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Laboratory Evaluations of Wound Dressings: Key Advances to Reflect Clinical Reality

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ABSTRACT

Laboratory evaluations are essential for determining the safety and effectiveness of wound dressings. These evaluations assist clinicians in selecting optimal products for their patients. It is crucial that laboratory tests closely mimic real clinical conditions. This review highlights the collaboration between scientists, clinicians and industry experts to improve laboratory testing methods for wound dressings. The goal is to ensure that laboratory tests are relevant to real-world use. Key advancements include a new simulated wound fluid and a fluid handling test system that better reflects actual wound care environments. These improvements aim to support more reliable, evidence-based decisions in clinical practice.

1 | Introduction

Wound dressings are designed to create an optimal environment that supports healing and improves the quality of life of patients. The material components, structure and construction of dressings are key to their clinical performance [1]. Like all medical devices, wound dressings must undergo standardised testing to allow for reliable product comparisons. Many dressing types are designed to absorb wound exudate; thus, their ability to manage fluid is a key part of their development. Moreover, the fluid handling performance of dressings should be evaluated across varying fluid volumes, flow rates and regimes, as exudate properties can differ significantly between wounds and during the healing process. To ensure clinical relevance, testing should take into consideration simulated wound size and anticipated dressing wear times. The availability of robust data on fluid handling properties aids clinicians in making evidence-based dressing choices that, in turn, help to prevent issues such as exudate leakage, maceration or overhydration and improve patient outcomes and cost-effectiveness in wound management.

This article provides a review of current laboratory standards for evaluating wound dressings, describing key limitations that disconnect these methods from real-world clinical use. We first highlight gaps in the existing EN 13726:2023 testing standard [2], particularly the fluid handling tests and the use of a simple saline-based solution, which may not accurately reflect the clinical performance of dressings. We then introduce two key innovations to address these challenges: a newly developed simulated wound fluid (SWF) that better mimics the properties of real wound exudates, and the fluid handling test equipment (FLUHTE) system, an advanced fluid handling test designed to simulate real-life conditions such as gravity and compression. These new methodologies aim to improve the relevance of laboratory tests, enhancing dressing selection and clinical outcomes in wound management.

Summary

- Laboratory tests must closely mimic clinical conditions to ensure relevance.
- The EN 13726:2023 standard requires improvements to reflect clinical scenarios.
- SWF-A improves dressing evaluations by simulating real wound exudate fluids.
- The FLUHTE system addresses gravity and compression effects in dressing tests.
- Our improved methods support better wound care decisions and patient outcomes.

The recently revised EN 13726:2023 standard (*Test methods for wound dressings – Aspects of absorption, moisture vapour transmission, waterproofness and extensibility*) guides the assessment of wound dressing performance in the laboratory [2]. The standard includes recommended test methods (described within annexes) and an indicator of which methods are suitable for testing different dressing types, such as foam dressings (Table 1).

Since the 2023 update of the EN 13726 standard, experts have highlighted some limitations, suggesting that the focus on simplicity and practicality in the test development may have moved the methodology further from real-world clinical scenarios [1–4]. For example, Annexes B–E of the standard refer to fluid handling tests where dressings are fully saturated with a test solution. This approach lacks clinical relevance, as many clinicians would change a dressing long before it becomes fully saturated. Additionally, the free-swell absorptive capacity test described in Annex B raises concerns because it allows fluid inflow from multiple sides of the dressing, whereas in clinical practice, exudate flows in only one direction, from the wound surface to the wound contact side of the dressing pad (Figure 1).

Another important issue is the test solution ('Solution A') described in the standard, which consists of an aqueous mixture of sodium chloride and calcium chloride. The solution, however, lacks the biophysical properties of real-world wound exudates (e.g. surface tension, wettability and viscosity). To address these limitations, an international panel of clinical, scientific and industry experts collaborated to develop more clinically relevant test methods [1]. These efforts have led to two important advancements: a new SWF and a novel fluid handling test method, both of which are reviewed below.

