilayer dressings for prevention at sacrum, heels and trochanters significantly decreased the incidence of pressure ulcers (PU) category 2 or worse from 6.3% to 4.0% in hospitalized at-risk patients. While this effect was clearly seen for sacrum (from 4.8% to 2.8%), no clear effect was seen for heels (from 1.9% to 1.4%), and the incidence for trochanter was too low (only a single patient developed a pressure ulcer). The results are consistent with those from previous trials conducted in ICU settings.</p> <p>In conclusion, this large multicentre trial showed no clear protective effect of multilayer dressings for pressure ulcers at heels or trochanter sites when applied in hospitalised at risk patients. This randomised trial confirmed previous reports that multilayer dressings reduce the incidence of sacral pressure ulcers in hospitalised patients in conjunction with standard of care, both on ICU as well as on other wards. With a number needed to treat of 50, a health-economic analysis could be informative before such intervention is routinely implemented in hospitals</p>