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# Bench to Bedside Evaluation of an Innovative, Non-Bordered Foam Dressing for Use in Exudating Chronic Wounds

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## ABSTRACT

To investigate a dimpled, non-bordered foam dressing with a soft silicone wound contact layer, the research spans from bench (fluid handling performance) to bedside (clinical effectiveness on exuding chronic wounds). In vitro methodology was used to monitor the fluid handling capacity and fluid retention capacity of the investigational dressing compared to other commercially available foam dressings according to standard EN 13726:2023. To provide complementary clinically relevant fluid handling results, more advanced laboratory tests were conducted using the FLUHTE (FLUid Handling Test Equipment) wound simulator. In a paired clinical investigation, moderately to highly exuding chronic wounds of patients had the investigational dressing applied as part of the wound management regime, and healing-related parameters were assessed for up to six weeks. The investigational dressing significantly outperformed the other dressings in fluid dispersion ability. Overall, the investigational dressing performed well in terms of fluid handling, including under compression. In the clinical investigation, the use of the dressing was associated with substantial wound improvement, reductions in size and exudate levels, and improved patient quality of life scores. At the final visit, nine (13.2%) patients had wounds that had healed. There were no adverse device effects reported. Data from the advanced laboratory tests highlighted the substantial impact of dressing design on fluid handling performance. The investigational dressing effectively handled fluid, even when subjected to mechanical forces mimicking those that it would be subjected to in the clinical setting. The clinical results support the use of the dressing on moderately and highly exuding chronic wounds of various clinical origins.

## 1 | Introduction

Wound exudate, fluid produced by the body in response to tissue damage and inflammation, is composed of water, electrolytes, nutrients, white blood cells, growth factors, waste products, and inflammatory mediators. It is an essential factor in the wound healing process and has many beneficial properties for a healing wound, including the maintenance of a moist wound bed and the delivery of nutrients and growth factors to the wound [1–3].

Wound exudate can be problematic when it increases in volume or its composition changes. Excess wound exudate damages the wound bed and surrounding skin, and increases the risk of infection [4]. It can also lead to dressing leakage and malodour, causing considerable distress to patients [5, 6]. Changes in exudate composition can promote an inflammatory environment. Elevated levels of inflammatory macrophages and increased levels of wound proteinases result in increased tissue destruction, degradation of beneficial growth factors, and delay in

**Summary**

- A crucial element in efficient chronic wound management is the selection of dressings with appropriate exudate management qualities.
- Data from clinically relevant laboratory testing and well-designed clinical studies should be utilised in the dressing selection process.
- The laboratory tests described in this article revealed differences between six commercially available non-bordered foam dressings in terms of their ability to handle and retain fluid, particularly under compressive forces.
- The investigational dressing (dimpled, non-bordered foam dressing with a soft silicone wound contact layer) was effective in handling fluid, even under compression.
- In the clinical study, non-healing wounds managed with the investigational dressing demonstrated a reduction in size and improved exudate management.
- Patients reported a substantial improvement in quality of life (QoL) measures over the course of the clinical study.
- The findings from the laboratory and clinical studies demonstrate strong fluid handling capabilities of the dimpled, non-bordered foam dressing and its suitability for use in exuding non-healing wounds along the healing trajectory.

healing [7]. Increased exudate viscosity due to heightened protein levels adversely affects cell migration, impedes diffusion of nutrients and oxygen into the wound bed, and increases the risk of systemic infection [8, 9].

Management of excess exudate requires dressings that can absorb and retain fluid (of varying volume and viscosity), while maintaining a balanced moist wound environment [10]. This, in turn, prevents leakage and protects the peri-wound skin [7]. Effective management of exudate also inhibits the propagation of microorganisms, reducing the potential for infection and malodour [3]. Dressings should be capable of effectively absorbing exudate even under the influence of expected or unexpected mechanical forces; they should also be able to release retained fluids via moisture vapour transmission to facilitate continuous absorbency [5].

When selecting wound dressings, it is crucial to consider both clinical and laboratory findings. The Skin Integrity Research Group at Ghent University in Belgium developed a core outcome set (COS) for evaluating bordered foam dressings in complex wounds, focusing on factors like staying in place, leakage, pain, peri-wound skin damage, wound size change, and overall patient satisfaction [11]. These outcomes are vital for assessing the ability of dressings to manage exudate.

Variability in patients, wounds, environmental conditions, and treatment protocols challenges clinicians when evaluating dressing performance in a clinical setting [5, 10]. Laboratory evaluations of fluid handling properties are essential for the development and assessment of dressings [10]. Recent studies emphasise the need for clinically relevant testing standards to enable objective, standardised comparisons between dressings [5, 10]. Combining laboratory and clinical studies provides comprehensive data to help clinicians choose the appropriate dressing.

Much of the laboratory-based efficacy research into the fluid handling properties of dressings is based on the EN 13726:2023 standard *Test methods for wound dressings, Aspects of absorption, moisture vapour transmission, waterproofness and extensibility* [12]. Updated in 2023, this standard includes several test methods (described within annexes). Recently published works have highlighted limitations with some aspects of the revised standard, suggesting that the focus on simplicity and practicality in test development has been counter-productive in terms of distancing the methodology from 'real world' clinical reality [1, 5, 13, 14]. In line with this, researchers have developed and validated a new simulated wound fluid (SWF-A), containing protein (albumin), buffers and salts that mimic the composition of chronic wound exudate [15]. Additionally, researchers have aimed to enhance the clinical relevance of laboratory testing of wound dressings through the development of simulated wound models that reflect clinical reality, as well as experimental metrics [10, 16].

These research activities build on the understanding that test methods need to reflect the added complexity of exudate in the clinical setting and replicate the key features of wound fluid and specific wound characteristics when testing dressings [1, 10]. The composition of exudate, which may vary during the healing process, influences the fluid handling properties of a dressing. Additionally, characteristics such as the flow rate play a significant role [10]. Furthermore, gravity may cause excessive localised saturation, leading to exudate backflow and leakage [10].

One such method, named FLUid Handling Test Equipment (FLUHTE), is a wound simulator designed to replicate the cylindrical shape of the lower leg, allowing vertical positioning to account for the effects of gravity on fluid distribution within dressings. FLUHTE offers improvements over other methods given that it is designed for high reproducibility for standardised testing, and by controlling critical factors that influence fluid handling of dressings, such as temperature, relative humidity, exudate flow rate, gravitational and compressive forces, and the composition of SWF [10]. FLUHTE also incorporates an irrigation region (simulating the wound bed) where SWF is released to imitate exudate production. This design enhances the precision of fluid handling evaluations, allowing for consistent interaction between fluid and dressings over extended periods of time. FLUHTE also enables tests to be conducted with or without compression applied to the test dressings, and provides several quantitative fluid handling performance metrics for dressings, including absorbed and retained fluid content, moisture vapour loss, common failure modes such as exudate leakage or pooling, and fluid dispersion measurements [10].

This article details the results of a two-part investigation evaluating the performance of an innovative, dimpled, non-bordered foam dressing with a soft silicone wound contact layer, Mepilex® Up (Mölnlycke Health Care, Gothenburg, Sweden). The dressing

design includes a flexible absorbent pad of compressed polyurethane foam (which helps to spread exudate across its structure in all directions, even working against gravitational forces, by means of its capillary action) and an outer polyurethane film (breathable to facilitate evaporation, but waterproof). Designed to absorb wound exudate of low-to-high viscosity, this conformable dressing is intended for use in the management of low-to-highly exuding wounds such as leg ulcers, foot ulcers, pressure injuries, traumatic wounds, and other wounds healing by secondary intention. It incorporates a soft silicone-coated (Safetac®) contact surface that is non-adherent to the moist wound but adheres gently to the dry peri-wound skin. The soft silicone adhesive technology enables the dressing to protect the wound and surrounding skin while preventing trauma to the wound bed and the surrounding epidermis, and minimising pain to the patient on removal [16–18].

## 2 | Aims

The aims of the research were to investigate (i) the fluid handling performance of the innovative foam dressing (utilising both standard and more clinically relevant laboratory methodology); and (ii) the clinical effectiveness of the dressing when used on exuding chronic wounds by monitoring progression to healing.

## 3 | Methods

### 3.1 | Laboratory Tests

The investigational dressing (Dressing A) was evaluated and compared with five other non-bordered foam dressings (Dressings B-F) (Table 1). Dressings B-F were chosen as suitable comparators because, like the investigational dressing, the accompanying manufacturer's instructions refer to them being used on wounds associated with high exudation, with the exception of Dressing B, which is indicated for moderately exuding wounds. A dressing that is indicated for moderately exuding wounds was included as a comparator to help understand the fluid handling dynamics of the dressings. It is important to note that Dressing B is designed and manufactured differently from Dressing A and is also known to present high fluid handling capacity (FHC) values.

**TABLE 1** | Evaluated non-bordered wound dressings.

| Dressing | Name and manufacturer |
|---|---|
| A | Mepilex® Up (Mölnlycke Health Care AB) |
| B | Mepilex® XT (Mölnlycke Health Care AB) |
| C | Allevyn◊ Gentle Non-Border (Smith & Nephew plc) |
| D | Aquacel™ Foam Non-Adhesive (ConvaTec Inc.) |
| E | Cutimed® Siltec® Plus (BSN Medical) |
| F | Biatain® Silicone Non-Border (Coloplast A/S) |

#### 3.1.1 | EN Standard Laboratory Tests for Fluid Handling Performance

A critical function of absorbent dressings is their ability to control fluid content (FC) by facilitating evaporation through a backing film. High moisture vapour loss (MVL) is thus of paramount importance, especially when dealing with moderate to high levels of exudate. Therefore, the dressings were evaluated using the standard EN 13726:2023 Fluid Handling Capacity (FHC) test methodology described in Annex E of the standard [12], using a validated procedure that includes the application of 50 mL of fluid at the start of the experiment, as reported previously [15]. The FHC is the sum of MVL and absorbency (ABS). The ability to retain absorbed exudate when subjected to acute compression has been highlighted as another important dressing performance feature. In line with this, the dressings were evaluated using the standard fluid retention capacity (FRC) test as described in Annex C of the EN 13726:2023 standard [12].