2 | Simulated Wound Fluids for Fluid Handling Performance Evaluations of Dressings

The production of wound exudate is a physiological response to injury and plays a critical role in healing, but it also affects how dressings interact with wounds. Chronic wound exudates are complex, containing proteins, cells, bacteria, electrolytes, enzymes and varying pH levels. These components influence the fluid viscosity, surface tension and wettability, thereby impacting the fluid handling capacity (FHC) and other performance metrics of dressings, such as thermal insulation (through the temporal retention and the spatial spread of fluid in the dressing). Simplified laboratory fluids like 'Solution A' fail to capture these complexities, often leading to overestimated FHC values and inadequate performance assessments [5]. Generally, proteins in the wound exudate alter the physicochemical properties of the fluid, affecting absorption and evaporation properties, which 'Solution A' overlooks [5]. Using biologically representative test solutions that mimic chronic wound exudate enables more accurate evaluations of dressing performance [5–7]. Although the EN 13726:2023 standard specifies 'Solution A' for determining fluid handling properties, its Annex L encourages the exploration of alternative fluids that simulate wound exudates (Table 1) [2]. The new SWF-A, which contains albumin to represent protein content, is a promising alternative SWF that enhances clinical relevance and is currently being evaluated in multiple laboratories (Figure 2) [5].

Proteins in fluids increase viscosity [8, 9]. Laboratory approaches to mimic protein content have used milk, porcine

TABLE 1 | The EN 13726:2023 test standard annexes of relevance to foam wound dressings [2].

Annex	Title (test type)	Description
B	Free-swell absorptive capacity	Measures absorbed test fluid after soaking dressing specimen until it is fully saturated
C	Fluid retention capacity	Measures the retained test fluid after temporary compression of a saturated dressing specimen, but disregards the fluid redistribution within the dressing as well as any reabsorption
D	Absorbency under compression	Measures absorbed test fluid after soaking dressing specimen under compression
E[a]	Fluid handling capacity	Measures absorption plus moisture vapour loss of a dressing specimen
J[a]	Waterproofness	Measures the waterproofness of outer surface (backing film) of a dressing specimen
K	Extensibility and permanent set	Measures resistance of a dressing specimen to stretching and deformation
L	Test solution A	Specifies the composition and preparation of the standard test solution, 'Solution A', but mentions that laboratories may use other test fluids that simulate wound exudate

[a]Only applicable to dressings with liquid impermeable backing film.

blood and thickeners like xanthan gum and guar gum. Whilst serum, a natural exudate source, seems a logical choice for testing the fluid handling of dressings, its natural variability complicates reproducibility, and thereby, increases the costs of testing. Synthetic alternatives, on the other hand, lack the complex interactions of serum proteins. The SWF-A, a new development, incorporates albumin (the main serum protein), salts and buffers to replicate exudate properties, such as pH, conductivity and surface tension (Figure 2). This innovation balances reproducibility with biological and clinical relevance, addressing the limitations of both natural and synthetic test fluids.

The new SWF-A was created to provide more accurate and clinically relevant assessments of how dressings handle fluids.

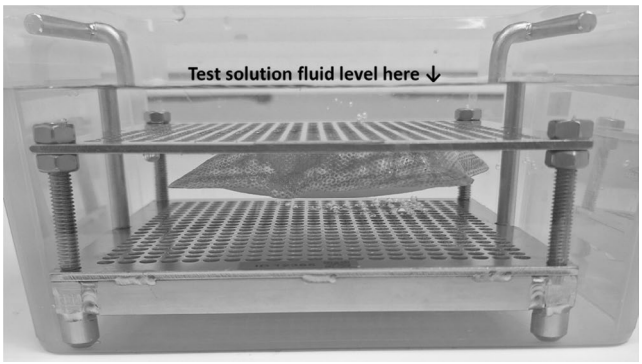

FIGURE 1 | The free swell absorptive capacity test allows fluid flow from multiple sides of a tested dressing, which never occurs in real-world scenarios. In clinical settings, when a dressing is appropriately applied to a wound, the flow of exudate is always unidirectional, from the wound surface to the wound contact side of the dressing pad.

