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Fluid handling by foam wound dressings: From engineering theory to advanced laboratory performance evaluations

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Abstract

This article describes the contemporary bioengineering theory and practice of evaluating the fluid handling performance of foam-based dressings, with focus on the important and clinically relevant engineering structure–function relationships and on advanced laboratory testing methods for pre-clinical quantitative assessments of this common type of wound dressings. The effects of key wound dressing material-related and treatment-related physical factors on the absorbency and overall fluid handling of foam-based dressings are thoroughly and quantitively analysed. Discussions include exudate viscosity and temperature, action of mechanical forces and the dressing microstructure and associated interactions. Based on this comprehensive review, we propose a newly developed testing method, experimental metrics and clinical benchmarks that are clinically relevant and can set the standard for robust fluid handling performance evaluations. The purpose of this evaluative framework is to translate the physical characteristics and performance determinants of a foam dressing into achievable best clinical outcomes. These guiding principles are key to distinguishing desirable properties of a dressing that contribute to optimal performance in clinical settings.

KEYWORDS

absorbency and retention, adhesion of adhesive dressings, leakage and failure of wound care, testing methods and standards, treatment

Abbreviations: DFUs, diabetic foot ulcers; ER, evaporation rate; EPR, exudate production rate; FC, fluid content; FHC, fluid handling capacity; FLUHTE, fluid handling test equipment; MMPs, matrix metalloproteinases; MVL, moisture vapour loss; PUs/PIs, pressure ulcers/injuries; SWF, simulated wound fluid; VLUs, venous leg ulcers; WCL, wound contact layer; WVTR, water vapour transmission rate.

For affiliations refer to page 13

Key Messages

- We present bioengineering theory and practice for foam-dressing fluid handling.
- Emphasis is on structure-function relationships and advanced testing methods.
- We analyze the impact of material and treatment factors on fluid handling.
- We discuss dressing microstructure, viscosity, temperature and force effects.
- A new method for dressing performance testing named fluid handling test equipment is described.

1 | INTRODUCTION

1.1 | The clinical and financial consequences of poor fluid handling by wound dressings

Production of exudate, a fluid that results from tissue damage and associated inflammation, is a normal and integral part of any wound healing process.[1] This fluid, rich in proteins and white blood cells, necessitates effective exudate management to maintain a moist wound-bed environment, a key element for healing.[1] Wound dressings, applied to various wound types, for example, surgical incisions, traumatic lacerations, diabetic foot ulcers (DFUs), pressure ulcers/injuries (PUs/PIs) and venous leg ulcers (VLUs), play a fundamental role in regulating the moisture in this environment.

Exudate management involves diverse requirements, from eliminating excess fluid to maintaining moisture for dehydrated wounds. Healthcare professionals must carefully choose dressings based on clinical evaluations, considering their impact on clinical outcomes and financial implications. Inadequate fluid absorbency and retention in a dressing can result in issues like exudate pooling, backflow or leakage, raising the risk of skin damage, infections and other wound complications.[2,3] Exudate from chronic wounds contains harmful components, hindering wound healing.[4–8] Dressing failures in exudate management can therefore lead to challenges such as delayed healing, overhydration and leakage, impacting the quality of life of patients. Psychosocial impacts may include impaired daily activities, pain and increased consumption of healthcare resources.[9,10] Notably, concerns about (foam) dressings causing dryness lack scientific evidence, with overhydration being the primary concern. Additionally, frequent dressing changes are costly in terms of materials and caregiver time.[11,12] The limited research on fluid handling capacity (FHC) in dressings emphasizes the need for advancements in this area to enhance wound care practices.[1,13,14]

1.2 | Factors affecting the fluid handling capacity of wound dressings

The FHC of modern wound dressings, including absorbency, retention and evaporation performance, is influenced by the characteristics of the inflowing exudate (e.g., its flow rate, composition, viscosity, surface tension and pH),[2] as well as by the unique specification of the dressing materials, structure and manufacturing process. Wound characteristics vary among patients and change over time, making a simplistic approach to dressing categorization flawed. Grouping dressings with polyurethane foam materials under 'foam dressings' and assuming similar performance are problematic. Key fluid handling metrics, including absorbency and retention, vary based on dressing materials and construction. The ability of dressings to allow continuous dissipation of absorbed exudate through evaporation depends on specific materials and construction, impacting the wear time[1] (Figure 1). Effective evaporation requires a dressing design that uniformly spreads exudate away from the wound pad surface, considering factors like wound aetiology, fluid viscosity, treatment protocol, environment and patient behaviour. Design goals must also ensure that moisture is kept away from wound edges and the peri-wound area. Attention is needed for localized dressing areas prone to oversaturation, particularly in vertical orientations (e.g., VLU or DFU treatments). Gravity may cause excessive saturation, leading to exudate backflow and leakage from lower dressing borders.[1,14,16–18] Various dressing features beyond the explicit 'fluid handling' further influence wound exudate management, including adhesive quality, impermeability for showering, gaseous exchange, temperature control and patient comfort and adherence. All of these factors can be, in fact, physically coupled to the fluid handling by the applied dressing type[3] and hence affect the fluid handling performance in real-world clinical settings.