#### 3.1.2 | Advanced FLUHTE (Fluid Handling Test Equipment) Wound Simulator

To test beyond the minimal standard, the fluid handling properties of the dressings were evaluated using an advanced version of the FLUHTE wound simulator [10] (Figure 1). The simulator was developed to better mimic real-life wound scenarios. The device consists of two aluminium half-cylinders (outer diameter: 100 mm, height: 20 cm) and was adapted to simulate compression bandaging by allowing for adjustable spacing between the half-cylinders, while simultaneously measuring the compression using an integrated pressure sensor. A pressure of 40 mmHg was chosen, reflecting the gold standard for treating venous leg ulcers (VLUs).

The front half-cylinder of the simulator is designed to replicate a wound bed. It features five shallow circular recesses, each with a diameter of 10 mm and a depth of 1 mm. At the centre of each recess is a 2 mm inlet hole through which simulated wound fluid is introduced. This configuration ensures that the fluid is distributed uniformly across a 10 $cm^2$ area. The simulator is positioned upright at a 90° angle to represent the worst-case scenario regarding the influence of gravity on fluid dynamics [10]. A 10-unit syringe pump (Legato 200, KD Scientific Inc. Holliston, MA, USA), with 20 mL syringes controls the flow rate of SWF-A into the simulator through plastic tubs, as detailed previously [10]. SWF-A was used as the test solution, closely resembling the protein, salt, and buffer concentrations found in real wound exudate [15]. The system thus allows for precise control over the volume, flow rate, and temperature of the fluid, thereby providing a consistent and reproducible environment for testing.

The surface temperature of the simulator was set to 32°C, with heating controlled and adjusted automatically by means of a digital temperature sensor connected to built-in electrical heating and a computer. The external temperature and humidity are also controlled, as the FLUHTE system is positioned in a climate laboratory room where these parameters are set to 23°C ± 2°C and 50% ± 5%, respectively (according to the ISO 554:1976 standard). No external devices were used to increase the air velocity

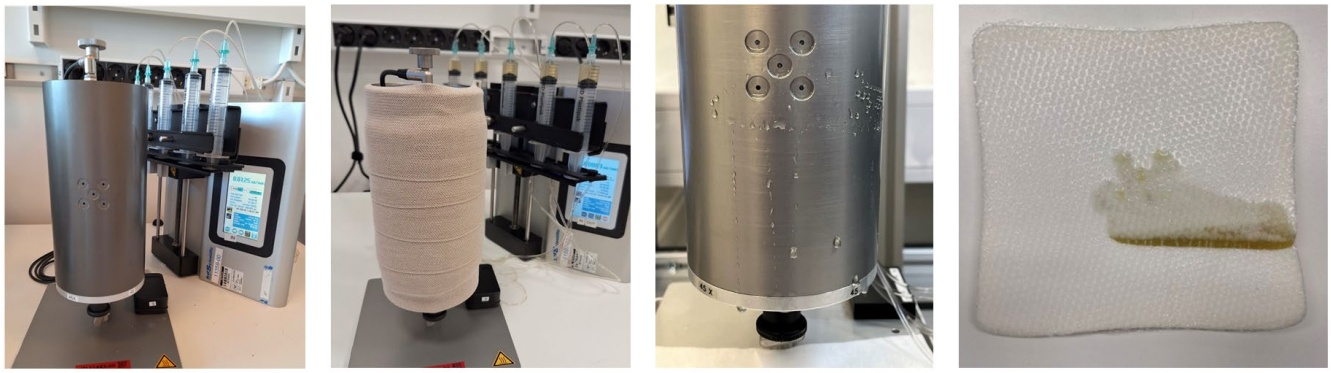


**FIGURE 1** | The advanced FLUHTE system and dressing failure under simulated conditions. (a) The FLUHTE system is designed to simulate a wound bed, comprising five shallow circular recesses (10 mm in diameter and 1 mm in depth), each with a central inlet hole. This setup is designed to release simulated wound fluid uniformly over a 10 $cm^2$ area at controlled volume, flow rate, and temperature. The system was positioned vertically in this study to account for the influence of gravity on fluid spreading. (b) The FLUHTE setup for testing a dressing under compression therapy, with an applied pressure of 40 mmHg, simulating clinical conditions such as venous leg ulcer management. (c) Fluid pooling under a standard foam dressing, due to insufficient absorption, was observed after 72 h of exposure to SWF-A at a constant flow of 0.75 mL/h. The fluid was collected on pre-weighed paper tissues and measured in grams. (d) Fluid distribution across the wound contact surface of the same dressing, showing SWF-A extending to the edge of the dressing (DtE = 0).

and thereby cause convection (which may influence the evaporation rate from the tested dressings).

The dressings were applied to the centre of the simulator, aligned vertically with the release liner centre cuts. Two different setups were used to cover the dressings: one with compression and one without. In the compression setup, a standard compression bandage was applied, consisting of two layers of Cellona synthetic padding (Ref 10 687, Lohmann-Rauscher) and a short-stretch bandage (Ref. 931 814, Hartmann), achieving a pressure of 40 mmHg, following the method described by Thomas et al. [19, 20]. In the non-compression setup, the dressings were covered with a lightweight tubular bandage (Tubifast®, Mölnlycke Health Care AB, Gothenburg, Sweden), achieving a pressure of 4 mmHg. At baseline (time zero), the pressure exerted by the compression bandage or tubular dressing on the simulator was mechanically controlled and adjusted to 40 and 4 mmHg, respectively.

The FLUHTE wound simulator is designed to output quantitative fluid handling performance metrics for a tested dressing, including the absorbed and retained FC and moisture vapour loss (MVL). To accurately describe the MVL, external leakage of fluid and pooling of fluid residuals under the dressing at the time of removal were recorded. MVL is calculated from the amount added (calculated from the applied fluid flow rate and the time) minus FC and pooling at the time of removal, as previously described [10].

The dispersion (spreading), of SWF-A across the dressing surface was documented digitally and quantified using the Distance to Edge (DtE) metric; a DtE of 0 was classified as a dressing failure. The dispersion of SWF-A, 36 mL administered at a high flow rate, was monitored across the dressings over a period of 72 h. The flow rate used aligns closely with values reported in the literature for highly exuding wounds in both clinical and laboratory settings, normalised to a wound area of 10 $cm^2$ [10, 21] The uniformity of fluid dispersion across the dressing was also assessed (Figure 2).

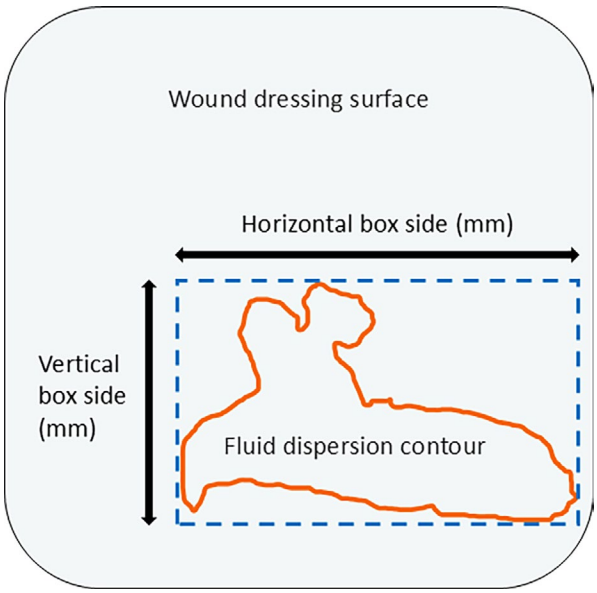


**FIGURE 2** | Quantification of uniformity in fluid dispersion. The dispersion of simulated wound fluid across the surface of each dressing sample was digitally documented at the end of each experiment, and the outer contour (orange line) was delineated. The uniformity of the dispersion pattern was quantified as the Fluid Spreading Pattern Box Ratio (SPBR). This was calculated by measuring the length of the fluid spread in the horizontal and vertical dimensions and computing the ratio of the shortest to the longest side. SPBR, shortest side/longest side and presented as mean ± SD. For reference, the SPBR for the fluid dispersion pattern shown is approximately 0.6. A perfectly symmetrical pattern would yield a ratio of 1.0.

## 3.2 | Clinical Investigation

### 3.2.1 | Study Design and Location

A prospective, open, non-comparative, multi-centre, clinical investigation was undertaken at four specialist wound care centres in the United States. The first patient was enrolled on October 31, 2022. The investigation was registered in Clinical Trials under the number NCT05588583.

### 3.2.2 | Ethical Considerations

Each participating centre obtained Institutional Review Board approval prior to patient enrolment. The investigation was performed in accordance with the ethical principles originating from the Declaration of Helsinki and applicable regulatory requirements. Before participation, an explanation of the nature, purpose, possible risks, and benefits of the investigation was given. Signed informed consent was obtained from the patients before conducting any procedure specifically for the investigation. Patients who did not want to participate in the investigation were treated in accordance with the study centre's wound care protocol.

### 3.2.3 | Participants and Selection Criteria

The inclusion and exclusion criteria applied are shown in Table 2.

### 3.2.4 | Interventions

Following enrolment, patients had the investigational device applied to their wounds as the primary absorbent dressing, alongside routine standard of care employed at the participating centres, which included wound bed preparation (cleansing and/or debridement) and the application of compression or offloading, when indicated. The investigators were instructed to select a dressing size that had to cover the dry peri-wound region by at least 1–2 cm for small wounds (up to 12.5 cm × 12.5 cm) and by 3–5 cm for larger wounds. If required, the dressing was cut to suit the wound shape and location. The dressing was fixated in accordance with the study centre's protocol of care. For patients with VLUs, compression devices provided fixation.

Clinical evaluations were performed by the investigator to assess wound healing progression, wound status, and wound dressing properties at baseline and at six weekly follow-up visits or until the wounds healed, whichever occurred sooner. Wounds were photographed (before removal of compression and fixation devices, before dressing removal, before and after wound cleansing and/or debridement) and measured. If dressing changes were deemed necessary in between the scheduled weekly visits, these were carried out at the study centres.

### 3.2.5 | Variables and Data Collection

Assessments and data collection were standardised across all study centres, according to the Clinical Investigation Plan. Details of dressing changes, wound bed preparation, and other wound management interventions were captured at each visit. An independent evaluator determined the wound area pre- and post-cleansing and/or debridement, assisted by digital planimetry software (PictZar); this software was used as it is validated, making it suitable for accurate and reproducible wound measurements [22]. For DFUs, wound volume was determined by multiplying the wound area by the wound depth. Gilman's formula (cm/day) was used to calculate linear wound healing.

