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The frictional energy absorber effectiveness and its impact on the pressure ulcer prevention performance of multilayer dressings

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Abstract

Pressure ulcers including heel ulcers remain a global healthcare concern. This study comprehensively evaluates the biomechanical effectiveness of the market-popular ALLEVYN® LIFE multilayer dressing in preventing heel ulcers. It focuses on the contribution of the frictional sliding occurring between the non-bonded, fully independent layers of this dressing type when the dressing is protecting the body from friction and shear. The layer-on-layer sliding phenomenon, which this dressing design enables, named here the frictional energy absorber effectiveness (FEAE), absorbs approximately 30%–45% of the mechanical energy resulting from the foot weight, friction and shear acting to distort soft tissues in a supine position, thereby reducing the risk of heel ulcers. Introducing the novel theoretical FEAE formulation, new laboratory methods to quantify the FEAE and a review of relevant clinical studies, this research underlines the importance of the FEAE in protecting the heels of at-risk patients. The work builds on a decade of research published by our group in analysing and evaluating dressing designs for pressure ulcer prevention and will be useful for clinicians, manufacturers, regulators and reimbursing bodies in assessing the effectiveness of dressings indicated or considered for prophylactic use.

KEYWORDS

bioengineering test methods for clinical efficacy, biomechanical protective performance, etiological research, posterior heel, pressure injury prophylaxis

Abbreviations: AL, ALLEVYN® LIFE; ICU, intensive care unit; ITT, intention-to-treat; NTT, needed-to-treat; PUs, pressure ulcers; PUP, pressure ulcer prevention; RCT, randomized controlled trial.

Key Messages

- Pressure ulcers including heel ulcers are a major concern in global healthcare.
- We evaluated the effectiveness of ALLEVYN® LIFE dressings against heel ulcers.
- Frictional sliding occurs between contacting but independent dressing layers.
- This layer-on-layer frictional sliding absorbs 30%–45% of the mechanical energy.
- This work aids clinicians and industry in preventative dressing efficacy tests.

1 | INTRODUCTION

Pressure ulcers (PUs) also known as pressure injuries remain one of the most significant healthcare challenges globally and are affecting patients at all ages in acute, residential or home care. The heels are a common anatomical location of bodyweight-related PUs, second in susceptibility only to the sacral area.[1–7] Heel PUs also often onset as deep tissue injuries, hence the name the 'purple heel' syndrome.[8] Etiological PU research has emphasized the role of sustained cell and tissue deformations caused by bodyweight-induced, unrelieved compressive and shear forces that lead to loss of cell homeostasis, inflammation, ischaemia and ultimately cell and tissue death.[2,3,9] The unique anatomy of the posterior heel generates peak mechanical strains and stress concentrations in the subdermal fat adjacent to the bone–fat and tendon–fat interfaces.[10,11] Anatomical variants such as in thicknesses of heel tissues and posterior calcaneal sharpness levels, disease-related factors like diabetes and atrophy, foot orientation and extrinsic factors, for example, shape and stiffness properties of the support surface or positioner, all influence the susceptibility of the individual to heel PUs.[2,11–15]

In addition to the existing standard of care, various medical devices are used to minimize tissue exposure to sustained mechanical stress concentrations: those include low-friction surfaces, offloading devices such as heel boots and importantly, prophylactic dressings.[3,6,16–18] Specifically, the prophylactic application of multilayer dressings has emerged as a promising approach with demonstrated clinical efficacy in pressure ulcer prevention (PUP) and large cohort data demonstrating reduction in PU incidence in patients who received these dressings are reported in the literature.[19,20] Indeed, their benefits include pressure redistribution, friction reduction and related inflammation modulation, as well as moisture management, which altogether enhance their efficiency in mitigating the PU risk.[10,19,21,22] Specifically, multilayer dressings have been shown to alleviate soft tissue stresses in weight-bearing body regions, by internally deforming under the compressive and shear forces of the bodyweight. The presence of these dressings therefore absorbs some of the mechanical energy acting to deform the soft tissues that would otherwise be transmitted to these tissues directly.[10,15]

The research group of author AG has been investigating for the last decade how wound dressings redistribute mechanical loads, reduce shear forces, maintain proper microenvironmental conditions (such as microclimate and moisture levels) and support tissue perfusion. Understanding these mechanisms helps in the design and selection of appropriate dressings for different clinical scenarios. The literature published by the AG research group quantified the stress relief in soft tissues at the heels as well as at the sacral region and defined quantitative protective performance and endurance metrics of dressings in prophylactic use, by means of a variety of material measurements and computer modelling and simulation methods. Previous research has primarily focused on the stiffness and anisotropy of multilayer dressings and their outer coefficient of friction (COF).[10,15,22–29] This extensive volume of published work supported the development of clinical guidelines for the use of prophylactic dressings, including during the COVID-19 pandemic time, and provided specific design guidance optimizing dressing materials and structures for PUP, which ultimately resulted in evidence-based recommendations for healthcare practitioners and administrators who make purchase decisions to prevent PUs in their facilities.[30–33]

Our current study aims to expand upon the above existing literature, by investigating the internal energy absorption mechanism of multilayer dressings and providing valuable insights into how these dressings mitigate the forces exerted on soft tissues, thereby advancing the understanding of PUP strategies by means of dressings. Specifically, we address the internal frictional phenomena in a multilayer dressing type that facilitates internal frictional sliding of its layers against each other. We

investigated this dressing structure by means of theoretical formulation and development of a new testing method and apparatus, which, altogether, enabled to study this newly reported mode of action (MOA) of energy absorption by the dressing for alleviating the stresses in the soft tissues in at-risk body regions. To place these findings into a clinical practice context, a review of the published literature focusing on prophylactic use of the multilayer dressing subject to the current investigation was also performed.