A study tested the FHC of eight foam dressings as detailed in the EN 13726:2023 standard method, with minor deviations [5]. In this test, dressings are placed on a Paddington cup containing a specified volume of SWF, for example 'Solution A' or SWF-A, incubated at 37°C for 24 h, and evaluated for fluid absorption and moisture vapour transmission, reported in grams per square cm over 24 h. To evaluate how different SWFs affect FHC results, the test used three SWFs: 'Solution A', SWF-A and a serum-containing solution (SCS) with 50% (w/w) horse serum and 50% (w/w) Solution A (Figure 3). The results showed statistically significant lower FHC values for half the dressings when tested with SWF-A or with SCS, compared to 'Solution A'. However, the FHC data obtained using SWF-A and SCS were similar (Figure 3). This suggests that 'Solution A' overestimates the FHC for many, but not all, dressings because it lacks protein components [5]. These findings highlight the need for more clinically relevant SWFs, like SWF-A, for evaluating the fluid handling performance of wound dressings in laboratory settings.

3 | New Leg Wound Simulator for Fluid Handling Performance Evaluations

In addition to the critique of using 'Solution A' in the EN 13726:2023 standard [2], several publications have highlighted additional limitations of the FHC test method, mainly related to it not accounting for the effects of gravity on exudate flow from the wound and within the dressing. This is particularly influential when the wound and dressing are tilted with respect to the ground, representing, for example, dressing placement on the leg whilst standing or sitting [10–12]. Additionally, the FHC test in the EN 13726:2023 standard does not consider the impact of bodyweight on dressings such as those used for diabetes-related