Wound exudates, rich in serum, cell components and circulating proteins, exhibit diverse biochemical and biophysical properties based on patient and wound

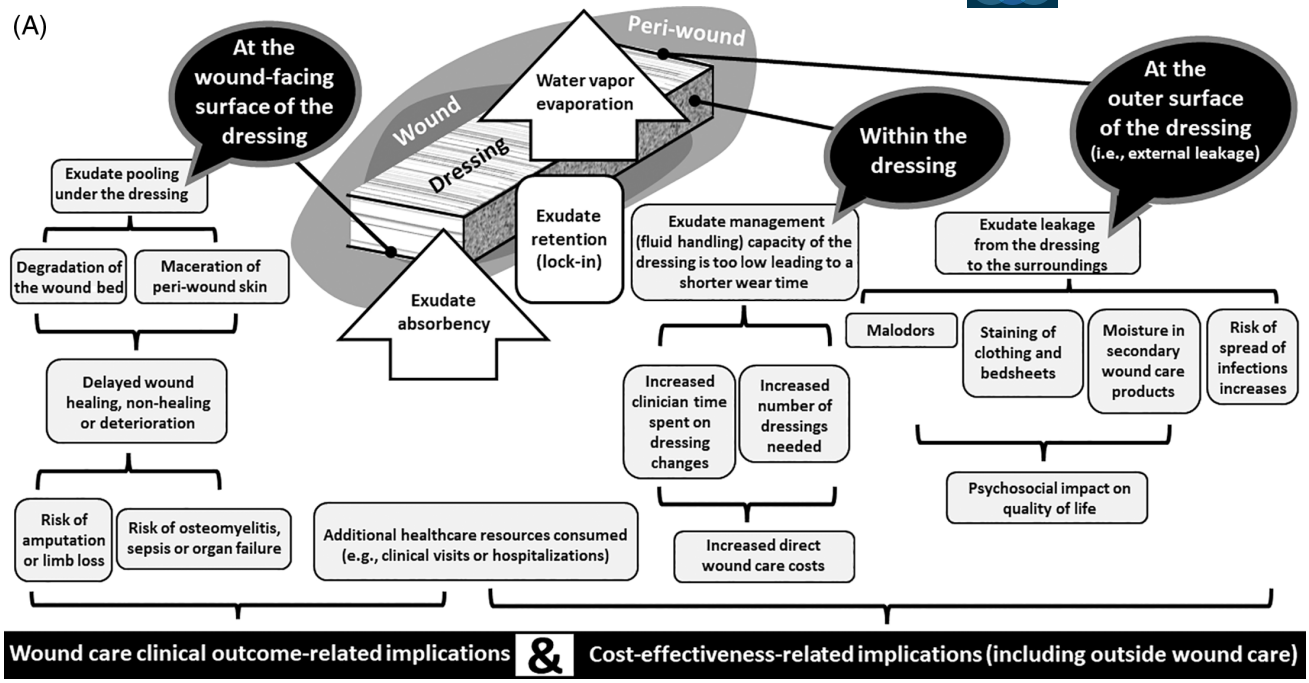


FIGURE 1 Wound care clinical outcome-related and cost-effectiveness-related implications of the performance of wound dressings (including outside wound care) depending on how specifically a dressing may fail to manage exudate in clinical practice: (A) Scheme of the factors involved in dressing failure scenarios. (B) An illustrative wound care case demonstrating the failure of a dressing involving a number of factors listed in panel (A), both at the wound-facing surface of the dressing and at the outer dressing surface. The case shown in panel (B) is of a 58 years-old male with a mixed wound aetiology (more venous than arterial). There are right medial and anterior superficial wounds, which were treated by a dressing and compression therapy. This patient could only tolerate low compression levels of approximately 20 mmHg and had returned to the clinic of author TS with the wound and exudate noted in the photos. The patient was visited by a district nurse twice a week but on the day when the photos were taken, the dressing has leaked massively. Visual inspection of the exudate type suggested that this patient might had local infection colonized with *Pseudomonas* and it was only after cleansing that the wound care clinician could determine that it was not a spreading infection. The dressing was supposed to be highly absorptive, however, due to gravity and possibly how the patient sleeps that dressing was clearly ineffective in capturing the wound fluid. The exudate gathered at the edges and was held by the film of the dressing, pooling at the edges and causing inflammation and maceration of the peri-wound. To treat the condition documented in panel (B), the wound and peri-wound were cleansed with antiseptic solutions and then mechanically debrided. A topical antimicrobial fibre dressing was applied, and a non-adherent absorbing secondary dressing was used along with the compression. The frequency of dressing changes was at least twice a week but may have increased if the level of exudation warranted it. Importantly, the leakage of wound fluid into the sides of the dressing caused substantial damage to the peri-wound. There are also multiple pressure points from the dressing, which likely exacerbated the inflammation of the peri-wound. In addition, it is noteworthy that although the dressing capacity to absorb more into the dressing was visible, the dressing did not have the capability to wick that fluid laterally to be absorbed vertically. Of note, the dressing failure case presented in panel (B and C) is a representation of a well-recognized problem that is associated with different wound care dressings manufactured by various companies. (C) Clinically documented cases of failure of different dressing products, related to the dressing selection interacting with the practice of treatment (courtesy of author TS).

characteristics, and healing stage.[20,21] Differences include pH levels, nutrient and mineral content, proteins, electrolytes, inflammatory mediators, enzymes (e.g., MMPs), growth factors (e.g., basic fibroblast growth factor) and cellular elements (e.g., neutrophils, macrophages and platelets).[22–27] Additionally, exudates may harbour various microorganisms, some pathogenic, contributing to wound deterioration.[28,29] Overall, these variable exudate components altogether determine the physicochemical properties of the fluid, including its surface energy[4] and surface tension, as well as its viscosity, which in turn influence the ability of the exudate to be effectively absorbed, and once absorbed, spread within the dressing structure, including under gravitational or any external (compressive, shear or combined) forces that may deform the dressing (Figure 2).

