UPPING THE GAME! APPLYING CLINICALLY RELEVANT LABORATORY TESTS TO THE EVALUATION OF AN INNOVATIVE, NON-BORDERED FOAM DRESSING

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Background

- Foam dressings are commonly used in wound care regimes to manage excess exudate.[1]
- Clinically relevant laboratory-based studies are essential for determining the safety and effectiveness of wound dressings and generating data to assist health care professionals in selecting appropriate products for their patients.[1-4]
- A **highly conformable, dimpled, soft silicone-coated, non-bordered foam dressing*** that can manage exudate corresponding to **low-to-high exuding wounds**, as well as absorbing both **low and high viscous exudates**, has been developed.[2]

STUDY AIM

To investigate the **fluid handling performance** of the **dimpled, non-bordered foam dressing (Dressing A*)**, in comparison with five other commercially available foam dressings (Dressings B-F*), utilizing standard and more clinically relevant laboratory methods.

Methods

Fluid Handling Capacity (FHC)

Determined by combining fluid absorption (ABS) and moisture vapor loss (MVL) according to standard EN 13726:2023.[3]

Fluid Retention Capacity (FRC)

Evaluation of fluid retention of fully absorbed dressings under acute compression (40 mmHg) according to standard EN 13726:2023.[3]

Fluid handling under the influence of gravity (FLUid Handling Test Equipment, FLUHTE)

Dynamic wound simulator that reflects real-world conditions[1,2], taking into consideration compression bandaging, gravity, protein (albumin)-containing simulated wound fluid (SWF-A)[5], and fluid flow (0.5 ml/h and 0.75 ml/h) over 72 hours aligned with values reported in the literature for highly exuding wounds[1, 2], normalized to a wound area of 10 cm².

Metrics:

- Distance to Edge (DtE), where a DtE of 0 indicates dressing failure.
- Fluid Spreading Pattern Box Ratio (SPBR), which measures the dispersion symmetry by calculating the mean ratio of horizontal and vertical spread.
- The amount of fluid evaporated (MVL) through the dressing over 72 hours was also measured.

Statistical analysis

- Welch's one-way ANOVA was performed, followed by Dunnett's T3 multiple comparisons test (threshold 0.05, 95% confidence interval).
- Statistical differences are indicated with asterisks, *$p < 0.05$, **$p < 0.01$ and ***$p < 0.001$. ns, non-significant.

Results

Fluid Handling Capacity (FHC): Dressing A exhibited significantly higher FHC values (3.67 ± 0.23 g/cm²/24h) compared to Dressings C-F ($p < 0.001$).[2]

Fluid Retention Capacity (FRC): Dressing A demonstrated high FRC (96.4%), outperforming Dressings B, D, and E ($p < 0.001$).[2]

- A **novel methodology** was developed to simulate the properties of a wound bed under compressive and gravitational forces. The FLUid Handling Test Equipment (FLUHTE) system is shown in Figure 1.