1.1 | Focused review of the clinical literature

A search of the published clinical literature for pivotal studies reporting on ALLEVYN® LIFE (AL) was performed. Randomized controlled trial data specifically pertaining to AL and reported as peer-reviewed (full) journal articles published in the English language were identified from electronic medical databases (e.g., MEDLINE, Embase) and reviewed to place the laboratory findings in context of the present study. Keywords used in this search were ALLEVYN, 'pressure ulcer'/'pressure injury', dressing, 'preventative'/'prevention', 'prophylactic'/'prophylaxis' and 'clinical trial', where the word ALLEVYN was defined as essential.

Three randomized clinical trials (RCTs) were reviewed to place the bench-top research reported above into clinical context. Forni et al.[20] performed a pragmatic, randomized controlled superiority trial of using AL dressings compared with standard PUP protocol (without the use of prophylactic dressings) to assess the incidence of sacral PUs in elderly patients (age ≥ 65 years) presenting at a university, orthopaedic hospital for hip fracture. The primary outcome was the rate of any category of PU (as defined by NPIAP/EPUAP/PPPIA) in the sacrum area detected within 8 days of hospitalization. Secondary assessed outcomes included the rate of PUs in other locations, incidence of ≥ category II PUs, and the number of rashes/skin lesions due to intervention. A total of 360 patients was determined as the necessary sample size to meet statistical power.

In total, 359 patients were enrolled into the study,[20] with 177 patients assigned to the intervention (AL) group and 182 patients to the standard PUP protocol arm. Patient baseline variables and demographics were balanced between groups. The total incidence of sacral PUs was 36 patients, with 8 patients (4.5%) in the intervention group and 28 (15.4%) in the control group developing PUs. This difference was statistically significant, with a 71% reduction in the relative risk of developing a PU with an AL dressing compared with control (relative risk: 0.29; 95% confidence interval [CI]: 0.14–0.61; $p < 0.001$). The number needed-to-treat (NTT) to prevent an incidence of PU was 9 (95% CI: 6–21). A post hoc Kaplan–Meier analysis demonstrated a statistically significant difference between the two groups with onset of PUs, with average onset at day 6 for those with an AL dressing and day 4 for the control group ($p < 0.001$). This study demonstrates that the use of AL dressings is capable of statistically significantly reducing the incidence of PUs compared with standard PUP protocols (i.e., without prophylactic use of dressings) in patients at risk for sacral PU. Importantly, in patients who did go on to develop a PU, this took a significantly longer time in those who received AL dressings compared with controls, suggesting a clear protective effect in minimizing skin and subdermal tissue damage with the use of this prophylactic dressing type.

A subsequent study conducted by the Forni group[33] was an open-label, parallel group multicentre randomized controlled trial of at-risk patients from medical, surgical and intensive care units across Italy. Similar to their previously published work,[20] their later study aimed to determine whether the use of AL dressings lowered the incidence of sacral PUs compared with standard PUP protocols (i.e., with no prophylactic dressing).[33] The follow-up duration for the primary outcome was 7 days. Secondary endpoints included incidence of sacral PU ≥ category II based on EPUAP, NPIAP and PPPIA parameters and the number of days needed to PU development. For the study to be considered statistically powered (at an 80% power), 228 patients had to be included and randomized into the study. This study therefore builds on previous research conducted by Forni et al.[20] using a larger sample size (total study sample size at randomization: 709 patients). Notably, this study was terminated earlier than initially planned due to the COVID-19 pandemic, although, given adequate enrolment into each arm, the study appeared to be adequately powered to detect a difference in the primary endpoint. However, sufficient enrolment was not accrued for evaluation of hospital area (e.g., medical, surgical, intensive care) sub-group analyses. The authors utilized a modified intention-to-treat (ITT) population when performing their statistical analyses with robust measures to account for missing patient data.[33] The results of the later Forni study[33] identified a balanced patient demographic between the intervention groups. The authors further found a statistically significant reduction in the incidence of sacral PUs of any category across all the studied care settings with the use of AL dressings compared with controls (relative risk reduction: 62.3%; 95% CI: 35.5%–78%) with NTT of 12 (95% CI: 8–26). There was no statistical difference between the intervention groups in any of the assessed secondary outcomes, including the incidence of discomfort and skin

adverse events with the use of the AL dressing type. Kaplan–Meier analysis showed that the AL dressings imparted its protective effect within the first few days of intervention initiation and continued throughout the seven-day follow-up period, compared to controls. However, in contrast to earlier findings reported by Forni et al.,[20] no statistically significant difference in the average onset of PUs was noted between the groups ($p = 0.869$). This discrepancy between studies may be explained by the more heterogeneous population investigated in their later study.[33] With that said, the findings from the Forni group in their later work[33] are consistent with their earlier research results on the lowering of PU incidence by applying AL dressings as a preventative intervention compared with standard PUP protocol (without dressings). Given the larger sample size and multicentre design of their newer study,[33] this increases the confidence in the interventional effect of AL dressings for sacral PUP as the data are more robust and generalizable in the later study.