These considerations point to a paradox in current efficacy research and industry evaluations of dressing performance in the aspect of fluid handling, which are predominantly based on the European Testing Standard EN 13726 (originally published in 2002–2003 and revised, renamed and made available as EN 13726:2023 by the European Committee for Standardization, CEN, in September 2023[31]).[5] This standard utilizes water solution of sodium chloride and calcium chloride, which completely ignores the above complexity of fluid

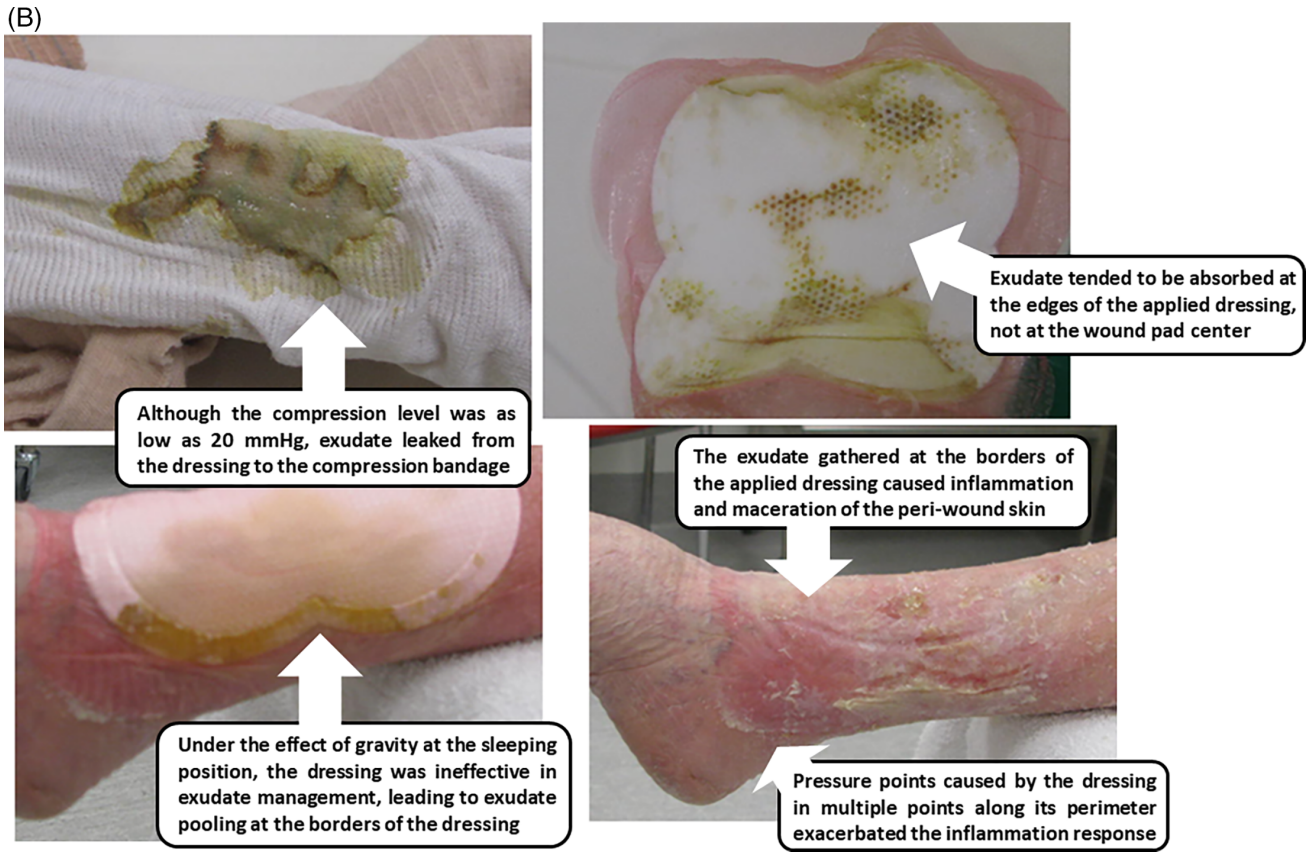


FIGURE 1 (Continued)

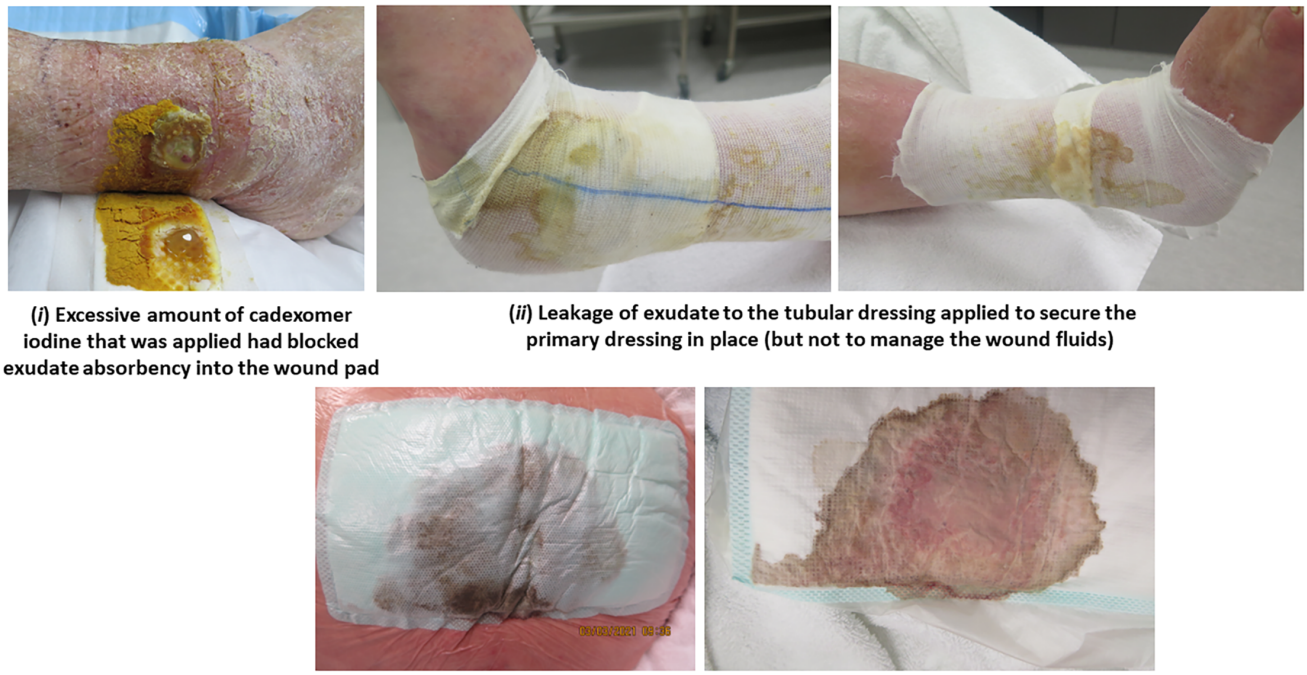
chemistry, physics and mechanics of real-world wound exudates.[1,13,14,18,32–34] The presence of proteins in an exudate, which is ignored in the EN 17326 standard, strongly influences the surface tension and viscosity of the fluid[6,7] and, in clinical practice, may vary from that of a watery exudate to a thick and tenacious discharge.[15,36–38]