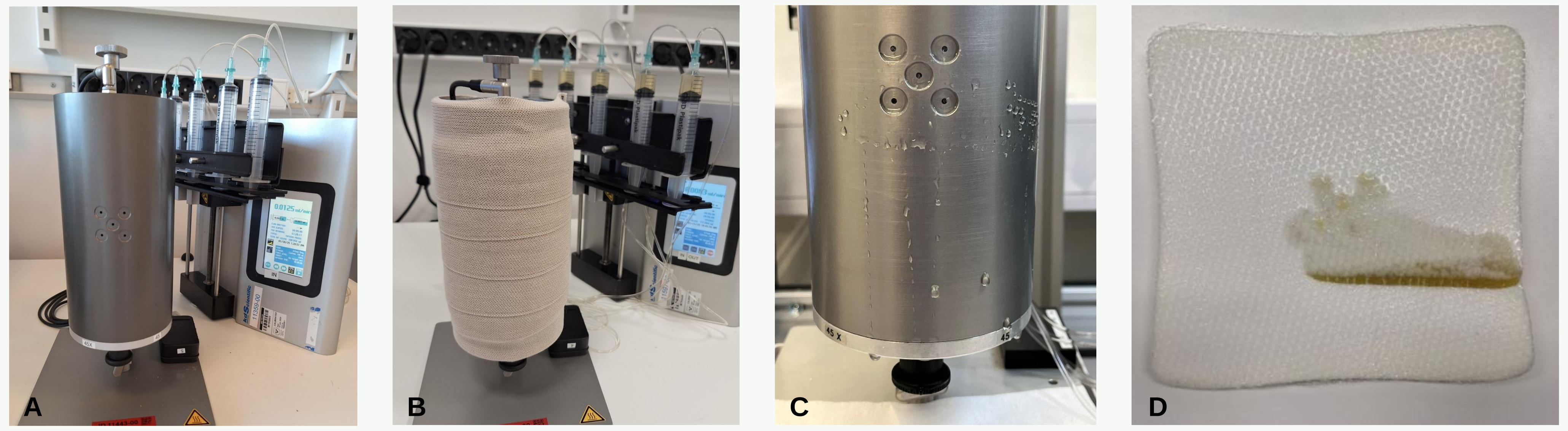

Figure 1. The FLUHTE system and dressing failure under simulated conditions. (A) The system simulates a wound bed; it features five circular recesses, each with a central inlet hole, designed to release SWF-A uniformly over an area of 10 cm² at controlled settings, and positioned vertically to account for gravity. (B) The setup tested a dressing under 40 mmHg compression, simulating clinical conditions for venous leg ulcer management. (C) Fluid pooling under a foam dressing, due to poor absorption, after 72 hours of exposure to SWF-A at 0.75 ml/h was quantified by weighing collected fluid on pre-weighed tissues (D) Fluid distribution showed SWF-A reaching the same dressing's edge (DtE = 0).

Fluid handling under the influence of compressive and gravitational forces (FLUHTE)

- Dressing A showed higher DtE values compared to Dressings C, D, E, and F ($p < 0.001$, $p = 0.01$, $p = 0.04$, $p < 0.001$) under compression bandaging (40 mmHg), indicating reduced risk of failure. Similar outcomes were observed without compression (4 mmHg) (Figures 2 and 3).[2]
- SPBR under compression for Dressing A was statistically higher than Dressings B, C, and F ($p < 0.001$).[2]
- MVL under compression was significantly higher for Dressing A compared to Dressings B ($p = 0.005$) and C-F ($p < 0.001$).[2]
- Notably, even at a total flow of 54 ml (0.75 ml/h for 72 hours), Dressing A showed no failure (DtE = 0), with 87% evaporation (MVL of 46.9 ± 0.7 ml) under compression.[2]

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

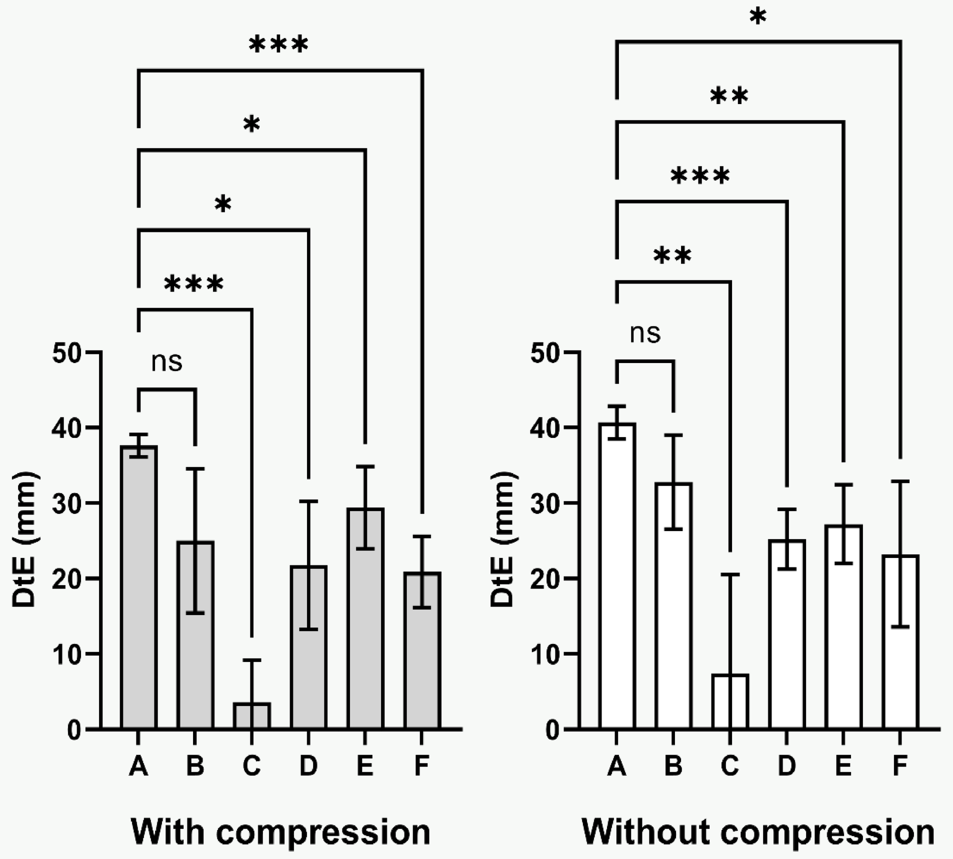

Figure 2. Dispersion of simulated wound fluid across dressings (A-F), evaluated in repeated experiments using the FLUHTE wound simulator, quantified as mean DtE ± 95% CI. The dressings (15 cm x 15 cm) were positioned vertically and centred over the simulated wound. SWF-A was administered continuously for 72 hours at a flow rate of 0.5 ml/h. 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 detailed in Lev-Tov et al. 2025.[2]