The investigator assessed the exudate amount and nature using a subjective five-level scale: 'None' (dry wound bed), 'Scant' (moist wound bed but no measurable amount of exudate on dressing), 'Small' (less than 25% of dressing surface area covered by exudate), 'Moderate' (wound tissue wet, and between 25% and 75% of dressing surface area covered by exudate), 'Large' (wound tissue filled with fluid, and more than 75% of dressing surface area covered by exudate). The percentages of wound coverage of slough and granulation tissue were captured by the investigator using a five-level scale (none, 1%–24%, 25%–49%, 50%–74%, 75%–100%). Assessments of patient comfort were undertaken using a four-item scale ('Very poor', 'Poor', 'Good', 'Very good'). Patients were asked to grade any peri-wound itch severity using a numerical rating scale from 0 to 10 (0 = no itch, 10 = worst itch imaginable).

Change in peri-wound skin condition over time was assessed by visual assessment in terms of the presence or absence of maceration, dry skin, erythema/redness, and other peri-wound skin conditions. Furthermore, three different skin sites (in VLU subjects) were assessed for changes in transepidermal water loss (TEWL) values over time. Wounds were also assessed for signs of infection.

Trauma to the peri-wound/wound area at dressing removal was assessed by the investigator at each dressing change. Wound pain during dressing wear and wound pain related to removal of the dressing over time was recorded using a numerical rating scale from 0 to 10, where 0 indicates no pain and 10 indicates the worst pain. Pre-procedural or intra-procedural pain medication administered at the time of dressing removal was recorded.

For quality of life (QoL) assessments, patients were asked to complete Wound-QoL-17, a validated self-report questionnaire consisting of 17 questions to determine the impact that the wound and related treatment had on them [23]. The questionnaire was completed at the baseline visit and at the second, fourth and sixth follow-up visits. Patients were asked to assess QoL status over the preceding seven days. For each question asked, patients had to respond using a 5-point Likert scale from 'Not at all' to 'Very much', with 'Not at all' being the most positive response.

Investigators assessed the technical performance of the dressing by evaluating properties such as exudate retention, ease of application, adherence to healthy skin, and occurrence of dressing residue on the wound bed or peri-wound skin.

Details of adverse events (AE) and serious adverse events (SAE) were collected from the time of provision of informed consent until study completion.

**TABLE 2** | Inclusion and exclusion criteria applied.

| Inclusion criteria | Exclusion criteria |
|---|---|
| Signed consent to participate (including consent for digital imaging) | Infected ulcer according to the judgement of the investigator (defined as any wound condition requiring the prescription or continuation of systemic antibiotic therapy at enrolment) |
| Aged ≥ 18 years | |
| Diagnosed chronic, exuding VLU or DFU | |
| Moderate to large exudation | Circumferential wound |
| Wound size from 3 to 30 $cm^2$ for VLU and ≥ 1 $cm^2$ for DFU | Known allergy/hypersensitivity to the components of the dressing |
| For VLU: Ankle brachial pressure index (ABPI) within 3 months > 0.7. If ABPI > 1.4, then big toe pressure > 60 mmHg was required or an alternative measurement verifying normal distal arterial flow | Use of wound fillers |
| For VLU: Willing to be compliant with compression therapy | Participation in previous clinical study of the investigational dressing |

The primary endpoint of the investigation was wound progress since the previous visit (starting with the first follow-up visit after the baseline visit). For the study, wound progress was based on an objectively measured wound area and subjectively evaluated wound condition and rated as 'Deteriorated', 'No change', 'Improved' or 'Healed' by the investigator.

### 3.3 | Statistical Analysis

For the laboratory testing data, descriptive statistics, including means, standard deviations, confidence intervals, and the coefficient of variation, were calculated for the different metrics. Welch's one-way analysis of variance (ANOVA) was performed as needed, followed by Dunnett's T3 multiple comparisons test, with a family-wise error rate threshold set at 0.05 and a 95% confidence interval. Pearson correlation analysis was conducted when appropriate. Statistical significance was defined as $\alpha$ 0.05. All statistical analyses and data visualisation were performed using Minitab Statistical Software version 17.2.1 for Windows (Minitab LLC USA) and GraphPad Prism version 9.3.1 for Windows (GraphPad Software, Boston, Massachusetts, USA). Regarding the clinical investigation, the SAS (version 9.3 or later) statistical software suite (SAS Institute Inc. Cary, North Caroline, USA) was used for analyses. The clinical results are presented with descriptive statistics by visit and as a change from baseline (absolute and percentual) to each follow-up visit, as applicable. The distribution of continuous variables and change in continuous variables are presented as mean, standard deviation (SD), median, minimum, and maximum. The distribution of discrete variables is given as numbers and percentages.

## 4 | Results

### 4.1 | Laboratory Tests

#### 4.1.1 | Standard Fluid Handling Capacity (FHC) and Fluid Retention Capacity (FRC) Tests

The results obtained using the EN 13726:2023 Annex E standard FHC test revealed considerable differences among the six dressings. Dressings A to F demonstrated FHC values (mean ± standard deviation [SD], g/$cm^2$/24 h) of 3.67 ± 0.23, 3.77 ± 0.23, 1.96 ± 0.33, 0.95 ± 0.11, 2.51 ± 0.01, and 1.06 ± 0.04, respectively. Detailed FHC results, including MVL values and corresponding statistical analyses, are presented in Table 3. Statistically, Dressing A (the investigational dressing) exhibited significantly higher mean FHC (and MVL) values compared to Dressings C through F ($p < 0.001$ for all comparisons). Additional validation testing of three independent batches of Dressing A ($n = 5$ per batch), conducted at an independent testing institute, confirmed its consistent performance with FHC values of 3.82 ± 0.15 g/$cm^2$/24 h (mean ± SD).

Significant variations in the FRC of the dressings were observed (Table 3). Dressing A exhibited significantly higher mean FRC values compared to Dressings B, D, and E ($p < 0.001$). Notably, only two dressings (A and F) demonstrated FRC values above 95%, with values of 96.4% and 97.2%, respectively.

**TABLE 3** | Differences in fluid handling performance of dressings evaluated according to EN 13726:2023.

| | | Dressing | | | | | |
|---|---|---|---|---|---|---|---|
| | | **A** | **B** | **C** | **D** | **E** | **F** |
| FHC (g/cm$^2$) | Mean | 3.67 | 3.77 | 1.96 | 0.95 | 2.51 | 1.06 |
| | SD | 0.23 | 0.23 | 0.33 | 0.11 | 0.01 | 0.04 |
| | Lower 95% CI | 3.54 | 3.64 | 1.78 | 0.89 | 2.45 | 1.04 |
| | Upper 95% CI | 3.80 | 3.91 | 2.14 | 1.01 | 2.56 | 1.08 |
| | Adjusted *p* value* | N/a | 0.77 | **< 0.001** | **< 0.001** | **< 0.001** | **< 0.001** |
| MVL (g/cm$^2$) | Mean | 3.22 | 3.14 | 1.45 | 0.65 | 1.93 | 0.77 |
| | SD | 0.24 | 0.21 | 0.27 | 0.08 | 0.091 | 0.03 |
| | Lower 95% CI | 3.09 | 3.02 | 1.30 | 0.60 | 1.88 | 0.75 |
| | Upper 95% CI | 3.35 | 3.26 | 1.60 | 0.69 | 1.98 | 0.79 |
| | Adjusted *p* value* | N/a | 0.88 | **< 0.001** | **< 0.001** | **< 0.001** | **< 0.001** |
| FRC (%) | Mean | 96.40 | 63.10 | 94.00 | 90.90 | 79.30 | 97.20 |
| | SD | 3.76 | 3.11 | 3.43 | 2.36 | 2.64 | 1.49 |
| | Lower 95% CI | 94.30 | 61.30 | 92.10 | 89.50 | 77.80 | 96.40 |
| | Upper 95% CI | 98.50 | 64.80 | 95.90 | 92.20 | 80.70 | 98.10 |
| | Adjusted *p* value* | N/a | **< 0.001** | 0.30 | **< 0.001** | **< 0.001** | 0.94 |

*Note:* Sample sizes: $n = 15$ (with the exception for Dressing B in FHC and MVL, $n = 14$). Significance level set at $p = 0.05$. Statistically significant *p*-values marked in bold.
Abbreviations: CI, confidence interval; FHC, fluid handling capacity; FRC, fluid retention capacity; MVL, moisture vapour loss; N/a, not applicable; SD, standard deviation.
*Compared to Dressing A.

#### 4.1.2 | Comparative Evaluation of Fluid Handling and Dispersion Under Compression

Results revealed notable differences in fluid handling performance among the six dressings when evaluated in an upright position on the FLUHTE wound simulator (i.e., under the influence of gravity). These differences were evident in both the quantitative metric outputs and the fluid spreading patterns, with statistically significant variations observed between the different dressings.

The graphical representations of fluid spreading across the different dressings, shown in Figure 3A (upper panels relate to the testing with compression), underscore the substantial impact of the dressing design on the fluid dispersion pattern. For Dressing C, fluid reached the edge of the dressing in two out of the five replicates. Quantitative evaluation of the fluid dispersion across the six dressings, in terms of mean Distance to Edge (DtE), revealed that Dressing A significantly outperformed the other dressings. Specifically, Dressing A presented a significantly higher DtE compared to Dressings C, D, E, and F ($p < 0.001$, $p = 0.01$, $p = 0.04$ and $p < 0.001$, respectively); with a higher value indicating decreased risk of dressing failure (Table 4). Further, clear differences between the dressings were observed in the relative variation in the DtE outcomes. Specifically, Dressing A exhibited a coefficient of variation (CV) value of only 5.6%, whereas Dressings B to F presented CV values of 30.9%, 125.2%, 46.7%, 14.9%, and 27.2%, respectively (Table 4). A lower CV suggests more reliable fluid dispersion, which is crucial for ensuring predictable dressing performance and reducing the likelihood of unexpected failures in clinical use. Notably, even with an increase in flow of simulated wound fluid by 50%, from a total of 36 mL to 54 mL, no dressing failure (defined as DtE = 0) was detected for Dressing A. The fluid was administered at a constant flow rate of 0.75 mL/h for 72 h using 15 cm × 15 cm dressings placed vertically. Of the 54 mL, 87% evaporated through the dressing, resulting in an MVL of 46.9 ± 0.7 mL (mean ± SD).