Wound dressing performance, influenced by material, structure and manufacturing, varies significantly across manufacturers even within the same sub-class, for example, foam dressings[13,16,17,39] (Figure 2). Optimal functionality requires efficient absorption, spreading, retention and evaporation of diverse exudates during clinical use. Fluid handling evaluations with simulated wound fluid (SWF) types reflecting specific wound characteristics are crucial, highlighting limitations in the EN 13726 standard.[1,14,40-42] Clinicians qualitatively describe wound exudates, but subjective language impedes the development of standardized bioengineering tests and metrics for dressings.[12,15,43] Without quantitative definitions, subjective clinical assessments can overshadow cost considerations in healthcare organizations. Standardized bioengineering tests aim to identify dressing failure modes and inform users of potential challenges in various wound care scenarios, promoting safety and quality control.[13,14,16,17,44] Rigorous experimental designs and quantitative measurements can guide optimal dressing selection, prevent complications, reduce costs and improve the quality of life of patients in need of wound care.[45-47] A cost–benefit study showed that unhealed wounds cost 2.5 times more than healed wounds, emphasizing the importance of effective wound dressing designs in minimizing costs and maximizing clinical effectiveness.[48] Laboratory efficacy research and clinically relevant testing standards therefore act as gatekeepers to enhance clinical effectiveness and optimize care costs.

1.3 | Focus on bordered foam dressings and the specific objectives of the current work

Bordered foam dressings, a central category of advanced wound dressings, feature a foam component for absorption and adhesive borders. They serve as both primary and secondary dressings for various wounds, offering exudate absorption, insulation and mechanical protection. As primary dressings, they create a moist wound healing environment. When used as secondary dressings, they act as reservoirs for absorbed fluids, providing

(C)



(*i*) Excessive amount of cadexomer iodine that was applied had blocked exudate absorbency into the wound pad

(*ii*) Leakage of exudate to the tubular dressing applied to secure the primary dressing in place (but not to manage the wound fluids)

(*iii*) Leakage of exudate from the lower edge of the dressing onto the peri-wound skin, shown at the external surface of the dressing (left frame) and confirmed at the wound-facing side once the dressing was removed (right frame)

FIGURE 1 (Continued)

additional biological and mechanical protection. The wear time of these dressings in clinical practice depends on factors like exudation level, infection status, peri-wound skin condition, contours and movement of the injured area, body weight, external forces and the need for clinical evaluations.[8,49,50] Creating a dressing with consistent fluid handling over days and formulating instructions for sustained effectiveness throughout the intended use pose major engineering challenges.

Bordered foam dressing products differ significantly among manufacturers in size, shape, thickness and the types and number of internal layers they contain, not all of which are necessarily foam materials.[9,51] Sussman[53] classified foam dressings as 'true foams', utilizing air spaces in hydrophilic polyurethane versus 'pseudo-foams', which physically expand, like those with embedded superabsorbent polyacrylate particles to enhance fluid handling. Regardless of whether a certain foam-based dressing is a 'true foam' or a 'pseudo foam', the chemistry and microarchitecture of the foam material/s such as the pore sizes, shapes, connectivity and the pore gradient[10] will affect the extent and rate of exudate absorbency into the dressing materials (Figure 2).

A typical multilayer bordered foam dressing comprises the following components (from the wound surface outwards): (i) A nonadherent, non-linting silicone-based mesh as the wound contact layer for gentle removal; (ii) an absorbent hydrophilic wound pad layer made of semipermeable open-cell polyurethane foam; (iii) a backing film for protection against external bacterial contamination and continuous fluid evaporation; (iv) an adhesive border, often made of soft silicone.[11,54–57] In some foam-based dressings, the foam serves as the initial absorbent layer collecting fluids from the wound. For instance, hydrophilic foam layers in dressings transport exudate internally to a superabsorbent layer, preventing backflow to the wound bed or peri-wound. Advanced dressings often incorporate a spreading layer between the absorbent foam and superabsorbent layer for uniform exudate transfer, thereby ensuring an effective lock-in action. In multilayer foam dressings, absorbed exudate is initially taken up by absorbent components and then retained in a retention layer, allowing evaporative fluid release through the backing film, to extend the useful life of the product.[58] Foam dressings may also lack adhesive borders (and then they are termed non-bordered) and/or may be impregnated with antimicrobial agents for treating infected wounds, such as ionic silver.[12] Efforts have been made to include various substances in foam dressings, such as bismuth, Manuka honey, chlorhexidine, polyhexanide (PHMB), methylene blue, cadexomer iodine, antibiotics (e.g., ciprofloxacin), antifungals (e.g., gentian violet) or surfactants for biofilm removal.[59-67]