Another major European RCT was that of Beeckman et al.[19] who performed a pragmatic, multicentre, randomized controlled trial conducted across eight Belgian hospitals. Patients were eligible for recruitment into the Beeckman study[19] if they were considered at risk for PU development (as defined by a Braden risk assessment score < 17), had been admitted to the hospital within 48 h, had no prior category II PU or above, and also no clinically significant incontinence-associated dermatitis or -related conditions. Patients from both intensive care unit (ICU) and non-ICU care settings were included, although <25% of patients were recruited from ICUs. Patients were randomly assigned to one of three intervention arms in a 1:1:1 allocation, receiving either an AL dressing, an alternative multilayer dressing product, or a standard PUP protocol, which did not include any prophylactic use of dressings. To clarify, the two prophylactic dressing groups also received the full standard PUP protocol that was applied to the control group (in addition to the use of dressings).[19] The primary assessed outcome in the Beeckman study[19] was the proportion of patients who developed at least one new PU of category II or greater on the sacrum, heels or greater trochanters during a 14-day follow-up period. Statistical analyses were performed using both ITT and per-protocol populations and by testing for superiority. Sensitivity analyses on the primary endpoint were further conducted to assess the impact of per-protocol testing and independent assessors. As no statistical differences in performance of the two dressing product types could be identified, the authors of Ref. 19 pooled the data from the sub-groups receiving the two product types to compare the pooled dataset against the standard, that is, no-dressing protocol (of note, this study was not originally powered to detect product-to-product performance differences). In total, 1633 patients were recruited into the Beeckman study[19] and randomized into one of the three study sub-groups. AL dressing: 542 (33.2%); an alternative multilayer dressing product produced by a different manufacturer: 545 (33.4%), and the standard, no-dressing protocol: 546 (33.4%). Patient baseline characteristics were similar across these three sub-groups. With regard to the primary outcome, there were 77 incidences of PU category II or above, with a total pooled 4% incidence in the dressing groups and a statistically significantly greater, 6.3% incidence in the control group. Specifically, a statistically significant reduction in the risk of developing a PU was found with the pooled prophylactic dressing sub-groups, with a relative risk: 0.64; 95% CI: 0.41–0.99; $p < 0.05$. That is, the risk of developing a category II PU or greater reduced by 36% with the use of prophylactic dressings compared with the standard, no-dressing protocol. Interestingly, this statistically significant risk reduction was also conserved when a sub-analysis isolating the sacral body location was performed, but the protective effect was not statistically significant for the heels (and insufficient data were available for a sub-analysis of the trochanter).

Overall, there is a small number of large RCTs in the field of prophylactic use of dressings for PUP, the work reviewed above; however, three of the published RCTs investigated the prophylactic performance of the AL dressing.[19,20,33] Based on these three major RCTs, taken together, illustrate that the use of AL in combination with a standard PUP protocol is capable of significantly reducing the incidence of category II and above PUs compared with standard protocols alone, demonstrating that the FEAE MOA introduced in the current work translates to clinical efficacy.

2 | METHODS

2.1 | Theory of the frictional energy absorber effectiveness

The application of wound dressings has been shown to be clinically effective in preventing PUs when used in addition to the relevant nursing standard of care.[19,21] Because the AL multilayer dressings (abbreviated thereafter as AL), manufactured by Smith & Nephew Limited (Hull, UK), which are indicated for treating PUs, are also suitable for PU prophylaxis (as will be further detailed in the literature review section), this study aims to determine the extent by which they reduce the mechanical energy generated by the bodyweight forces applied to the

posterior heels. Specifically, the current focus is on experimentally investigating the hypothesis that a non-negligible part of the mechanical energy exerted on the heel soft tissues is absorbed by frictional sliding of the interfacing dressing layers against each other, when the dressing is subjected to mechanical loading conditions comparable with those in clinical use.

Considering the frictional force $F_f = \mu N$ as the product of the COF μ and the normal force exerted by the weight of the heel $N = m_h g$, where m_h is the mass of the posterior foot and g is the gravitational acceleration, the frictional work W_f that takes into account the relative displacements of the dressing layers $d_{i,i+1}$ in frictional sliding (at each interface between adjacent layers $i, i+1$) can be expressed as follow:

$$W_f = m_h g \sum_i \mu_{i,i+1} |d_{i,i+1}| \quad (1)$$

In addition, the compressive work is defined as $W_c = m_h g y$, with y being the vertical compression due to the weight of the posterior foot. An approximation of the percentage internal energy loss in the dressing due to internal friction within the dressing, that is, the frictional energy absorber effectiveness (FEAE) of the dressing, is defined as the ratio of the frictional work W_f (i.e., the work occurring internally in a deformed dressing) and the compressive work W_c (i.e., the work invested by the bodyweight force to deform the soft tissues of the posterior heel):

$$\mathrm{FEAE}\,[\%] = 100 \times \frac{\sum_i \mu_{i,i+1} |d_{i,i+1}|}{y} \quad (2)$$

Each of these variables in the above FEAE formulation (Equation (2)) was measured empirically. Specifically, the $d_{i,i+1}$ and y values were measured by means of a custom-made combined compression and shear testing apparatus simulating in-use conditions for the tested dressings. The $\mu_{i,i+1}$ values were measured using an electronically controlled tilting table tribometer. The specimens, test conditions, equipment and methods for these measurements are described in the following sections.

2.2 | Dressing specimens

The dressing studied here is a silicone-gel adhesive, composite hydrocellular foam dressing. Depending on the needs of the different experiments, either full dressings or reconstituted interfaces made from plain sheets of each contacting layers were used. The layers of interest are referred to in this work as follows: The hydrocellular foam ($i = 1$), the hyper-absorber with gelling fibres ($i = 2$) and the masking/protective layer ($i = 3$), which is bonded to the outer dressing layer and made out of a breathable film, as shown in Figure 1. The coefficients of friction $\mu_{i,i+1}$ and the dressing layer displacements $d_{i,i+1}$ were studied at the two relevant inner interfaces 1,2 and 2,3 where frictional sliding may occur. The interface of *skin* and $i = 1$ is considered as fixed because layer no. 1 is attached to the skin using a silicone-based adhesive; therefore, their COF and relative displacements were not measured.

In addition to the study of the internal displacements in a commercial dressing, a comparison has been made with a bonded dressing configuration where the layers have been glued to the adjacent ones using a thin layer of acrylic adhesive. This allowed assessment of the relative contributions of sliding between the dressing layers versus the internal material shearing within each layer.