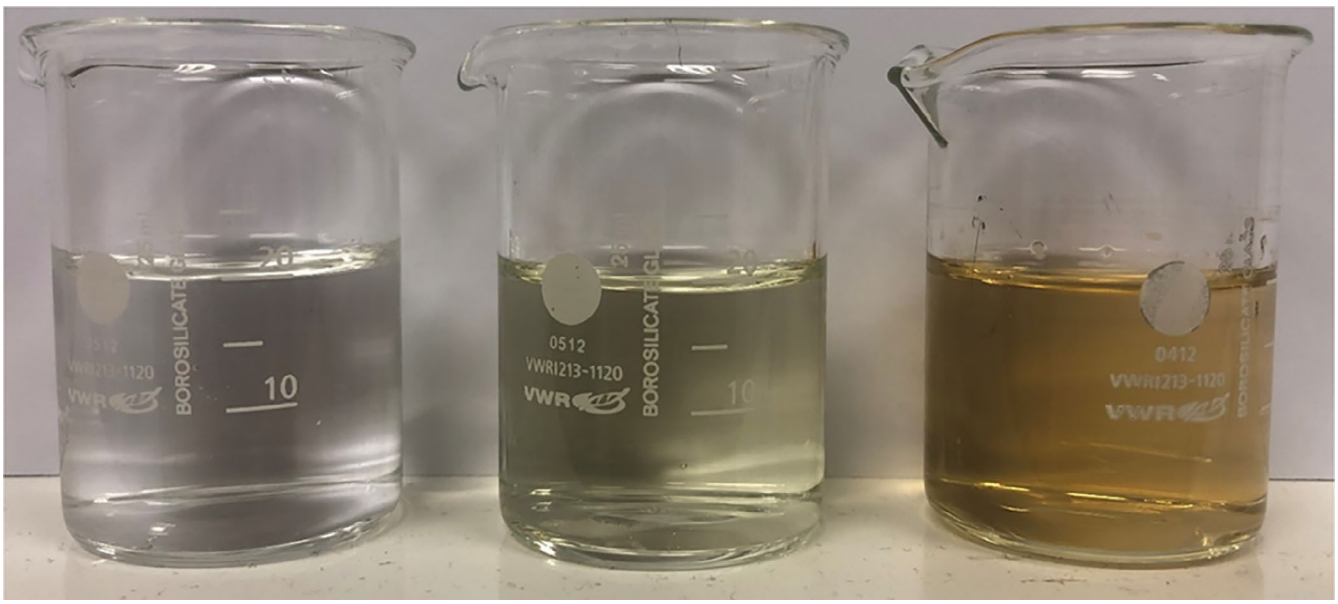

FIGURE 2 | The simulated wound fluids (SWFs) on which this article focuses (from left to right): 'Solution A' (Sol-A), SWF-A and a serum-containing solution (SCS) containing 50% (w/w) horse serum and 50% (w/w) Sol-A. The visual appearance of the three test fluids varies based on their composition. 'Solution A' is clear and colourless due to its simple salt content whereas SWF-A has a pale straw colour from the inclusion of bovine serum albumin. The SCS appears light yellow to amber, reflecting the natural pigmentation of horse serum. Whilst not directly visualised here, the fluid surface tension decreases from 'Solution A' (highest) to SWF-A (moderate) to the SCS (lowest), reflecting the increasing presence of proteins and biological molecules. Inversely, the fluid viscosity increases from Solution A (lowest) to SWF-A (moderate) to the SCS (highest), likewise due to the addition of proteins and other biomolecules that enhance fluid thickness.

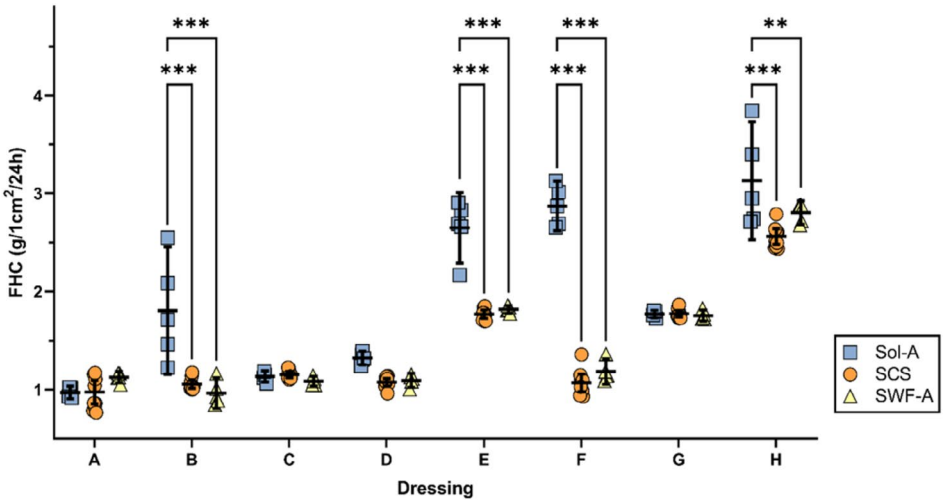

FIGURE 3 | Fluid handling capacity (FHC) data (mean plus 95% confidence intervals) for eight test dressings (A–H) using 'Solution A' (Sol-A, squares), serum-containing solution (SCS, circles) containing 50% (w/w) horse serum and 50% (w/w) Sol-A and simulated wound fluid with albumin (SWF-A, triangles). **p-values between 0.01 and 0.001. ***p-values < 0.001. Reproduced from the published work of Nygren and Gefen [5] under the Creative Commons licence.