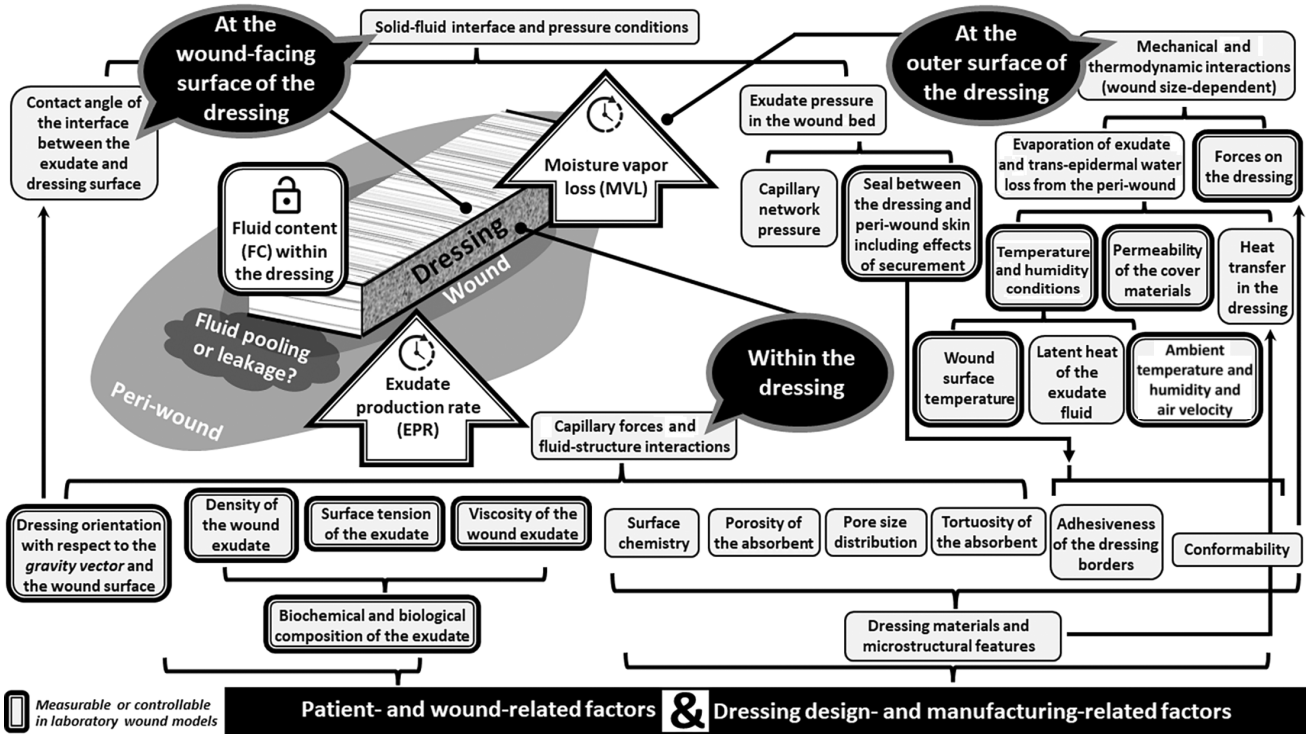


FIGURE 2 Patient-related and wound-related factors as well as dressing design-related and manufacturing-related factors that may associate with the failure of a dressing to handle wound fluids in a clinical setting (of note, there may be additional factors involved that were not considered here, but the many factors listed demonstrate the complexity of the relevant physico-chemical interactions). Failure of the dressing to handle the fluid is often a result of the exudate production rate (EPR) exceeding the sum of the absorbed or retained fluid content (FC) that can be locked-in within the dressing and the moisture vapour loss (MVL) per unit time. The occurrence of EPR > FC + MVL over a critical time period may result in overflow of the applied dressing. This then leads to pooling of exudate in the wound bed under the dressing or spillover/leakage of exudate outside the dressing, which may compromise the wound bed and peri-wound skin and/or stain the clothing and bedsheets and create malodors, or affect medical devices (e.g., secondary or compression bandaging) in the vicinity. The clinical and cost-effectiveness implications of such events were depicted in Figure 1A.

Additionally, foam dressings with ibuprofen for topical pain treatment are available. Combining foam dressings with other topical treatments may significantly impact their fluid handling characteristics, altering their macro/microstructure, micro-surfaces, overall foam chemistry and potentially influencing the exudate composition and secretion rate; no published studies quantified these effects. Recent research using novel robotic wound systems highlighted challenges with commercially available foam-based dressings in highly exuding wounds, wounds with viscous exudates or wounds with localized exudate concentrations due to positioning.[1,13,14,16-18,68,69]

This article provides a comprehensive review of the scientific theory and practice of evaluating fluid handling performance in foam-based wound dressings. Emphasizing clinically relevant engineering structure–function relationships and advanced laboratory testing methods, the work introduces a novel wound simulator for standardized, industry-oriented pre-clinical quantitative evaluations. Technical formulations, derivations and data are included in multiple Appendices for readers interested in the mathematical–physical and engineering details. Key results are presented in the main text, offering clinical relevance to wound care for a diverse readership including scientists, engineers, clinicians, hospital administrators, insurers, reimbursement bodies and regulatory authorities.

2 | SIMPLIFIED MODEL OF FLUID HANDLING BY A MULTILAYER DRESSING

'Foam' dressings can have multiple design features and be constructed in numerous different ways resulting in many unique functions. There can be a combination approach to include various foam materials, or foams can be further combined with nonwoven and superabsorbent layers in multilayer dressings. As a scientific introduction to the topic, and to illustrate the effects of material specifications and material combination selection in foam dressings, we will use Darcy's law to explain concepts of material design.

Darcy's law describes the flow of viscous fluids in porous media, and it is therefore a useful first and simple approximation[13] to explain the synergistic interactions between key wound-related, dressing-related or treatment-related physical factors and their impact on the absorbency and overall fluid handling of foam-based dressings. Such factors are the fluid viscosity and temperature, action of external forces (e.g., a VLU treated by a dressing over which compression therapy is applied) or the dressing microstructure (e.g., the porosity which depends on both the dressing design and application of external forces) (Figure 2).