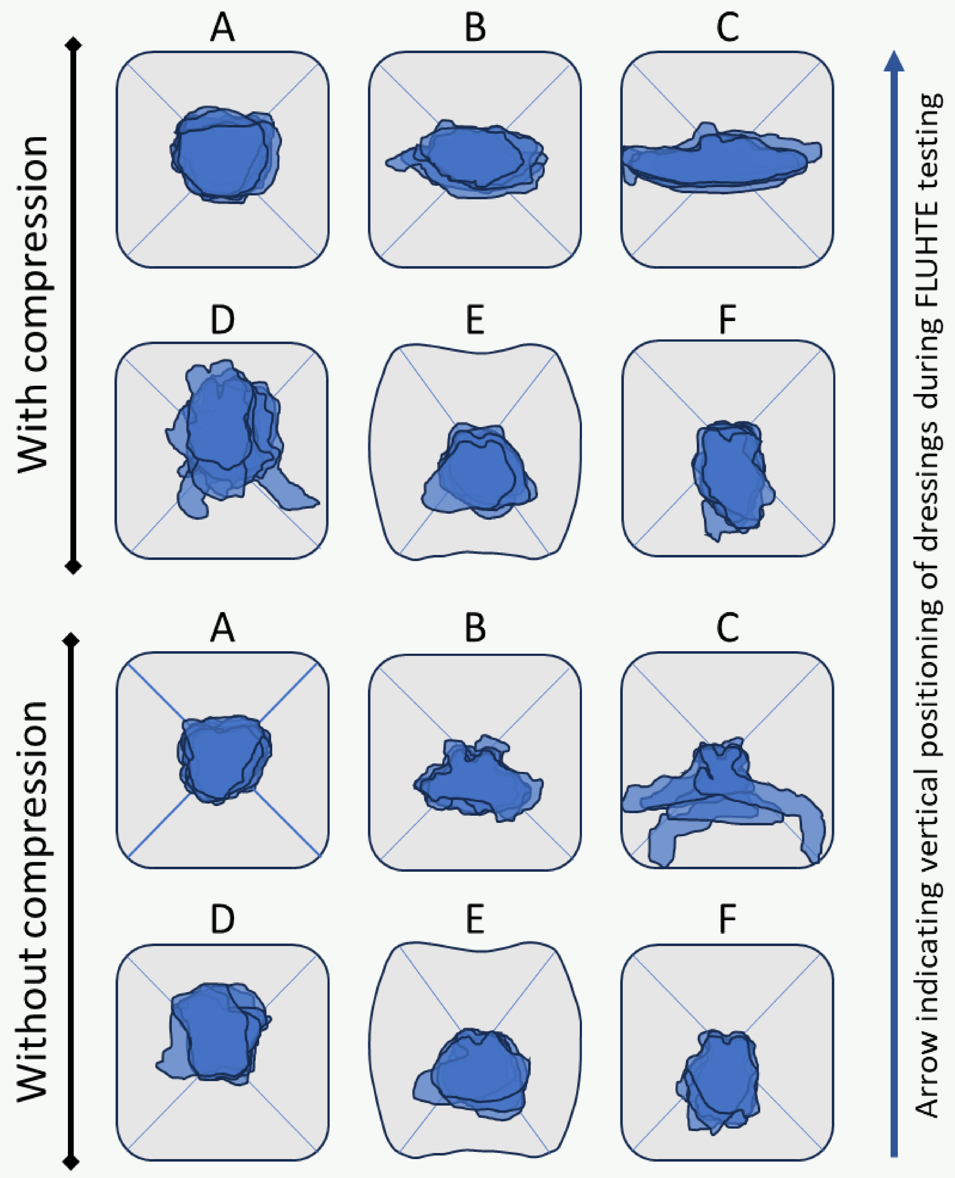

Figure 3 Graphical illustrations of the fluid dispersion patterns across dressings (A-F), evaluated in repeated experiments using the FLUHTE wound simulator. For experimental details, see Figure 2. Overlays of individual fluid spreading patterns are presented, corresponding to tests conducted with and without compression.

Conclusions

- The dimpled, non-bordered foam dressing (Dressing A) demonstrated excellent fluid handling and retention capacities, outperforming five other dressings in standard EN 13726:2023 FHC and/or FRC testing.
- The advanced wound simulator (FLUHTE) testing confirmed the dressing's performance under clinically relevant conditions.

References: [1] Gefen A et al. Fluid handling by foam wound dressings: From engineering theory to advanced laboratory performance evaluations. Int Wound J. 2024; 21(2):e14674. [2] Lev-Tov H et al. Bench to bedside evaluation of an innovative, non-bordered foam dressing for use in exudating chronic wounds. Int Wound J. Accepted for publication. 2025 Mar 17. [3] Nygren E et al. Little news is good news? What is missing in the recently published EN 13726:2023 test standard for wound dressings. Int Wound J. 2024; 21(3). [4] Nygren E et al. From Lab to Clinic: The necessity of realistic testing conditions in evaluating wound dressing performance. Wound Masterclass. 2024; 3:1-8. [5] Svensby AU et al. The importance of the simulated wound fluid composition and properties in the determination of the fluid handling performance of wound dressings. Int Wound J. 2024; 21(5).

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