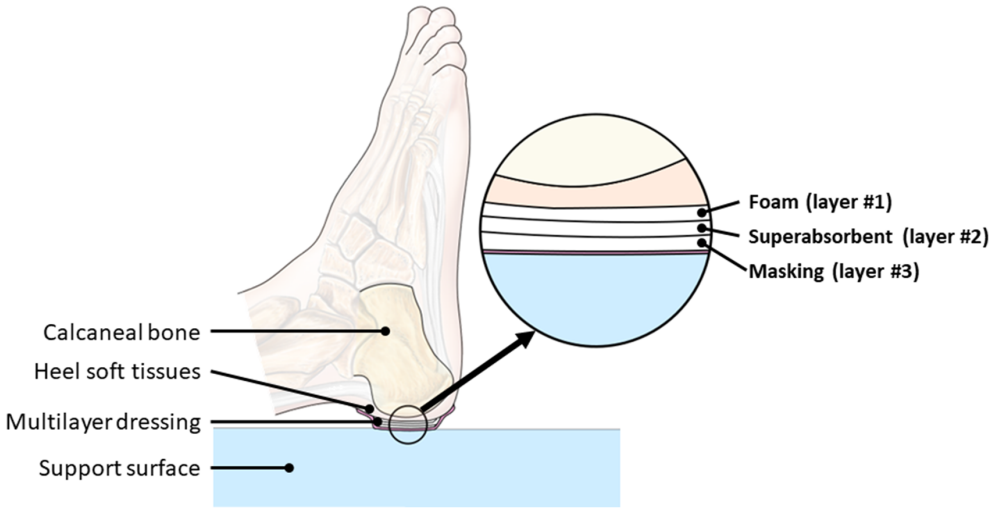

FIGURE 1 Cross-sectional schematic view of an ALLEVYN® LIFE dressing applied on a heel, with a detail showing the three inner layers of the dressing that are relevant for the current frictional energy absorption effectiveness studies.

Lastly, to account for the potential influence of the shape of the dressing on the measured parameters, both square- and quadrilobe-shaped dressing specimens were tested and their data were subsequently compared. The baseline, bonded and alternatively shaped configurations are denoted here as L, LB and LA, respectively.

2.3 | Test conditions

To test the dressings in conditions similar to the state in which they are worn in clinical reality, two factors were considered: the moisture and the wear level. First, two wear levels were studied: new (as in out-of-the-box) and used (i.e., after being subjected to an accelerated ageing before being tested). The used state was emulated by applying loading cycles to simulate the repetitive shear and compression that would be exerted by the foot weight and the potential leg movements of a patient for the maximum wearing duration of 1 week (for a preventative application). In total, the pre-loading involved 10 loading cycles of coupled compression (exerted by a mass of approximately 1.1 kg, as justified below) and shear stress (up to 10 N at a speed of 50 mm/min), using the test apparatus described in Figure 2.

Both the 'new' and 'used' measurements were taken considering that the dressing would be slightly moist when worn in a clinical setting. Indeed, the perspiration rate during sleeping (450–2280 g/m^2 per day)[34] is lower than the moisture vapour transfer rate of AL (1800–2600 g/m^2 per day)[17,35]; consequently, there can be no substantial moisture accumulation inside the dressing in a preventative use scenario. This was verified in a convenience sample of healthy participants ($N = 3$): A very low weight mass gain delta (≈0.3 g per dressing) was measured overnight. Hence, to simulate the moisture amount accumulated in the dressing, the dressings were left overnight on a flat, semipermeable 1-mm-thick dense chamois cloth, which simulates sweaty moist skin.[36] This cloth was moistened by sparsely spraying it with a 0.9% isotonic saline solution, prepared by dissolving 9 g of NaCl in 1 litre of distilled water. Hence, the following combinations of conditions have been tested: 'new & moist' and 'used & moist', the latter condition is the most clinically relevant one as it represents the factor of time of product usage (days to a week) for prophylactic dressing applications.

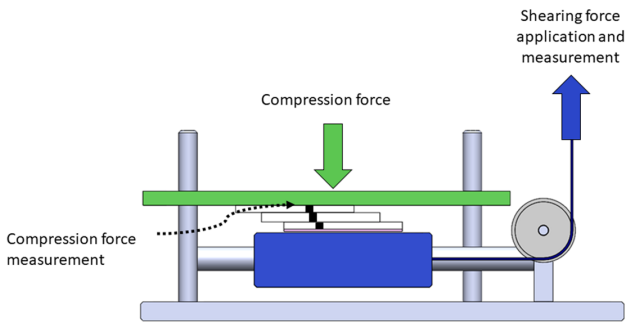

FIGURE 2 Cross-sectional schematic view of the test apparatus designed to measure the vertical compression y as well as the internal displacements $d_{i,i+1}$ under specific magnitudes of applied compression and shear stresses in order to ultimately calculate the frictional energy absorption effectiveness.

2.4 | Testing equipment

2.4.1 | Measurements of the coefficient of friction

The dimensionless values of the COF μ for each interface of interest between the dressing layers were measured using an electronically controlled tilting table tribometer, which has been developed in-house at the Gefen laboratory at Tel Aviv University (Figure 3) and following an experimental protocol reported in our previously published work.[36–38] The angle of the plate of this tilting table is gradually and slowly increased by means of a computer-controlled electrical motor. When the sliding of the weight is initiated due to this gradual inclination,

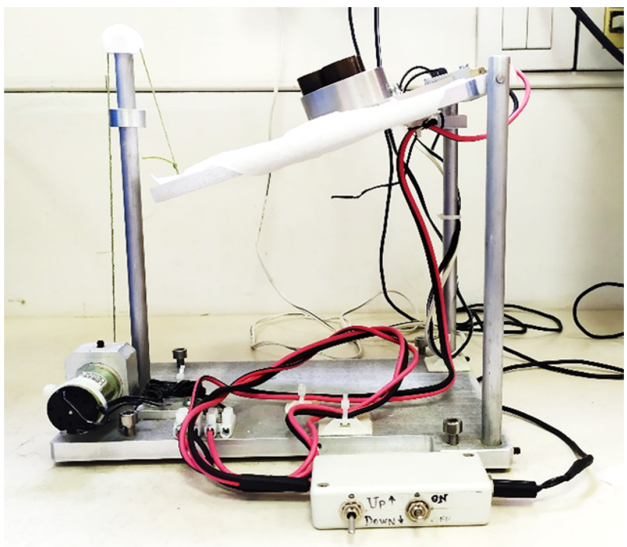

FIGURE 3 The electronically controlled tilting table tribometer that has been developed in our laboratory and used for the measurements of the coefficients of friction between the ALLEVYN® LIFE dressing layers. A steel weight is applied on the tested dressing layer specimen to ensure its uniform contact against the support layer sample during the frictional sliding phase of the test.

an electrical switch opens instantaneously, causing the motor to immediately stop. The angle θ of the plate, at which frictional sliding had started, was then measured using an inclinometer that was thoroughly calibrated at the start of each set of experiments. The COF $\mu_{i,i+1} = \tan(\theta_{i,i+1})$ was then calculated for each specific interface between dressing layers.