Darcy's law determines that there is a proportional relationship between the flow rate and the pressure gradient, that is, the more pressure forcing fluids to discharge from the wound bed the greater the exudation rate. Darcy's law further governs an inverse relationship between the exudate flow rate (the fluid volume flowing through the wound contacting surface of the dressing per unit time) and the viscosity of the fluid, that is, the less viscous (thinner) the exudate is, the higher the flow rate of exudation.[13] Through these relations and the dimensions of the problem (surface area and thickness of the dressing materials), Darcy's law is used to compute a fundamental property of porous materials, including foams in dressings, which is the *permeability*.

In simple terms, the permeability is a measure of the ability of a porous material (such as foams) to allow fluids to pass through it.

A detailed analytical-mathematical analysis of Darcy's law applied to foam-based dressings and the formal definition of the permeability constant of a material are provided in Appendix 1. The derivations in this Appendix lead to several primary implications with regards to the fluid handling performance of multilayer foam dressings, as follows: (i) The thickness and permeability of individual layers in multilayer foam dressings interact, impacting the overall absorbency. (ii) The least permeable layer between the wound bed and the core of the dressing (typically the retention layer) acts as a significant barrier to exudate flow. (iii) The permeability of preceding layers is crucial for fluid handling; suboptimal properties may hinder exudate penetration, leading to poor retention.[13] (iv) The outer backing layer, often a semi or totally occlusive film, influences fluid transfer between adjacent dressing layers and evaporation rate, affecting the fluid occupancy.[13] (v) Dressings face challenges with highly viscous exudates (Figure 1) as the flow rate is inversely proportional to the fluid viscosity.[1,13,16,47]

Darcy's law is used here (Appendix 1) to develop a relatively simple, introductory physical theory to explain certain basic science principles affecting fluid flow in multilayer foam dressings, in particular the effect of viscosity on the rate of exudation (albeit ignoring the influence of transient flow changes, capillary action, gravity and external forces, as well as evaporation). The current derivation based on Darcy's law (Appendix 1) can serve as an educational example for why wound dressings can perform differently across various wounds with a similar size, or even on the same wound at different healing stages or when the viscosity of the exudate changes. Darcy's law also elucidates that the FHC of any foam dressing depends on the dressing materials and structure, that is, on the permeability of each layer a multilayered dressing (Appendix 1), which are unique to the manufacturer.

Thereby, bordered foam dressings cannot be used as a generic term; each bordered foam dressing will perform differently, including in fluid handling aspects. Lastly, it should be noted that Darcy's theory (Appendix 1) only focuses on permeability and does not explain why wound exudate viscosities differ across wound etiologies, types and healing stages. Further, it does not consider additional key aspects in the function of wound dressings, that is, the effects of gravity and bodyweight forces (e.g., a patient walking on their dressing) or external forces (e.g., from skin-contacting medical devices) as well as capillary action; these additional topics are addressed in the following sections.

3 | HOW IS THE FLUID HANDLING AFFECTED BY EXUDATE COMPOSITION AND PROPERTIES

The viscosity of wound exudates can vary widely due to many physico-chemical factors, including the molecular surface charge and conformation of proteins, the numbers of suspended cells, pH of the wound environment and the concentration of suspended salts, as indicated by Zhang & Liu[70] for concentrated protein solutions. However, in the specific context to wound exudates (where the pH and molecular profile are bounded within pathophysiological ranges), the free protein contents within the exudate and the temperature of the exudate are key factors.

Specifically, it is well established that the viscosity of a protein-containing fluid increases with the concentration of the proteins in the solvent (i.e., the 'carrier fluid' such as a serous fluid) and numerous theories were developed to quantify this phenomenon in the biopharmaceutical literature (as reviewed by Gonçalves et al.[71]). Einstein's theory (Appendix 2) is the simplest physical description for this phenomenon. It explains the increase in viscosity by the increase in nanoscale friction of the

relatively large and long protein molecules against each other when flow occurs, which intensifies when more protein molecules are present in the fluid. In infected or surgically debrided wounds, the volume of protein in exudates tends to increase over time,[23,24] rendering the fluid more viscous.[9,37] In addition to the nano-frictional interactions between protein molecules contributing to a rise in the fluid viscosity, the presence of microorganisms would have a similar and cumulative effect, as individual microorganisms or bacterial aggregates in the liquid culture (as in biofilms) may also frictionally slide against each other or collide during fluid flow (for above-critical concentrations), which slows down the flow.[14,72,73] Of note, the major proteins present in a wound exudate (besides albumin) are fibronectin and fibrin(ogen), which are both large and sticky proteins. Fibronectin is generally present as an extracellular matrix for cells to adhere to and fibrin(ogen) is forming a matrix to trap red blood cells and thereby, prevent bleeding. Hence, not only does the amounts of proteins affect the exudate viscosity but also, the specific protein content and in the case of wound exudate, there is a large quantity of sticky matrix proteins and fragments thereof present and a large variability in these exudate compositions across patients and wounds. Using scanning electron microscopy of specimens from in vivo soiled dressings, Malone et al.[19] recently showed that protein structures are indeed forming on hydrophobic dressing surfaces.