Moreover, an analysis of the symmetry in fluid dispersion shown in Figure 3A, quantified by measuring the fluid spread in both horizontal and vertical dimensions and computing the mean ratio of these measurements (i.e., the Fluid Spreading Pattern Box Ratio, SPBR, Figure 2), revealed substantial variations in performance. The SPBR for Dressing A was statistically higher than that of Dressings B, C, and F, with a significance level of $p < 0.001$ for all comparisons.

In addition, quantitative comparisons of the evaporation (MVL) through the dressing, padding, and compression bandage over 72 h demonstrated considerable differences between the six dressings. Statistically significantly higher mean MVL values were observed for Dressing A compared to Dressing B ($p = 0.005$) and Dressings C–F ($p < 0.001$) when tested with compression bandages (Table 4). A Pearson correlation analysis of the mean MVL values for the six dressings, obtained by standard FHC testing and FLUHTE (as shown in Table 3

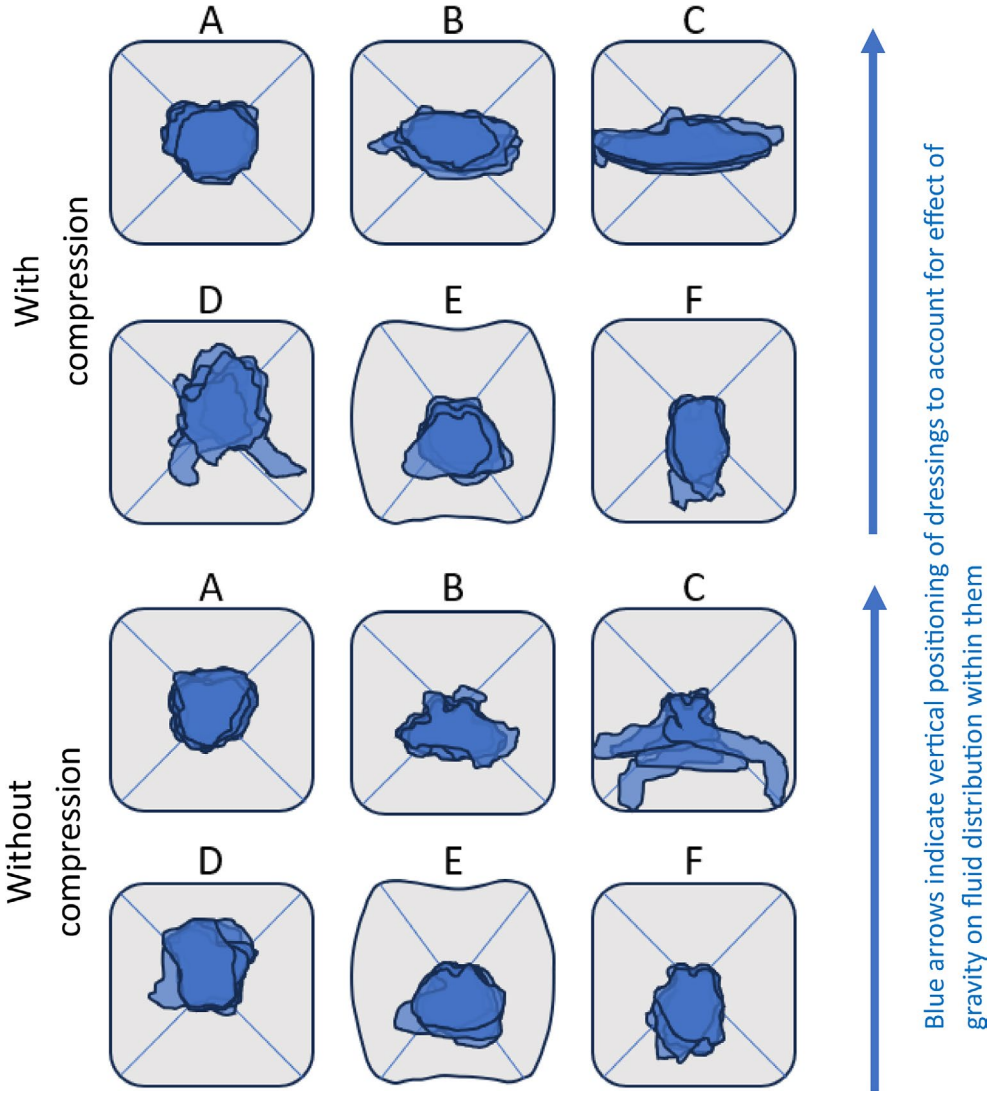


**FIGURE 3A** | Graphical illustrations of the fluid dispersion patterns across dressings, evaluated in repeated experiments on the FLUHTE wound simulator, with and without compression. The dressings, sized 15 cm × 15 cm, were positioned vertically and centred over the simulated wound (10 $cm^2$). SWF-A was administered continuously for 72 h at a flow rate of 0.5 mL/h. Overlays of the individual fluid spreading patterns are presented. Experimental details and complementary results are presented in Tables 3 and 4, corresponding to tests conducted with and without compression, respectively.

and Table 4, respectively), indicated no significant correlation ($p = 0.11$, $r^2 = 0.506$).

The correlation analysis was included to provide insights into the relationship between the two fluid handling test methods applied. These results suggest that standard FHC testing does not predict dressing performance under the combined influence of gravity and compression, highlighting the need for complementary testing methods to better reflect clinical conditions.

#### 4.1.3 | Comparative Evaluation of Fluid Handling and Dispersion Without Compression

The graphical representations of fluid spreading across the different dressings are shown in the lower panels of Figure 3A; and the quantitative results are shown in Figure 3B and Table 5. Similarly to the results observed under compression, at 72 h Dressing C showed fluid reaching the dressing edge in 2 out of 5 replicates when evaluated without compression. Fluid dispersion across the dressings revealed significantly higher DtE values for Dressing A compared to Dressings C, D, E, and F ($p = 0.009$, $p < 0.001$, $p = 0.003$, and $p = 0.02$, respectively). Furthermore, statistical analysis of the evenness of fluid spreading across the dressings showed that the SPBR was significantly higher for Dressing A compared to Dressing B ($p < 0.01$). In addition, quantitative comparisons of evaporation through the dressings again demonstrated considerable differences between the six dressings. Statistically significant higher mean MVL values were observed for Dressing A compared to Dressing C ($p = 0.01$) and Dressings D–F ($p \leq 0.01$). Consistent with the observations under compression, a Pearson correlation analysis of the mean MVL values for the dressings—obtained through standard FHC testing and FLUHTE without compression (as shown in Tables 3 and 5, respectively)–revealed no significant correlation ($p = 0.16$, $r^2 = 0.431$).

**TABLE 4** | Fluid handling performance of dressings by FLUHTE with compression.

| | | Dressing | | | | | |
|---|---|---|---|---|---|---|---|
| | | **A** | **B** | **C** | **D** | **E** | **F** |
| Dispersion (DtE) (mm) | Mean | 37.6 | 25.0 | 3.6 | 21.8 | 29.4 | 20.9 |
| | SD | 2.1 | 7.7 | 4.5 | 10.2 | 4.4 | 5.7 |
| | Lower 95% CI | 36.1 | 15.4 | −2.0 | 13.3 | 24.0 | 16.1 |
| | Upper 95% CI | 39.1 | 34.6 | 9.2 | 30.2 | 34.9 | 25.6 |
| | Adjusted *p*-value* | N/a | 0.08 | **< 0.001** | **0.01** | **0.04** | **< 0.001** |
| | Coefficient of variation (%) | 5.6% | 30.9% | 125.2% | 46.7% | 14.9% | 27.2% |
| Fluid dispersion symmetry (SPBR) | Mean | 0.89 | 0.52 | 0.33 | 0.79 | 0.89 | 0.63 |
| | SD | 0.07 | 0.07 | 0.03 | 0.12 | 0.07 | 0.10 |
| | Lower 95% CI | 0.84 | 0.43 | 0.29 | 0.68 | 0.80 | 0.55 |
| | Upper 95% CI | 0.94 | 0.60 | 0.37 | 0.89 | 0.98 | 0.71 |
| | Adjusted *p*-value* | N/a | **< 0.001** | **< 0.001** | 0.2 | > 0.99 | **< 0.001** |
| Moisture vapour loss (g) | Mean | 31.6 | 31.2 | 29.6 | 30.6 | 29.4 | 28.9 |
| | SD | 0.2 | 0.2 | 0.3 | 0.3 | 0.3 | 0.6 |
| | Lower 95% CI | 31.4 | 31.0 | 29.3 | 30.4 | 29.0 | 28.4 |
| | Upper 95% CI | 31.8 | 31.4 | 30.0 | 30.9 | 29.8 | 29.4 |
| | Adjusted *p*-value* | N/a | **0.005** | **< 0.001** | **< 0.001** | **< 0.001** | **< 0.001** |

*Note:* Sample sizes: $n = 10$ for Dressing A; $n = 5$ for Dressings B and C; $n = 8$ for Dressings D, E, and F. Significance level set at $p = 0.05$. Statistically significant *p*-values marked in bold.
Abbreviations: CI, confidence interval; DtE, distance to edge; N/a, not applicable; SD, standard deviation; SPBR, spreading pattern box ratio.
*Compared to Dressing A.

## 4.2 | Clinical Investigation

### 4.2.1 | Patient Disposition

In total, 72 subjects completed the clinical investigation (36 in the VLU group and 36 in the DFU group); 68 patients were included in the full analysis set (FAS) (34 in the VLU group and 34 in the DFU group). The baseline patient and wound characteristics for all patients are presented in Table 6. The mean wound age at baseline was 74.9 weeks, with similar averages in the VLU and DFU sub-populations. The mean wound area for VLUs and DFUs was 8.2 (SD 6.7) $cm^2$ and 4.2 (SD 4.4) $cm^2$ respectively. The average depth of DFUs was 0.3 cm (SD 0.35), and the average volume was 1.6 $cm^3$ (SD 4.24). Most wounds were associated with moderate levels (85.3% of all wounds) of low viscosity (89.7% of all wounds) exudate.