Contact between the tested dressing layers was ensured using a weight designed to replicate the average pressures exerted on the dressing in-use, which are reported to be between 15 and 25 mmHg according to Refs. 10, 16, 39. The peak pressure applied by the heel on a support surface can be substantially higher locally than the above mean pressure values: When measured over a localized, small contact area, often linked to the size of the sensor used, reported peak pressure values may reach 200 mmHg.[40,41] In order to measure the COFs under realistic conditions, a pressure level of 30 mmHg was chosen, simulating a worst-case scenario where the calve does not support a substantial bodyweight and thereby does not reduce a considerable portion of the loading from the posterior foot. Each tested specimen was cut from each of the layers to fit either a circular weight or the top plate of the tilting table tribometer, and each measurement was obtained using a different pair of specimens. Samples were conditioned to be dry/moist and new/used using the conditioning procedures detailed above.

2.4.2 | Compression and displacement measurements

A novel test apparatus was designed to facilitate the optical measurements of frictional sliding displacements between interfacing layers of the dressing under investigation when subjected to realistic in-use loads. In order to apply both a shearing force and a compressive force simultaneously, this apparatus was composed of three main parts: a fixed base, a sliding shearing plate and a compression plate (Figure 2).

First, because the weight of a foot ranges from 1.29% to 1.43% of the total bodyweight of a patient according to Refs. 42–44 and considering an average bodyweight of 76 kg of patients at risk of developing bodyweight-related PUs as reported in Ref. 45, the mass of a 'typical' foot and hence the magnitude of the related compressive load can be estimated to be 1.1 kg. The top plate was designed accordingly and the resulting compressive force that it applies on the sample was controlled using a force sensing resistor (Interlink Electronics, Camarillo, California); this force was sampled via a NI-DAQmx control unit and a custom-made LabVIEW program (National Instruments, Austin, TX, USA). Second, to estimate the maximum shear force that the dressing is subjected to during normal use, we considered that it would be the force at which the dressing would start slipping on the support surface. Accordingly, the external layer of the dressing was fixed to the bottom plate, which was pulled until the shear force reached a sufficient value to slip against the standard cotton bedsheets that were attached to the top plate. This slipping threshold shear value was measured to be 6 N. Consequently, the shear force value was dynamically measured using a load cell with a nominal range 2–2 kN $\pm$ 0.5% of accuracy, connected to an electromechanical material testing machine (Instron Corp., model 5944, Norwood, MA, USA) operating with BlueHill software (Instron Corp.). The measurements were stopped when the shear force reached the above 6 N limit. In addition to measuring the shear force values, the compressive work of the dressing was quantified by comparing the thickness of a pre-loaded sample subjected to a minimal weight of 70 g to only flatten its surfaces, versus that of a sample that was loaded and sheared to the full capacity of both the compression and shear loads (1.1 kg and 6 N as detailed above). The vertical compression y was then calculated for each fully loaded dressing sample with respect to the minimally pre-loaded samples.

The two variables of interest, namely, the internal displacements at each interface $d_{i,i+1}$ as well as the vertical compression y, were extracted from videos taken using a high-resolution digital video camera of the digital single-lens reflex (DSLR) type (D3500, Nikon Co., Tokyo, Japan). These video data were automatically processed using a custom MATLAB program for digital image correlation (DIC), a non-contact 2D strain measurement method based on Ref. 46. This program converts the displacements from pixels to millimetres, measures the height of the pre-loaded and loaded dressings, tracks the displacements of the markers in a user-defined area (chosen in a central area of the tested dressing to avoid border effects and to include high-contrast markers) and translates the measured values from pixels to millimetres using calibration values that are gauged for every set of measurements. To gain insight into the relative internal movements at the different dressing interfaces, each test specimen was obtained from cutting a dressing in half. The support-facing layer of the dressing was taped to the weight that is vertically compressing the dressing, and the skin-facing layer was fixed to the plate translating in the shearing direction. Furthermore, the samples were conditioned to be moist and either 'new' or 'used' as per the conditioning procedures detailed above. Finally, the cut side of the dressing faced the DSLR camera to allow capturing the displacements of the dressing layers, and

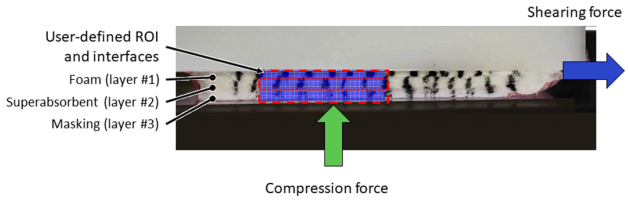

FIGURE 4 Picture of a dressing sample prepared for digital image correlation (DIC) measurements with high-contrast black markers. An example of a user-defined region of interest (ROI) outlined in red dashed lines is overlaid to the picture, as well as the two internal dressing layer interfaces in dotted lines. Each blue cross marks a pixel in the digital image that will be tracked by means of DIC at each frame of the video.

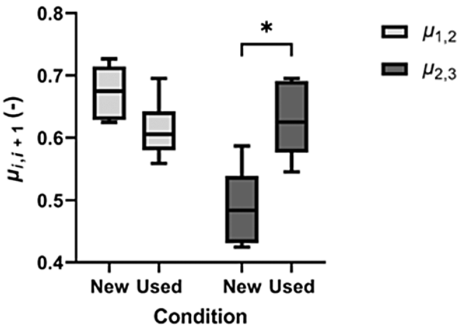

FIGURE 5 Standard box plot of the coefficients of friction $\mu_{i,i+1}$ values for moist ALLEVYN® LIFE samples and for both new and used dressings. *$p < 0.001$.

black markers were created by spraying paint or using a permanent marker to create a high-contrast pattern to facilitate the DIC optical tracking (Figure 4).