Another important factor influencing the exudate viscosity is temperature. Gethin et al.[74] reported that the weighted mean of means for wound-bed temperatures was 31.7°C for VLUs, 31.6°C for DFUs; 33.3°C for PUs/-Pis; 30.9°C for mixed arterial venous ulcers; and 32.0°C for wounds with unknown aetiology. Based on their comprehensive review work, Gethin et al.[74] determined that mean wound-bed temperatures for chronic wounds are typically within the domain of 30.2–33°C, that is, the temperature means vary across a range of nearly 3°C.[15] Increased local wound-bed temperature is one of the classic signs of wound infection and inflammation due to vasodilation. A wound is expected to exhibit a lower temperature after the inflammatory phase or after the infection was resolved. The above temperature range may be significant in terms of its potential influence on the exudate viscosity, as fluid viscosity is strongly temperature-dependent.[75] The most common formulation of this relationship is the Andrade equation, $\eta = \alpha e^{\beta/T}$, which indicates that the viscosity of fluids η decreases as the temperature T increases (α and β being empirical constants). Another simple variation of this is a power law, $\eta = \Gamma t^{\delta}$, and the accuracy of both can be improved by adding terms and parameters.[76] Given the exponential or power-law nature of these phenomenological descriptions, clinically relevant wound temperature changes may have a meaningful influence on the exudate viscosity. For example, Harkness[77] reported that the sensitivity of plasma viscosity to temperature changes is approximately 2%–3% per degree Celsius within the 15–40°C range, hence, even a 3°C temperature variation related to the wound aetiology, or its inflammatory status as reported by Gethin et al.[74] may affect the exudate viscosity by 6%–9%, which is far from negligible. Accordingly, for consistently studying the performance of wound dressings in managing viscous exudates in a laboratory setting, the wound model temperature must be controlled. However, given that a relatively narrow range of mean wound-bed temperatures have been observed empirically, the impact of the protein contents and microbial load in the exudate on its viscosity should exceed that of the wound temperature, as explained in Appendix 2. With that said, in wounds where the temperature is expected to increase after a dressing change, the exudate will become less viscous and therefore, per the above physical principles, flow faster. Failure of a clinician to recognize and consider this may result in suboptimal clinical outcomes. Likewise, in a clinical context, infection of the wound-bed changes its pH conditions, typically producing exudate fluids with a more alkaline pH,[78,79] which may interact with the surface chemistry of the dressing, and hence, the wound dressing interaction must be viewed by a clinician as being subjected to potential changes over time.

The permeability of individual dressing layers (and therefore, the average or effective permeability of the dressing as a whole) to the exudate further relates to the microstructure of the material components, namely, both to the porosity Ø (total fraction of the spaces in the solid polymer in the foam, which ranges from zero to unity) and to the interconnectivity in the foam microstructure, as detailed in Appendix 3.[80] External mechanical forces may have additional influence on the microstructure of foams. For example, even though the total free volume in the foam is decreased due to external compressive forces, the capillary force may increase and compensate for the loss of reservoir volume by spreading exudate in the foam through capillary action. Of course, again, the wound dressing interaction must be seen as inherently unstable, for example, in a patient with a DFU who is walking and causing microtrauma to their wound due to the repetitive stresses, the exudate flow rate will likely increase post-walking, thus affecting the above absorbency interactions in the dressing.

In this regard, the Lucas–Washburn equation indicates that the capillary pressure rises with the surface tension and with a decrease in the pore size.[81] Furthermore, the Young-Laplace equation consistently

demonstrates that the capillary pressure increases with the curvature of the microstructure, which in turn should typically increase due to any macro-deformations applied by external forces on dressing materials.[82] Derivations of these complex interactions are outside the scope of the current article and are mentioned here for completeness. In addition, as demonstrated analytically in Appendix 3, identical applied external mechanical forces will have distinct effects on the fluid handling of foam dressings containing different foam materials, which is yet another example for why it is misleading to categorize foam dressings made by different manufacturers as a unified 'class' of products and then continue to assume that their function will be equivalent.

To summarize this part, from a clinical perspective, exudate viscosity and volume serve as indicators of the wound status. High viscosity and/or volume may suggest inflammation or infection, potentially linked to changes in pH and/or temperature, indicating high protein content. Conversely, watery exudate may result from low protein content, such as malnutrition or patient hydration levels. The amount of the secreted exudate is also a clinical indicator; low production may signal dehydration or hypovolemic shock. The fluid handling performance of applied dressings is influenced by their specific materials and construction, interacting with individual medical conditions and the wound environment. These factors can be formulated in bioengineering theory for scientific evaluations of dressing performance in fluid handling (Appendices A2 and A3).

4 | THE ROLE OF CAPILLARY ACTION TO MITIGATE GRAVITY FORCES ACTING ON EXUDATE

The capillary uptake or transport of fluid within a given dressing is essentially a property of the dressing materials and is quantified using the measure of sorptivity. This describes the extent to which exudate fluids can be lifted and moved away from the wound surface through a capillary effect, even if the gravity vector is opposing the direction of the flow into the dressing (Appendix 4). Good sorptivity of a wound dressing is essential for absorbing and retaining excess exudate, particularly if the dressing should absorb wound fluids against the influence of a gravitational force, as some patient positions and wound locations may require in clinical practice. Low sorptivity of the dressing will cause a so called 'plugging effect'[47] where the dressing essentially acts as a plug, hindering fluid flow from the wound bed and into the depth of the dressing. This promotes exudate pooling (accumulation) under the dressing and does not facilitate the sufficient transfer of fluid into the core of the dressing and towards the backing film from where it can evaporate.

Such plugging eventually also promotes backflow of new inflowing exudate back into the wound bed making the dressing excessively wet, or promoting leakage from the dressing that can cause maceration, spillovers and staining of the clothing and bedsheets, malodors and overall exacerbation of the wound and patient conditions[14] (Figure 1A). As a consequence of this backflow, microorganisms and microbial compounds can return to the wound bed and increase the risk for colonization, infection and inflammation. It is important to note that the level of sorptivity achieved by a certain dressing that is applied to a specific wound is influenced by the individual patient and wound characteristics (through the unique exudate content and viscosity which affect the sorptivity into certain material types), by the specific dressing materials and microarchitecture, and by the interaction of the specific dressing and wound. All of the above physical, chemical and biological wound dressing interactions are further influenced by the environmental conditions of the wound such as the presence of external forces or the orientation of the wound and dressing with respect to the gravity vector, as demonstrated in Appendix 4.