The most common dressing type used prior to entering the clinical investigation was gauze (45.6%), and the most common compression system for patients with VLU was a two-layer compression bandage system (67.6%); all but one patient with a VLU (1 out of 34, 2.9% did not have compression prior to study participation) had some form of compression applied prior to study participation. Prior to study participation, offloading was used for 91.2% (31/34) of the DFUs.

During the investigation, high compliance of nearly 100% was achieved in both compression (for VLU) and off-loading (for DFU).

### 4.2.2 | Wound Healing Status (Primary Endpoint)

Despite the high mean wound age at baseline (74.9 weeks, SD 126.94), significant wound improvement was observed during the six-week investigation, with 71.4% of all wounds assessed as improved or healed over a total of 367 follow-up visits (significant, 95% confidence interval [66.47% to 75.96%], $p < 0.0001$ relative to the previous visit) (Table 7). Nine (13.2%) patients completed the clinical investigation with healed wounds. At only 5.7% of all follow-up visits, wounds were assessed as 'deteriorated'. The proportions were similar for DFUs and VLUs. The percentage of improved or healed wounds with moderate exudate levels at baseline was 73.8%, while the percentage for wounds with large exudate levels at baseline was 56.0% (Table 8).

### 4.2.3 | Wound Area and Volume

The area of both VLU and DFU wounds reduced during the investigation, with a 63.1% decrease in median wound area at

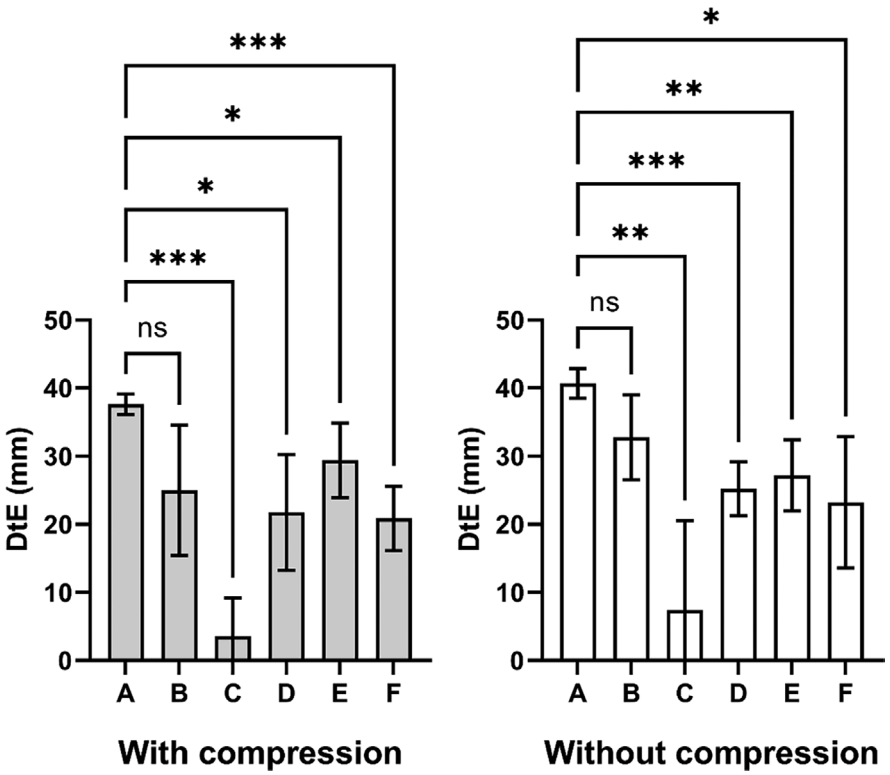


**FIGURE 3B** | Dispersion of simulated wound fluid across dressings, evaluated in repeated experiments on the FLUHTE wound simulator, quantified as mean DtE ± 95% CI. Results from the evaluation performed with compression are shown on the left (grey bars), and results obtained without compression are shown on the right (white bars). Experimental details and complementary results are presented in Tables 3 and 4, corresponding to tests conducted with and without compression, respectively. Statistical differences are indicated with asterisks, $*p < 0.05$, $**p < 0.01$, and $***p < 0.001$. ns, non-significant.

the final visit, compared to baseline (Figure 4). DFU wound volume also reduced over the course of the investigation. At the final visit, following cleansing/debridement, DFU volume was reduced with a mean change of −65.43% (SD 48.295%) (median −92.15%) compared to baseline; throughout the investigation, these wounds continuously reduced in volume (a similar trend was seen in the before cleansing/debridement data).

A wound healing rate of 0.12 (SD 0.214) (follow-up visit 1) to 0.07 (SD 0.086) (follow-up visit 6) cm per day was calculated using Gilman's formula, showing consistent linear healing over time, with the highest rate of healing observed in the initial stages of the investigation. This trend was the same in both DFU and VLU groups.

#### 4.2.4 | Wound Condition

The proportions of patients assessed as having 'moderate' or 'large' levels of exudate decreased from 100% (68 out of 68) at baseline to 47.4% (27 out of 57) at follow-up visit 6. The proportion of patients assessed as having 'none', 'scant' or 'small' exudate amounts changed from 0% (0 out of 68) at baseline to 52.6%(30 out of 57) at follow-up visit 6 (Table 9). Similar trends were observed for both DFU and VLU wounds. The nature of exudate remained stable throughout the investigation; the majority of subjects had serosanguinous exudate both at baseline (83.8%) and visit 7 (87%). The majority of wounds had low viscosity exudate throughout the investigation (89.7% at baseline, 90.7% at visit 7).

A slight reduction in slough wound coverage was observed, with the percentage of wound area with no slough measured at 7.4% at baseline compared to 17.6% at the final visit (investigator assessments). The wound area covered by 75%–100% coverage granulation tissue increased from 76.5% at baseline to 80.9% at the final visit (investigator assessments).

#### 4.2.5 | Peri-Wound Skin Condition

The results of the overall peri-wound skin condition over time showed a slight decrease in the proportion of healthy status from 69.1% at baseline to 57.9% at follow-up visit 6 in the combined group (all wounds).

The number of subjects with maceration increased from 3/68 (4.4%) at baseline to 13/62 (21.0%) at the halfway point of the follow-up period, and then decreased to 8/57 (14.0%) at the final visit. Wounds with large exudate levels showed a tendency for more maceration, and TEWL values were higher for wounds with maceration. Similar to maceration assessments, there was an initial increase in TEWL values, which declined later in the investigation; notably, there was a large distribution of values, providing some uncertainties about the results.

At baseline, 7 (20.6%) DFU subjects experienced dry skin, decreasing to 3 (11.1%) at follow-up visit 6. For the VLU group, eight subjects (23.5%) had dry skin at baseline and 12 (40%) subjects had dry skin at follow-up visit 6. No erythema was

**TABLE 5** | Fluid handling performance of dressings by FLUHTE without compression.

| | | Dressing | | | | | |
|---|---|---|---|---|---|---|---|
| | | **A** | **B** | **C** | **D** | **E** | **F** |
| Dispersion (DtE) (mm) | Mean | 40.7 | 32.8 | 7.4 | 25.2 | 27.2 | 23.2 |
| | SD | 2.9 | 5.0 | 10.6 | 3.2 | 4.2 | 7.8 |
| | Lower 95% CI | 38.5 | 26.6 | −5.7 | 21.2 | 22.0 | 13.6 |
| | Upper 95% CI | 42.9 | 39.0 | 20.5 | 29.2 | 32.4 | 32.8 |
| | Adjusted *p*-value* | N/a | 0.09 | **0.009** | **< 0.001** | **0.003** | **0.02** |
| | Coefficient of variation (%) | 7.1 | 15.3 | 142.9 | 12.7 | 15.5 | 33.4 |
| Fluid dispersion symmetry (SPBR) | Mean | 0.91 | 0.63 | 0.71 | 0.86 | 0.85 | 0.80 |
| | SD | 0.09 | 0.052 | 0.21 | 0.06 | 0.10 | 0.13 |
| | Lower 95% CI | 0.84 | 0.57 | 0.46 | 0.80 | 0.73 | 0.64 |
| | Upper 95% CI | 0.97 | 0.70 | 0.97 | 0.93 | 0.98 | 0.96 |
| | Adjusted *p*-value* | N/a | **< 0.001** | 0.35 | 0.78 | 0.84 | 0.47 |
| Moisture vapour loss (g) | Mean | 32.2 | 32.0 | 30.1 | 31.2 | 29.6 | 29.9 |
| | SD | 0.22 | 0.18 | 0.68 | 0.26 | 0.37 | 0.27 |
| | Lower 95% CI | 32.0 | 31.8 | 29.3 | 30.9 | 29.2 | 29.5 |
| | Upper 95% CI | 32.3 | 32.2 | 31.0 | 31.6 | 30.1 | 30.2 |
| | Adjusted *p*-value* | N/a | 0.42 | **0.01** | **0.001** | **< 0.001** | **< 0.001** |

*Note:* Sample sizes: $n = 9$ for Dressing A; $n = 5$ for Dressings B–F Significance level set at $p = 0.05$. Statistically significant *p*-values marked in bold.
Abbreviations: CI, confidence interval; DtE, distance to edge; N/a, not applicable; SD, standard deviation; SPBR, spreading pattern box ratio.
*Compared to Dressing A.

reported for the DFU subjects at baseline or at follow-up visit 6; erythema was reported for very few DFU subjects in-between these visits. For the VLU group, erythema increased from four subjects (11.8%) at baseline to 9 (30%) at follow-up visit 6. There were minimal reports of 'other' (calluses, psoriasis, lipodermatosclerosis) peri-wound statuses throughout the investigation period.

#### 4.2.6 | Trauma to the Peri-Wound Skin and Wound Area at Dressing Removal

In a total of 367 follow-up visits, peri-wound skin trauma was reported as 'None' at 94% (345/367) of visits and wound bed trauma was reported as 'None' at 97% (356/367) of visits.

There were 22 incidences of trauma to the peri-wound skin; of these, 11 incidences were considered 'Very slight' and 11 were considered 'Moderate. There were 11 incidences of trauma to the wound bed; nine of these were considered 'Very slight'; there was one incidence of 'High' trauma and one incidence of 'Moderate' trauma.