2.5 | Statistical analysis

All the above measurements were taken with a sample size of six dressings for each configuration and condition combination. Descriptive statistics of means and standard deviations were calculated for all the input variables (COFs $\mu_{i,i+1}$, inter-layer displacements $d_{i,i+1}$ and the vertical compression y) as well as for the FEAE data and presented as box plots. Then, one-way analysis of variance followed by Tukey–Kramer pairwise comparisons were used to identify any potential statistically significant effects of the (new/used) dressing condition on the FEAE and the aforementioned input variables, with the level of statistical significance level set as $p < 0.05$.

3 | RESULTS

The average values of the COFs $\mu_{i,i+1}$ measured for each dressing interface and condition combinations are depicted in Figure 5. No significant differences between the new and used values were observed for $\mu_{1,2}$; however, for $\mu_{2,3}$, there was a significant increase in the COF in the loaded state ($p < 0.001$).

This finding is coherent with our visual observations, as the fibrous layer nos. 2 and 3 tended to appear less cohesive after repetitive testing, which most likely increased the surface roughness at the interface between these layers. The trends of influence of the wear state on the values of the input variables for the FEAE calculations for all three configurations are shown in Figure 5. It is noteworthy that the relative layer displacements at the interface 1,2 tended to be consistently greater in the mechanically preconditioned dressing states (Figure 6A). However, the only statistically significant increase was for the displacement on interface 2,3 of the baseline configuration (L) ($p < 0.0001$), whereas the vertical compression y did not exhibit a clear tendency to consistently increase or decrease when the dressings were mechanically preconditioned.

The FEAE results are shown in Figure 7A. It is demonstrated there that the absorption of mechanical energy through internal frictional sliding within the dressing is substantial with respect to the compressive energy (associated with the bodyweight forces): On average, for all conditions, the magnitude of the frictional sliding accounts for more than 30% and up to ~45% of the magnitude of the compressive energy (which therefore contributes considerably to reducing the mechanical energy acting to distort the soft tissues of the posterior heel). In addition, as a logical consequence of the increased inter-layer COFs and the increased relative, interfacing layer displacements, the FEAE increased by approximately 1.3-fold after mechanical preconditioning (repetitive loading), indicating that there is an increase in the extent of internal energy dissipation by inter-layer frictional sliding in used dressings (though without statistical significance).

Additionally, to evaluate the relative contributions of sliding between contacting dressing layers versus internal material shearing within each layer, a comparison was made between baseline (commercial) dressing samples (L) and specially-prepared (non-commercial) samples with the layers bonded (LB). In the former, both layer material shear and inter-layer sliding are possible, whereas in the latter, only layer material shear deformations can lead to apparent internal displacements within the dressing structure. Accordingly, the above relative contribution was calculated as a shear/sliding ratio of the total displacement as detailed in Table 1. These analyses revealed that a non-negligible (≥69%) portion of the observed internal dressing

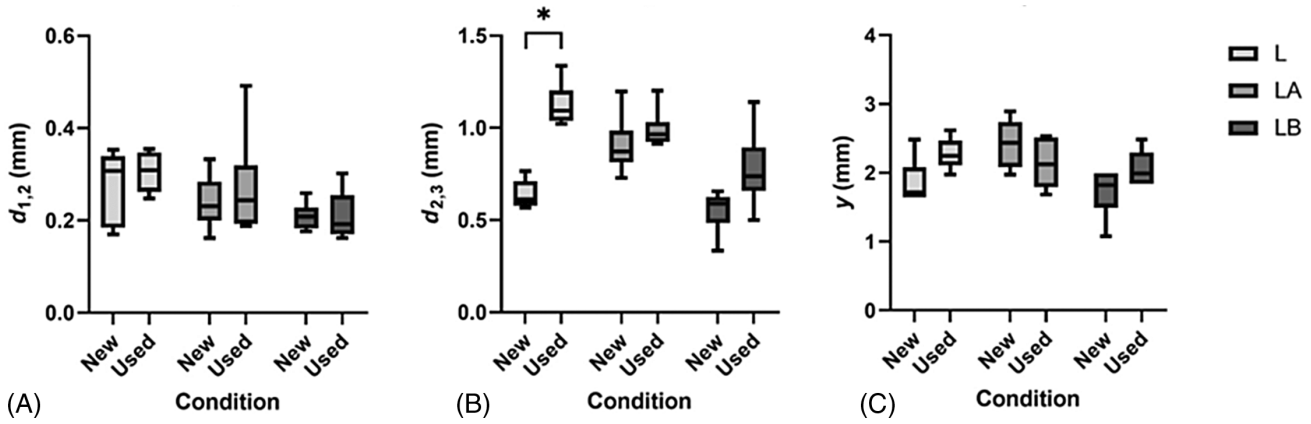

FIGURE 6 Standard box plot of the internal displacements $d_{i,i+1}$ (A) and (B) and compression y (C) for moist dressing samples for both new and used dressings of all three configurations: baseline ALLEVYN® LIFE (L), alternative shape (LA) and the bonded configuration (LB). *$p < 0.0001$.