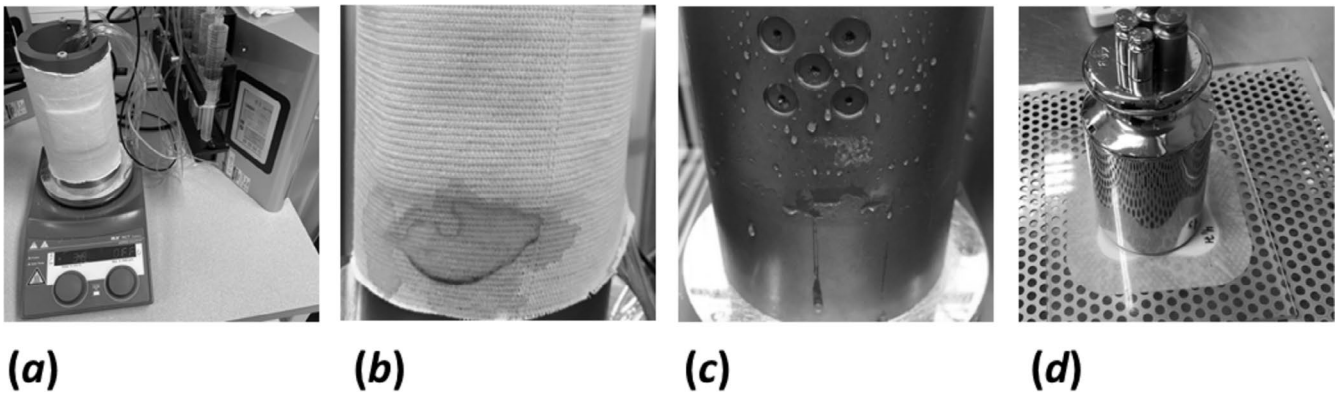

FIGURE 4 | The fluid handling test equipment (FLUHTE) system, featuring a heating plate and computer-controlled syringe pump (a). Examples of fluid handling after simulated use for 24 h at a flow rate of 0.75 mL/h are shown, demonstrating the leakage of simulated wound fluid (SWF) from a primary to a secondary dressing (b), pooling of SWF on the simulated wound after removal of another dressing type (c) and a retention test of a dressing post-simulated use under an applied pressure of 40 mmHg (d). Reproduced (in greyscale) from the published work of Nygren and Gefen [14] under the Creative Commons licence.

foot ulcers, or the pressure from medical devices such as compression therapy on venous leg ulcers (VLUs), which can deform the dressing and compromise its FHC [1, 12].

The FLUHTE system [13] is an advanced wound simulator designed to evaluate the FHC of wound dressings more realistically than traditional methods, including that described in the EN 13726:2023 standard (Figure 4). The FLUHTE simulates the cylindrical shape of a lower leg with a VLU, and positions dressings vertically, incorporating the natural effect of gravity on the fluid flow and distribution. This vertical orientation allows for more realistic testing of how wound exudate spreads and accumulates, especially in challenging areas like the lower extremities, where gravity can cause exudate pooling or leakage (Figure 4b). The FLUHTE method and system addresses the need for vertical testing methods noted in Annex Q of the EN 13726:2023 standard [2], which encourages the development of tests that simulate wounds on the legs of mobile patients. The FLUHTE system is designed to control for several additional important variables that influence fluid dynamics. These include the convex shape of the surface onto which the dressing is applied, the temperature of the simulated wound surface, the ambient temperature and humidity, and the directional flow rate of the fluid from the simulated wound into the dressing [13].

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 releases SWF uniformly over a 10 cm^2 area at controlled volume, flow rate and temperature, mimicking wound exudate. The FLUHTE setup also evaluates how additional barriers, like secondary dressings or compression therapy devices, or textiles representing the clothing or linen, affect moisture vapour transport (Figure 4a,b). When testing dressings under compression, a sensor can be applied to monitor the pressures, typically set between 20 and 40 mmHg (to simulate the pressures typically delivered by compression

bandaging in VLU management). By incorporating these elements, the FLUHTE method closely replicates real wound environments, taking into consideration factors like gravity, body and wound temperatures, orientation of the wound and dressing in space, potential pressure applied on the wound and dressing, and evaporation barriers such as compression bandaging or clothing.

The FLUHTE system uses protein-containing SWFs to mimic the viscosity, surface tension and wettability of chronic wound exudate. This feature helps researchers understand how dressings perform under various conditions, offering insights that standard testing (like the EN 13726) will very likely miss [5]. This makes FLUHTE a superior tool for predicting dressing performance in clinical settings, aiming to improve patient outcomes and support better product choices. It allows testing in orientations that reflect real-world conditions, such as the impact of gravity on exudate secreted into dressings applied to leg ulcers, and when the tested dressings are applied on curved surfaces (again as occurs in the real-world), that is, not just on flat horizontal surfaces as in traditional testing methods. Moreover, when dressings are subjected to external forces like those generated by compression bandages, their FHC typically changes, which the FLUHTE system can replicate to better predict real-life clinical performance.