#### 4.2.7 | Pain

Pain levels were generally low during dressing wear, with the majority of subjects rating pain between 0 and 2 (on a scale from 0 to 10, where 0 indicated no pain and 10 indicated the worst pain imaginable). For the DFU subjects, 90.2% of the assessments were rated at 0–2. For the VLU subjects, 60.4% of the assessments were rated at 0–2. Pain levels did not change significantly throughout the investigation. DFU subjects showed an indication of decreased pain as the subjects progressed through the investigation. Pain levels during dressing removal were similar to pain during wear; 77.7% of the VLU subjects reported their pain to be in the 0–2 range, and 91.0% of the DFU subjects reported it to be in the 0–2 range. There were indications of reduced pain at dressing removal toward the later visits.

#### 4.2.8 | Patient-Reported Experience

Across 188 assessments (responses) for VLUs and 178 for DFUs, 95.2% of responses from VLU subjects and 97.2% of responses from DFU subjects rated comfort as 'good' or very good' (Table 10). Patient assessment of peri-wound skin itch prior to removal of the dressing remained low throughout the investigation with an average of 1.22 (SD 1.938) at baseline and 1.33 (SD 1.746) at follow-up visit 6. Patient responses as measured by the Wound-QoL-17 assessment questionnaire are detailed in Figure 5. As the patients progressed through the investigation, positive responses to questionnaire questions increased and negative responses decreased. All patients' QoL responses showed a substantial improvement over the course of the investigation.

**TABLE 6** | Baseline demographics.

| Characteristic | Measure | All ($n = 68$) | DFU ($n = 34$) | VLU ($n = 34$) |
|---|---|---|---|---|
| Subject age (years) | Mean ± SD | 61.6 ± 11.26 | 56.5 ± 10.12 | 66.6 ± 10.11 |
| | Median [min–max] | 61.0 [35–90] | 58.0 [35–76] | 66.5 [47–90] |
| Gender | Male | 70.6% (48/68) | 88.2% (30/34) | 52.9% (18/34) |
| | Female | 29.4% (20/68) | 11.8% (4/34) | 47.1% (16/34) |
| Body mass index (kg/m$^3$) | Mean ± SD | 28.863 ± 5.7428 | 27.950 ± 4.8749 | 29.776 ± 6.4404 |
| | Median [min–max] | 27.875 [18.82–48.05] | 27.215 [20.42–41.54] | 28.320 [18.82–48.05] |
| Mean wound duration | Weeks ± SD | 74.9 ± 126.94 | 73.9 ± 152.52 | 75.8 ± 97.22 |
| | [range] | [1–780] | [1–780] | [5–416] |
| Recurrent ulcer | No | 61.80% | 64.70% | 58.80% |
| | Yes | 38.20% | 35.30% | 41.20% |
| Wound area (cm$^2$) | Mean ± SD | 6.4 ± 6.1 | 4.2 ± 4.4 | 8.2 ± 6.7 |
| Wound depth (cm) | Mean ± SD | 0.3 ± 0.35 | 0.3 ± 0.35 | N/A |
| Wound volume (cm$^3$) | Mean ± SD | 1.6 ± 4.24 | 1.6 ± 4.24 | N/A |
| Exudate amount | None/Scant/Small | 0% | 0% | 0% |
| | Moderate | 85.30% | 88.20% | 82.40% |
| | Large | 14.70% | 11.80% | 17.60% |
| Exudate | Low | 89.70% | 97.10% | 82.40% |
| viscosity | High | 10.30% | 2.90% | 17.60% |

Abbreviations: DFU, diabetes-related foot ulcer; *n*, number; N/A, not applicable; SD, standard deviation; VLU, venous leg ulcer.

**TABLE 7** | Wound healing status, relative to previous visit.

| | Classification | Total ($n = 68$) | DFU ($n = 34$) | VLU ($n = 34$) |
|---|---|---|---|---|
| Wound progress (% visits/*n*) [range] | Deteriorated | 5.7% (21/367) [3.58%–8.61%] | 3.4% (6/179) [1.24%–7.15%] | 8.0% (15/188) [4.53%–12.82%] |
| | No change | 22.9% (84/367) [18.69%–27.53%] | 22.3% (40/179) [16.47%–29.16%] | 23.4% (44/188) [17.55%–30.12%] |
| | Improved | 69.5% (255/367) [64.49%–74.16%] | 73.2% (131/179) [66.06%–79.52%] | 66.0% (124/188) [58.71%–72.70%] |
| | Healed | 1.9% (7/367) [0.77%–3.89%] | 1.1% (2/179) [0.14%–3.98%] | 2.7% (5/188) [0.87%–6.10%] |

Abbreviations: DFU, diabetes-related foot ulcer; *n*, number; VLU, venous leg ulcer.

**TABLE 8** | Healing status of wounds with moderate-to-high exudate levels at baseline, relative to previous visit.

| Exudate level | Classification | Total | DFU | VLU |
|---|---|---|---|---|
| Moderate (% visits/*n*) [range] | Deteriorated or No change | 26.2% (83/317) [21.4%–31.4%] | 25.2% (40/159) [18.6%–32.6%] | 27.2% (43/158) [20.5%–34.9%] |
| | Improved or Healed | 73.8% (234/317) [68.6%–78.6%] | 74.8% (119/159) [67.4%–81.4%] | 72.8% (115/158) [65.1%–79.6%] |
| Large (% visits/*n*) [range] | Deteriorated or No change | 44.0% (22/50) [30.0%–58.8%] | 30.0% (6/20) [11.9%–54.3%] | 53.3% (16/30) [34.3%–71.7%] |
| | Improved or Healed | 56.0% (28/50) [41.3%–70.0%] | 70.0% (14/20) [45.7%–88.1%] | 46.7% (14/30) [28.3%–65.7%] |

Abbreviations: DFU, diabetes-related foot ulcer; *n*, number; VLU, venous leg ulcer.

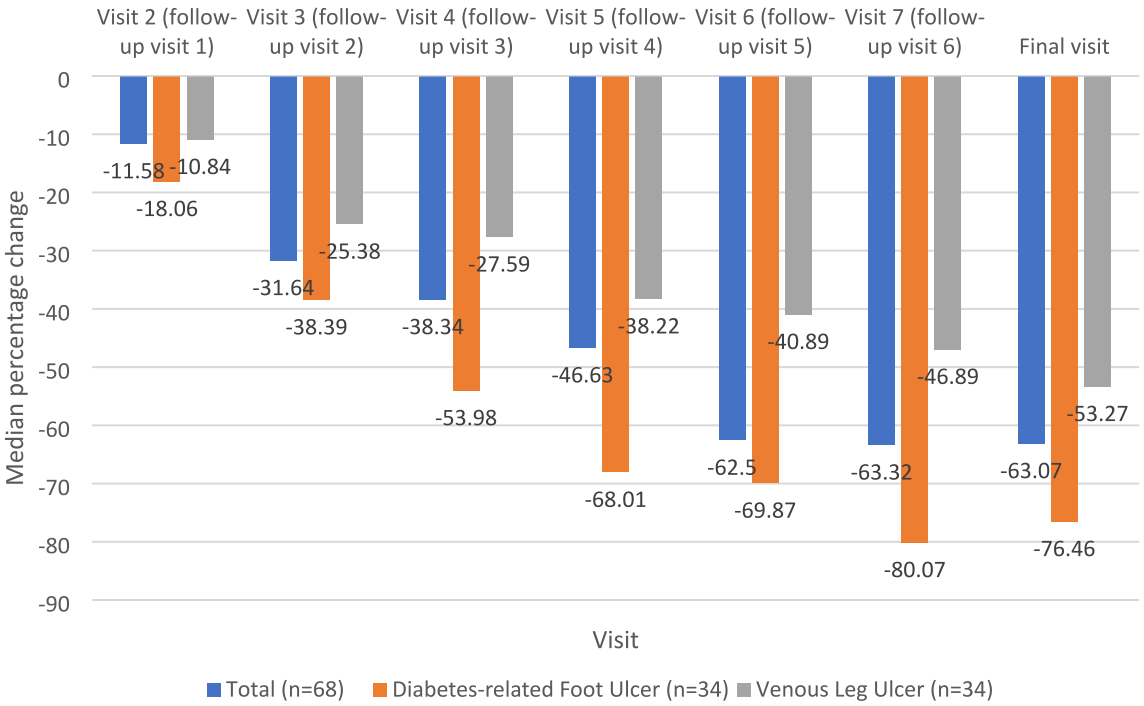


**FIGURE 4** | Median percentage change in wound area over 6 weeks of treatment.

#### 4.2.9 | Technical Performance of the Dressing

The dressing's ability to absorb and retain exudate was rated by the investigators as 'good' or 'very good' at 88.4% and 85.9% of visits, respectively. Adherence of the dressing to the healthy skin and not the wound bed was also confirmed. Adherence to the healthy skin was rated as 'Good' or 'Very Good' at 94% of all visits; non-adherence to a moist wound bed was rated as 'Good' or 'Very Good' at 92.9% of all visits. A total of 508 dressings were used during the clinical investigation by 68 subjects. The mean dressing wear time was 5 ± 1.9 days (subjects with a DFU 4.9 ± 1.82; subjects with a VLU 5.2 ± 1.97) (ranging from 1 to 14 days). The majority of dressing changes were done at days 3 (26.2%), 4 (27.2%) and 7 (36.1%) (range 1 to 14 days). The data were similar for VLUs and DFUs. Wounds with large exudate levels showed a somewhat shorter average wear time (5.2 ± 1.89 days for moderate exudate levels and 4.3 ± 1.77 days for large exudate levels). Most dressing changes 99.1% (448/452) were reported as 'routine change' as part of the standard of care, that is, not due to dressing saturation or other dressing performance related factors. Ease of dressing application, conformability, and ability of the dressing to be repositioned during application were all rated as 'good' or 'very good' throughout the investigation period (investigator-reported). There were close to no occurrences of product residue in the wound bed or on the peri-wound skin on removal of the dressing, throughout the investigation period.