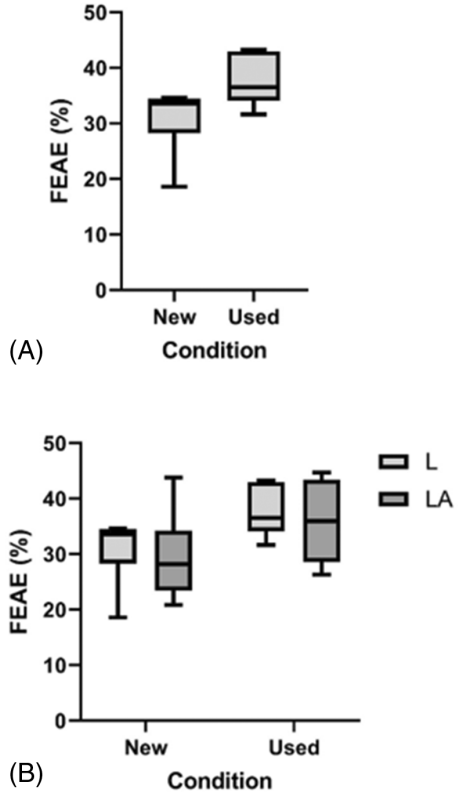

FIGURE 7 Standard box plot of the frictional energy absorption effectiveness values (A) for moist ALLEVYN® LIFE samples and for both new and used dressings, as well as for (B) the comparison of the baseline (L) and alternatively shaped (LA) dressings. FEAE, frictional energy absorber effectiveness.

displacements is indeed due to layer-internal material shear, which, in our case, is analogous to internal sliding between contacting fibres in the low-density fibrous layers.

Additionally, the sliding-to-shear ratio increased when the dressing was in its 'used' condition. When comparing the baseline and the bonded dressing configurations, these differences were found to be statistically non-significant, except for the displacements between interfaces 2 and 3 for the 'used' condition. This result aligns with our visual observations, where it was noted that inter-layer sliding tends to become easier after the dressing was subjected to repetitive shear loading.

Lastly, to test whether there is potential influence of the shape of the dressing on the FEAE measurements, both square- and quadrilobe-shaped dressing samples were tested and subsequently compared. When comparing the FEAE values of either shape in one given condition to one another, none of the differences in FEAE presented here (Figure 7B) were found to be significant nor in any of the other intermediate variables examined. These results suggest that the shape and size of the tested dressings do not have a significant impact on the measured parameters, particularly the FEAE values. A Supplementary Data section was included with this article to provide the numerical values for all the input parameters used for the calculations of the FEAE data for the new/used test conditions and their variability.

4 | DISCUSSION

Etiological PU research focusing on preventing heel PUs has highlighted that the interactions between the skin and the underlying soft tissues of the posterior foot and the support surface results in considerable compressive and shear forces, which, altogether, contribute to the risk of injury.[2,3,9] Various PUP methods are available, with an important one being the prophylactic application of multilayer wound dressings on the heels, which is the focus of this study. Indeed, theoretically, several key mechanisms grant such wound dressings their efficiency in a

TABLE 1 Means and standard deviations of the internal displacements $d_{i,i+1}$ and the relative contributions of the baseline (L) and bonded (LB) ALLEVYN® LIFE dressing configurations for the moist condition and for both new and used dressings.

	$d_{1,2}$				$d_{2,3}$		
	L	**LB**	**Relative contribution**		**L**	**LB**	**Relative contribution**
New	0.28	0.21	76%	New	0.64	0.55	87%
Used	0.31	0.21	69%	Used	1.12	0.77	69%

preventative capacity: allowing pressure distribution to help alleviate localized peak pressures; reducing friction between the skin and the support surface due to a low-friction outer surface of the applied dressing; and preventing moisture accumulation; and consequently, avoiding excessive skin hydration that would lead to skin fragility.[10,19,21,22] This study adds to the existing literature on PUP by means of dressings, by providing new knowledge on the mechanism (also known as the MOA) of internal energy absorption in multilayer dressing types in which relative movement between the layers is possible. For these dressing designs, the current work details the bioengineering theory and provides valuable empirical insights into the mechanism by which the forces exerted on the soft tissues of the posterior heel are alleviated through frictional sliding occurring within the dressing and between its layers. A quantitative criterion allowing to determine the effectiveness of mechanical energy absorption within a tested dressing and an associated new test method were further developed and named the FEAE, to allow robust laboratory testing and comparison of the frictional properties of different multilayer dressing configurations under controlled and clinically relevant conditions.

Our current findings overall demonstrated that the internal structure and composition of the ALH dressing efficiently absorb frictional energy, thereby mitigating the occurrence of sustained soft tissue loading (i.e., concentrated mechanical strains and stresses) at the posterior heel (Figure 7). Second, to consider the range of real-world mechanical conditions that are relevant to a prophylactic use of the tested dressings, the effects of usage during the wear period have been taken into account. Based on that investigation, we have shown that internal layer-to-layer displacements tended to be higher for repetitively loaded (i.e., used) dressings, leading to higher FEAE values (Figure 7A). However, the said difference did not emerge as statistically significant for our sample size, indicating that the internal layered dressing structure is unlikely to change (or degrade) during the wearing period (Figure 7A). Third, the bonded layer study allowed to prove that a significant portion of the displacements observed between layers is due to shear that occurs internally in the dressing as a result of layer-to-layer frictional movements (Table 1). It is noteworthy that the sliding-to-shear ratio increased considerably when the dressing was tested in its used condition, that is, post repetitive loading (Table 1). Lastly, the current results indicated that the shape of the dressing does not have a significant impact on the FEAE values, nor on any of the other intermediate variables used to calculate the FEAE (Figure 7B).