The FLUHTE wound simulator measures key performance metrics, for example, absorbed and retained fluid content (FC), moisture vapour loss (MVL) and detects common dressing failure modes such as exudate leakage, pooling or backflow (Figure 4c). It can also facilitate optical fluid dispersion measurements to detect potential leakage risks. By overcoming the limitations of traditional fluid handling tests, FLUHTE significantly improves the prediction of how dressings will perform in real-world settings [5]. This is particularly relevant given the recent findings of the International Wound Dressing Technology Expert Panel (iWDTEP) which identified leakage and the ability to stay-in-place as two of the six core outcomes that should be reported in clinical trials of wound dressings [14–18]. Furthermore, the other core outcome parameters such as dressing-related peri-wound skin changes, pain and user satisfaction also likely depend, at least partially, on the fluid handling performance of dressings [14–18]. This indicates that the FLUHTE system is highly relevant for evaluations of wound dressings.

4 | Summary and Conclusions

This article highlights the need for clinically relevant testing standards for wound dressings to better align laboratory results with real-world clinical outcomes. Whilst current standards, such as EN 13726:2023, are important, they fail to accurately reflect the complex conditions under which dressings are used in patient care. The methods outlined in EN 13726:2023, such as the free swell absorptive capacity and the use of 'Solution A' for fluid handling, are disconnected from clinical realities. More accurate, clinically representative laboratory testing methods are needed, ones that incorporate factors such as protein content in fluids, exudate flow direction and gravity to facilitate best practices.

To help bridge these gaps, two key advancements have been developed. First, SWF-A, a new test fluid was introduced, incorporating albumin, salts and buffers that better represents the composition and behaviour of chronic wound exudates, providing more realistic results in fluid handling assessments. Adding albumin to the fluid makes the assessment more clinically relevant [5], as wound exudates are more complex than saline solutions. Second, the FLUHTE system has been developed to simulate real-life wound dressing conditions, accounting for gravity, orientation, compression forces and the effects of secondary dressings or compression therapy. The FLUHTE system offers a dynamic and adaptable testing environment, critical for evaluating dressing performance under conditions that reflect their intended clinical applications. Whilst these advancements significantly enhance laboratory-based assessments of wound dressing performance, no single test can fully and simultaneously account for real-world factors such as exudate variability, posture, ambulation, oedema and medical conditions that influence the dressing wear time or change frequency in specific, individual patients. However, our findings support a more evidence-based approach to wound dressing selection, by integrating clinically relevant laboratory testing into the decision-making process. To summarise this point, bridging the gap between product development and clinical practice requires a combination of robust laboratory performance data and high-quality clinical evidence to establish both the safety and efficacy of wound dressings.

It is already evident that the EN 13726:2023 standard requires further revisions to accurately reflect clinical realities. Importantly, Annex L of the EN 13726:2023 standard acknowledges the limitations of 'Solution A' [2], stating that laboratories may opt to use alternative test fluids that better simulate wound exudate. This provision empowers industry and wound care institutions to request or generate FHC data obtained using clinically relevant SWFs, which makes the testing more appropriate for representing real-world applications. Notably, SWF-A has been made available for independent laboratory FHC testing [5], supporting the adoption of advanced SWFs in dressing evaluations. Moreover, the growing body of published evidence supporting simulated wound models, including FLUHTE and similar systems [10–13], demonstrates that integrating such methodologies into the next revision of the standard is both justified and technically feasible. Importantly, the modular structure of the EN 13726:2023 standard allows for the inclusion of informative methods within annexes, providing a clear and practical pathway for adopting improved testing approaches, even before the completion of Round Robin validation studies. This flexibility not only accelerates the incorporation of advanced testing methodologies but also promotes continuous improvement in wound dressing evaluation practices, ensuring that the standard evolves in line with emerging scientific evidence and clinical needs. These factors highlight the importance and urgency of aligning laboratory testing with real-world clinical conditions, facilitating more reliable, clinically meaningful wound dressing evaluations.

In conclusion, the findings emphasise the limitations of traditional laboratory methods for evaluating wound dressings and suggest innovative solutions to improve their clinical relevance. By using SWF-A and the FLUHTE system, researchers and manufacturers can generate more accurate data and predicted performance, helping clinicians to choose dressings based on

reliable, reproducible, standardised and quantitative evidence, as opposed to cost alone.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

Data sharing not applicable to this article as no datasets were generated or analysed during the current study.

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