#### 4.2.10 | Adverse Events

There were no adverse events related to the investigational dressing. Seventeen adverse events were reported, of which five were classified as serious—cellulitis ($n = 2$), Sweet's syndrome ($n = 1$), sepsis ($n = 1$), pneumonia ($n = 1$). The adverse events classified as non-serious included localised wound infection ($n = 1$), additional foot/leg ulceration ($n = 4$), cellulitis ($n = 1$), blister ($n = 1$), abrasion ($n = 1$), jaundice ($n = 1$), asymptomatic COVID-19 ($n = 1$), acute lower extremity pain ($n = 1$), and full-thickness left hallux ($n = 1$).

## 5 | Discussion

Management of exudate is essential for optimal wound healing and patient wellbeing. A dressing that fails to absorb excess wound exudate and release fluid into the environment will lead to increased inflammation in the wound bed and maceration of the periwound skin. The result is delayed wound healing [5]. Furthermore, the high volumes of exudate associated with chronic wounds can impact a patient's quality of life and wellbeing [7]. If not managed properly, excess exudate can exacerbate pain, itch, and odour. High levels of exudate will also adversely impact the wound microbiome [24–27]. The effect of poorly managed exudate can also be costly to healthcare providers. For instance, the leakage of chronic wound exudate onto the peri-wound region can lead to moisture-related damage, such as maceration, which also has economic implications on payers [28].

Wound dressings are designed to create an optimal microenvironment supportive of wound healing; as part of that function, effective management of exudate is essential. A dressing's absorptive, retentive, and vapour permeability properties are paramount to its function.

Importantly, not all dressings in a category, for instance foam dressings, are equal in terms of performance; dressing performance is based on dressing composition and construction [5].

**TABLE 9** | Exudate amounts over time.

| Visit | Classification | Total ($n = 68$) | DFU ($n = 34$) | VLU ($n = 34$) |
|---|---|---|---|---|
| Baseline | None | 0.0% (0/68) | 0.0% (0/34) | 0.0% (0/34) |
| | Scant | 0.0% (0/68) | 0.0% (0/34) | 0.0% (0/34) |
| | Small | 0.0% (0/68) | 0.0% (0/34) | 0.0% (0/34) |
| | Moderate | 85.3% (58/68) | 88.2% (30/34) | 82.4% (28/34) |
| | Large | 14.7% (10/68) | 11.8% (4/34) | 17.6% (6/34) |
| Follow-up visit 1 (Day 7 ± 2 days) | None | 0.0% (0/65) | 0.0% (0/33) | 0.0% (0/32) |
| | Scant | 1.5% (1/65) | 3.0% (1/33) | 0.0% (0/32) |
| | Small | 15.4% (10/65) | 15.2% (5/33) | 15.6% (5/32) |
| | Moderate | 73.8% (48/65) | 72.7% (24/33) | 75.0% (24/32) |
| | Large | 9.2% (6/65) | 9.1% (3/33) | 9.4% (3/32) |
| Follow-up visit 2 (Day 14 ± 2 days) | None | 1.6% (1/63) | 0.0% (0/31) | 3.1% (1/32) |
| | Scant | 1.6% (1/63) | 3.2% (1/31) | 0.0% (0/32) |
| | Small | 25.4% (16/63) | 25.8% (8/31) | 25.0% (8/32) |
| | Moderate | 60.3% (38/63) | 61.3% (19/31) | 59.4% (19/32) |
| | Large | 11.1% (7/63) | 9.7% (3/31) | 12.5% (4/32) |
| Follow-up visit 3 (Day 21 ± 2 days) | None | 0.0% (0/62) | 0.0% (0/30) | 0.0% (0/32) |
| | Scant | 4.8% (3/62) | 3.3% (1/30) | 6.3% (2/32) |
| | Small | 30.6% (19/62) | 30.0% (9/30) | 31.3% (10/32) |
| | Moderate | 51.6% (32/62) | 53.3% (16/30) | 50.0% (16/32) |
| | Large | 12.9% (8/62) | 13.3% (4/30) | 12.5% (4/32) |
| Follow-up visit 4 (Day 28 ± 2 days) | None | 1.7% (1/60) | 3.4% (1/29) | 0.0% (0/31) |
| | Scant | 6.7% (4/60) | 0.0% (0/29) | 12.9% (4/31) |
| | Small | 26.7% (16/60) | 37.9% (11/29) | 16.1% (5/31) |
| | Moderate | 51.7% (31/60) | 48.3% (14/29) | 54.8% (17/31) |
| | Large | 13.3% (8/60) | 10.3% (3/29) | 16.1% (5/31) |
| Follow-up visit 5 (Day 35 ± 2 days) | None | 1.7% (1/59) | 3.6% (1/28) | 0.0% (0/31) |
| | Scant | 11.9% (7/59) | 3.6% (1/28) | 19.4% (6/31) |
| | Small | 25.4% (15/59) | 42.9% (12/28) | 9.7% (3/31) |
| | Moderate | 50.8% (30/59) | 35.7% (10/28) | 64.5% (20/31) |
| | Large | 10.2% (6/59) | 14.3% (4/28) | 6.5% (2/31) |
| Follow-up visit 6 (Day 42 ± 2 days) | None | 5.3% (3/57) | 0.0% (0/27) | 10.0% (3/30) |
| | Scant | 10.5% (6/57) | 11.1% (3/27) | 10.0% (3/30) |
| | Small | 36.8% (21/57) | 48.1% (13/27) | 26.7% (8/30) |
| | Moderate | 40.4% (23/57) | 33.3% (9/27) | 46.7% (14/30) |
| | Large | 7.0% (4/57) | 7.4% (2/27) | 6.7% (2/30) |

Abbreviations: DFU, diabetes-related foot ulcer; *n*, number; VLU, venous leg ulcer.

The results from the laboratory tests using the EN 13726:2023 standard demonstrated considerable differences between six commercially available non-bordered foam dressings in terms of their ability to handle fluid (FHC), ability to retain fluid (FRC) following acute compression and release retained fluids via moisture vapour transmission (MVL). The investigational dressing (Dressing A) performed well in each test, demonstrating its capacity (and in most tests, its superiority) to absorb, retain, and

release fluid into the environment. The superior performance of the investigational dressing, as evidenced by its consistent fluid spreading patterns and higher DtE values, indicates its potential to deliver reliable outcomes in clinical settings; in the clinical setting, the spreading of fluid toward the dressing edges would likely influence the need for dressing change. The consistency in fluid management is likely to minimise the risk of dressing failure and reduce the frequency of dressing changes, thereby positioning the investigational dressing as a robust option for effective wound care.

**TABLE 10** | Evaluation of dressing comfort.*

| | VLU ($n = 34$) | DFU ($n = 34$) |
|---|---|---|
| Very poor | 1.1% | 0.6% |
| Poor | 3.7% | 2.2% |
| Good | 51.1% | 69.7% |
| Very good | 44.1% | 27.5% |

Abbreviations: DFU, diabetes-related foot ulcer; *n*, number; VLU, venous leg ulcer.
*Across 188 assessments for VLUs and 178 for DFUs.

The advanced FLUHTE method, based on the previously reported system [10], designed to more closely mimic clinical conditions than standard fluid handling capacity tests, and facilitate crucial complementary performance data, was employed in this investigation to enhance the understanding of dressing fluid handling properties beyond the data obtained from the EN 13726:2023 standard. Overall, the investigative dressing demonstrated excellent fluid handling performance when evaluated

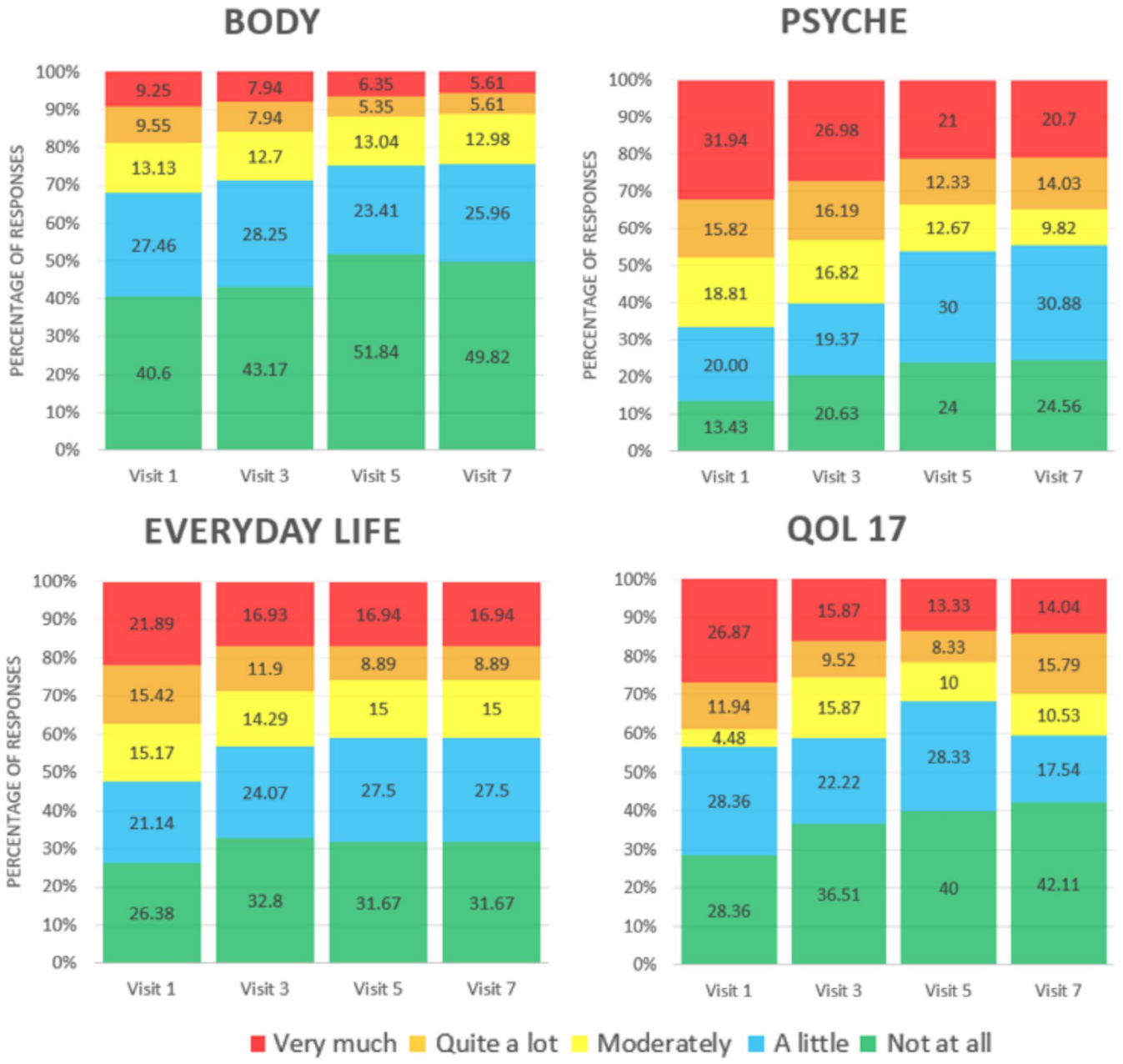


**FIGURE 5** | Change in wound-related quality of life (QoL) over 6 weeks of treatment. The graph shows merged responses from all subjects and all questions. 'Not at all' was the most positive response and 'Very much' was the most negative response.