The novel method described in this study will allow to iterate on the design of existing and prospective dressings and facilitate performance comparisons in different conditions, which are highly needed in the field of preventative dressings. This has been the main goal of the global prophylactic dressing standards initiative (PDSI, https://npiap.com/page/PDSI), which author AG is co-leading.[24] As highlighted by the PDSI, clinical practice guidelines such as the NPIAP/EPUAP/PPPIA guideline (www.epuap.org/pu-guidelines) recommend the use of wound dressings for preventing PUs, and this has become the standard in many medical settings worldwide. The wound dressing industry has responded to this demand by promoting the use of existing wound dressings for preventative purposes; however, there are two main challenges. First, none of the many clinical studies conducted so far in this regard are able to explain how these preventative effects work (simply because clinical studies are not designed for this purpose). Second, the wound dressings evaluated or marketed for PUP vary remarkably in their materials and composition. The above issues make it difficult for clinicians, regulators, payors and manufacturers to make informed decisions about how to develop, evaluate and make purchase decisions regarding wound dressings for preventing PUs.[18] For multilayer dressings, the FEAE should be included in a metrics of performance that can also potentially further include durability, thermal performance, moisture management and adhesiveness properties, as proposed by the PDSI. The current work further provides guidance for a new type of dressing that is not dual-purpose, that is, dressings designed solely for PUP, for which the FEAE can be further increased through certain design features without potentially compromising other dressing features that are critical in treatment of wounds (but are irrelevant in prevention), primarily fluid handling but also antimicrobial features,

for example. Prior to that, it is also worthwhile to extend the current work to additional body parts that are susceptible to PUs, in particular, the sacral region (which bears different bodyweight forces).

In order to put the FEAE MOA into a clinical outcome context, a literature search was conducted which identified three relevant, major European RCTs in which AL dressings were used as means for PUP.[19,20,27] Findings from reviewing these studies indicated that the FEAE MOA of the AL dressings translates, in fact, into observable clinical benefits in PUP (in addition to standard PUP protocols) among different high-risk populations. It is important to note that it is extremely challenging and expensive to power even the largest, multicentre RCTs to detect product performance differences, but bioengineering analysis of product structure and function, and development of theoretical framework, such as FEAE, first identify unique MOAs, and second, explain clinical effects. In other words, not all dressings are created equal (either for prophylactic or treatment usage), as they are designed and constructed differently, and therefore, knowing and understanding MOAs and differences in MOAs help clinicians make wiser, clinical and cost-effective choices. Evidence-based dressing products should support and complement evidence-based PUP nursing practice, to ultimately achieve optimal clinical outcomes. Clinicians evaluating PUP products should focus on the careful analysis of the quality and validity of the supporting clinical and bioengineering peer-reviewed literature. Continuous advocation for evidence-based PUP products is critical; PUP of course has a price tag, but it is a consensus in the literature that it is always more cost-effective when compared with the alternative of treating new PUs. The intersection of bioengineering and healthcare sciences has paved the way for wound care clinicians to understand how and why dressings work for PUP objectively. This synergistic relationship will help inform and direct future product development. Most importantly, this multidisciplinary collaboration will help implement PUP products that aim to improve patient outcomes, reduce harm, pain and suffering, and enhance the quality of life by lowering PU rates to a minimum. Defining MOAs and developing methods and metrics for quantifying the effectiveness of MOAs of dressings used or designed for prophylaxis is a corner stone in these efforts. In this context, the FEAE is an important MOA in the prophylaxis action of (AL) dressings, reported here for the first time.

A limitation of this work, which can be addressed in a next study, is that the test apparatus does not mimic the complex anatomy of the heel and deliberately simplifies it for the robustness of the testing method and repeatability of the results. For this reason, the work should be complemented in the next step with a hierarchical computational (finite element) modelling framework that will link the inter-layer sliding occurring within the dressing to the state of loading of the soft tissues of the posterior heel for different foot positions and body postures, for example, inclined foot for a patient who is spontaneously moving or sliding in bed due to a head-of-bed elevation and gravity pulling their body downwards. Such anatomically realistic in silico modelling of the heel has been developed and previously reported by the research group of author AG and should be connected with the current FEAE test method and data for completeness, as a next step in the research.[13] Another potential important next step in this line of research can focus on thermal characterization, given that inadequate thermal properties of dressings in prophylactic use can lead to ineffectiveness in prevention or even to promotion of tissue damage, by trapping heat and moisture, thus creating an environment conducive to PU formation. Our previously published work[30,36,47] emphasizes the importance of understanding the thermal behaviour of dressings in contact with skin, and specifically, the thermal conductivity analyses of dressing materials and composites, to ensure optimal heat dissipation and effective management of the coupled moisture production, which, when balanced with adequate mechanical properties of the dressing materials,[48] supports the goal of PUP.

In conclusion, this study has shed light on the mechanisms underlying the efficiency of multilayer wound dressings in PUP. The current laboratory data demonstrated that the non-bonded, independent layers within the AL dressing and their ability to slide against each other are responsible for the FEAE MOA. These dressings aim to reduce sustained mechanical loading in skin and underlying soft tissues when the heel is resting on a support surface, thus reducing the risk for a heel PU. The current research explained how these dressings function in preventative use and specifically, described a new theory, laboratory test method and equipment to understand and measure mechanical energy absorption within these dressings and assess their biomechanical protective performance. Our findings revealed that the multilayer dressing investigated here, ALH, effectively absorbs the bodyweight-related mechanical energy, thereby alleviating the sustained loading on the soft tissues of the posterior heel. We accounted for real-world conditions and found that the dressing structure remains stable during use. Internal frictional movements between the dressing layers contributed substantially to the absorption of mechanical energy within the dressing as the current FEAE data showed, with an increased contribution after repetitive loading. The shape of the dressing did not

significantly impact its FEAE performance. Our novel FEAE theory and test method aid in designing and comparing preventative dressings, directly addressing existing challenges in the field as identified by the PDSI, which highlighted that despite clinical guidelines endorsing dressings for PUP, challenges persist due to the lack of mechanistic understanding and variability in dressing designs. The current work therefore contributes to optimizing dressings for a dual prevention/treatment purpose or future dressings specifically designed for prevention, albeit further work is suggested for other PU-prone areas, particularly the sacral region. The findings overall demonstrate that the prophylactic application of the ALH dressing effectively absorbs mechanical energy through both material shear and layer-to-layer frictional sliding occurring internally in the dressing, thus alleviating the sustained soft tissue stresses on the heel. While the study offers valuable insights into the internal energy absorption of dressings in preventative use, further research linking these results to in silico work focusing on anatomical realism of the heel region is needed, for enhancing the generalizability of the current findings.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest other than those stated in the Acknowledgements.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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