using the FLUHTE wound simulator, including under compression. The FLUHTE method provides clinically relevant insights into wound dressing performance, which are not captured by standard test methods. Testing of six different dressings revealed that MVL measurements obtained via FLUHTE did not statistically correlate with those derived from the standard FHC test. This finding underscores the limitations of the EN 13726:2023 standard and highlights the value of dynamic wound simulation in replicating real-world clinical conditions. For clinicians, this advanced approach offers a more realistic evaluation of how dressings manage simulated wound fluid under critical parameters, such as prolonged application of protein-containing fluids and the influence of gravity on vertically oriented dressings, all while under compression [5, 15]. By providing data that align more closely with clinical scenarios, FLUHTE testing equips healthcare providers and procurement teams with actionable insights for selecting dressings that best meet patient needs. These results support a call to expand the EN 13726:2023 standard to include dynamic testing methods like FLUHTE. Incorporating these advancements into routine evaluation protocols would improve the alignment of dressing performance metrics with the complex demands of wound care, enabling better clinical outcomes.

The absorptivity of a primary dressing is vital in removing excess exudate, wicking it away from the wound bed, especially if a secondary dressing is used. This dressing characteristic is even more important when a dressing with capillary action has to perform against gravitational forces resulting from certain patient positions [29]. The FLUHTE system is designed to replicate the cylindrical shape of the lower leg, allowing vertical positioning to account for the effects of gravity on fluid distribution within dressings. The results generated from this system for the investigational dressing are indicative of a device that provides versatility in terms of fluid management for wounds with different levels of exudate and when used on wounds whereby gravitational forces may affect the flow of wound exudate.

Data from the FLUHTE system testing highlight the substantial impact of dressing design on fluid dispersion. Quantitative evaluation of the fluid dispersion across the six dressings, in terms of mean Distance to Edge (DtE), revealed that the innovative dressing significantly outperformed the other dressings; the investigational dressing demonstrated a significantly higher DtE compared to four of the other tested dressings, with the higher DtE indicating decreased risk of dressing failure. In the clinical setting, this dressing property would translate to minimised risk of exudate leakage from the dressing and patient distress caused by leakage of exudate onto clothes and linen [5–7, 30].

Using the FLUHTE model, the investigational dressing also demonstrated significantly higher mean MVL values compared to the other five dressings when tested with compression bandages. In the context of the clinical setting, this would relate to the dressing's ability to release wound fluid into the environment over a three-day wear time, an essential dressing property in terms of exudate management; the ability of a dressing to allow continuous dissipation of absorbed exudate through evaporation affects the fluid occupancy of the dressing and impacts dressing wear time [10].

Notably, even with an increase in the flow of simulated wound fluid by 50%, from a total of 36 to 54 mL, no dressing failure (defined as DtE = 0) was detected for the investigational dressing. This further underscores the robustness of the investigational dressing, as it maintained its performance under increased fluid load conditions, highlighting its potential for reliable use in more demanding clinical scenarios.

Correlating laboratory success with human data is critical to effective translation of any technology into the clinic. Indeed, we found that the clinical study results aligned with the laboratory-generated data in demonstrating the ability of the innovative dressing to effectively manage exudate in moderately to large exuding wounds of long duration, resulting in favourable patient outcomes. The dressing efficiently managed moderate to large amounts of exudate, with high ratings from clinical investigators regarding the ability of the dressing to absorb and retain exudate. In line with an overall general reduction in the volume of exudate over the course of the clinical investigation period and an improvement in the wound condition (with reduced levels of slough and increase in granulation tissue), significant wound progress was observed. The area of both VLU and DFU wounds and the volume of DFU wounds reduced during the investigation. A wound closure rate of 0.12 to 0.07 cm/day was calculated, showing consistent linear healing over time. Furthermore, little to no peri-wound skin itch was reported throughout the investigation. There was also minimal pain reported during wear and during dressing removal, and few reports of trauma to the wound bed and peri-wound skin.

The reported occurrence of maceration in the clinical investigation may, at first glance, seem a little surprising, in view of the performance of the dressing in the laboratory-based fluid handling tests. However, the incidence of maceration observed in this study is less than the rates demonstrated in previous studies of other absorbent dressings [31–35]. Furthermore, tissue maceration typically occurs after prolonged exposure to moisture; hence, it seems reasonable to assume that the maceration observed in a small number of subjects in this clinical investigation resulted from moisture-related damage incurred pre-baseline. The downward trend in maceration occurrence in the second half of the follow-up period is an indicator of the ability of the innovative dressing to effectively manage exudate. A longer follow-up period may have been useful to determine the length of time to complete resolution of the maceration.

Given that the use of compression and offloading are a fundamental part of wound management in VLUs and DFUs, respectively, it is essential that wound dressings are designed in such a way that their performances are not impeded by the mechanical forces imposed on them by devices such as compression bandaging and orthotic footwear [16]. Compliance with compression (VLUs) and offloading (DFUs) was high throughout the investigation. Patients reported that the investigational dressing was comfortable to wear, both with compression (VLU) and without compression (DFU).

The investigator-reported ease of dressing application, conformability, and ability of the dressing to be repositioned during application were all rated as 'good' or 'very good' throughout the

investigation period. The investigational dressing has a low profile (it is thinner than all but one of the comparator dressings), making it highly conformable, easy to handle and non-bulky; the results presented here have demonstrated that, despite its thinness, the investigational dressing can effectively manage fluid whilst remaining conformable and comfortable to wear. The impact of living with chronic wounds on a patient's QoL can be significant. The challenges associated with managing excess exudate and issues such as pain and wound odour can cause immense patient distress [2]. Indeed, excessive exudate and odour are the two factors associated with the highest patient depression scores in QoL assessments [31]. Unpleasant wound odour is usually associated with high volume exudate and an increased bacterial load [32]. It is therefore imperative that excess wound exudate is managed effectively, not only to minimise the risk of damage (e.g., maceration) to the wound and peri-wound skin, but also to minimise the risk of harm to patients' QoL. In alignment with the positive results from the present clinical investigation relating to exudate management, patients reported a marked improvement in QoL throughout the investigation, as assessed by Wound QoL-17 questionnaire.

Clinical choices regarding dressing selection should be made with the available published clinical and scientific evidence in mind to ensure the selection of the safest and best performing dressing on an individual patient basis [5]. Clinicians should think critically in terms of dressing technologies and specifications [5] and informed decision making should be based on robust and clinically relevant evidence, both in terms of laboratory testing and clinical evaluation. Purchasers would also benefit from taking into consideration the available research data pertaining to wound dressings. For example, a dressing with proven fluid handling capabilities has the potential to be left in place on a wound (when clinically indicated) longer than lesser performing dressings, which can increase the interval between dressing changes that, in turn, is likely to reduce nursing time and treatment costs. Here, we present a comprehensive combination of clinical and laboratory data to help guide all these stakeholders.

### 5.1 | Limitations

Solution A was used for FHC and FRC testing according to standard EN 13726:2023 given its routine use, allowing for comparisons with previous publications. However, it should be noted that Solution A lacks the protein and physiochemical properties of wound exudate, and thus the results should be interpreted accordingly. Furthermore, it should be recognised that the FRC test used in this investigation is only an informative test according to EN 13726:2023, due to documented inter-laboratory variations for this method (not owing to application of Solution A). Comparisons of the FRC results presented in this paper with those of other laboratories are therefore discouraged. To overcome these limitations, this work has complemented the standard FHC and FRC testing, including performance evolutions using an advanced laboratory-based test method, that is, the FLUHTE wound simulator (employed with and without compression, and SWF-A). The advanced FLUHTE method, although designed for standardisation and also validated, is not yet widely available, which currently limits inter-laboratory comparisons of performance outcomes; however, similar test systems have been developed [20, 21] and these can be expected to present similar outcomes.

The clinical investigation presented in this paper used a non-comparative design. A randomised study design where the investigational device is compared against a similar dressing could provide additional insights into optimum wound care management for chronic wounds with moderate to heavy exudate levels. Given that chronic wounds typically take a long time to heal, a longer follow-up period (longer than six weeks) may have provided further understanding of the ways in which dressings can influence exudate management and the consequent clinical outcomes. Another limitation of the clinical investigation was the subjective measurement of exudate quantity. Future studies would potentially benefit from the utilisation of more objective measures; for example, by weighing dressings before they are applied and after they are removed, with the difference in weight being used as an indicator of wound exudate levels.

## 6 | Conclusions

This paper has highlighted positive outcomes in terms of fluid handling of an innovative dressing using the FLUHTE system that mimics the clinical setting in terms of exudate management. In support of these results, the clinical investigation demonstrated the capacity of the dressing to support wound advancement to healing; significant wound progress was observed for all wounds and nine patients completely healed by the end of the investigation period. Providing stakeholders with a robust dataset that pairs stringent and clinically meaningful laboratory test results with a human subject clinical investigation will result in improved patient outcomes.

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#### Conflicts of Interest

Hadar Lev-Tov and Thomas Serena provide consultancy to Mölnlycke Health Care AB and have received speaker's fees from Mölnlycke Health Care AB. Erik Nygren is an employee of Mölnlycke Health Care AB.

#### Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publically available due to privacy or ethical restrictions.

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