5 | MOISTURE VAPOUR TRANSMISSION THROUGH THE DRESSING

Foam dressings must effectively transmit water vapour between the wound and external environment, quantified as the moisture vapour loss (MVL) or water vapour transmission rate (WVTR), expressed as $g/m^2/24$ h. The WVTR is calculated as $(MVL/\Delta t)\cdot 24/A$, where MVL is the mass of water loss, Δt is a time interval and A is the effective transfer area for the dressing.[83] The WVTR is influenced by various factors including exudate composition, wound and peri-wound temperatures, ambient conditions, air velocity, backing film properties, additional coverings and the wound orientation (Figure 2). Achieving clinical relevance requires testing in wound simulators, which allow to consider these factors simultaneously. The EN 13726 FHC test, while a best-case scenario, may not represent real-world conditions accurately. Factors like the gravity vector, fluid types, relative humidity (RH) and air velocity in the test may differ from clinical settings, affecting the MVL. Reference values for intact skin and open wounds highlight the importance of optimizing WVTR to regulate wound hydration[84,85] (Appendix 5). Desired WVTR values

depend on exudation levels, but reported laboratory values may overestimate those in clinical settings. Queen et al.[86] suggested 2000–2500 g/m^2/24 h for optimal moisture without desiccation risk. Dressings with advanced wound contact layers can maintain higher WVTR, emphasizing the need for a holistic approach in dressing selection.[82,87-90]

6 | LABORATORY TESTING OF THE FLUID HANDLING PERFORMANCE OF WOUND DRESSINGS

6.1 | The current state of the art in laboratory fluid handling testing methods

Most modern wound dressings are multilayered dressings designed to absorb, spread and retain wound exudate differently in their individual layers.[11,91-94] The backing films of wound dressings are often designed to be breathable in order to facilitate continuous evaporation of the absorbed exudate. The ability of a given dressing to handle wound exudate should be studied as a time-dependent process, whereby the exudate enters the dressing from the wound interface, is then absorbed and spread into the wound pad and is finally evaporated from the backing film. Furthermore, wound dressings must be able to retain the inflowing exudate such that it is unlikely to flow back to the wound, pool at the wound cavity or leak out onto the peri-wound skin. Additionally, under the presence of external mechanical forces that may occur during normal wear and deform the dressing, the wound dressing must maintain a similar performance as described above. The performance of wound dressings therefore depends greatly on their specific materials and the construction chosen for the design of the specific dressing. To compare the efficacy of exudate management across different wound dressings, experimental systems and/or methodologies that are clinically relevant are required. This includes the ability to better mimic the pathophysiology of real wounds and to incorporate the relevant protocols of wound care and common patient behaviours. Such systems can also be in the form of robotic (synthetic) patients or wounds, which allow researchers to test the performance of dressing materials under realistic conditions that can be standardized and repeated.[17,47] Alternatively, industry-oriented laboratory methods can be developed with a focus on robust and easily reproducible testing, as a practical approach leading to industry testing standards suitable for global implementation among dressing companies and regulatory bodies.

Clinical observations and patient feedback about problems associated with leaking wound dressings (and the resulting frequent dressing changes and reduced patient quality of life), despite the dressings being far from full/saturated, are common and are well documented in the wound care literature.[1,14,15,68,74,95,96] This is exemplified in Figure 1B; the dressing failure mode shown in this panel is common and characteristic to many products from a broad range of wound care companies. Standard fluid handling tests for dressings, which includes the industry EN 13726 test, are commonly used for both performance comparisons and product development to reduce the likelihood of such clinical observations and also to guide healthcare professionals to match clinical wound observations with the appropriate dressing. The fact that these types of dressing failures still commonly occur is therefore suggestive that current test methods, including the EN 13726, are insufficient predictors of real-world clinical performance. Furthermore, it has been argued that existing testing standards to evaluate fluid handling are oversimplified, leading to insufficient information regarding the performance of many advanced wound dressings. This is particularly true for many of the multilayered silicone foam dressings that are designed to handle wound exudate by combining distinct functionalities and materials. The outcome of such design flaws essentially translates into a dressing that performs well in the laboratory but fails or demonstrates poor clinical performance when used on patients.

In the standard for wound care dressings EN 13726, several tests are based on fully saturated dressings, such as the 'Free-Swell Absorptive Capacity' test and the 'Fluid Handling Capacity' test, which are providing only a gross value of the maximum fluid a dressing can absorb. Specifically, as dressings are soaked in saline solution and brought to a fully saturated state, information on the extent of absorption and lateral spreading in each of the individual layers of the dressings and how it has progressed over time cannot be obtained.[1,14] Moreover, critical data regarding interactions between the MVL (or the WVTR) from the backing film and the capacity to absorb (additional) exudate over an extended time are not acquired with this FHC test (EN 13726).[16] Lastly, the EN 13726 standard does not realistically consider effects of external or environmental factors such as the influence of the ambient temperature, relative humidity or gravitational forces. Nor does it consider wound-specific characteristics, for example, the exudate flow regime, rate of flow and exudate composition and viscosity. These factors can greatly affect the entire fluid handling metrics of dressings as demonstrated in the current article. Considering these important criticisms, there have been calls for the development of more

clinically relevant bioengineering test methods that take into account a wider range of factors and provide more detailed information about the fluid handling performance of wound dressings.[1,14,32] In addition, over the years, several different advanced laboratory wound models and associated SWFs have been developed, with the aim of allowing fluid handling by dressings to be researched and product performance to be quantitatively evaluated in more clinically relevant ways.[16-18,32,40-42,47,97] Despite these advancements, none are implemented in any current industry standard. The main purpose of advancing bioengineering laboratory tests is therefore to identify *clinically relevant* conditions where a certain wound dressing may fail, as well as to provide guidance to clinicians as to which dressing is more likely to meet the needs of the patients and wounds they are treating. Thus, any new laboratory test method should be representative of the ability of a dressing to sufficiently manage wound exudate, either temporarily or consistently, in an objective, standardized and quantitative manner.

Dressing failures that include backflow of exudate into the wound bed, or spillover onto the peri-wound skin may be identified in sufficiently accurate and sensitive laboratory tests for certain products. This can then, for example, be useful information to inform clinicians, averting them to usage of these products under certain clinical or wound-related scenarios. In doing so, realistic laboratory test methods can ensure a wound care product is used on the right person, for the right wound at the right time. This may reduce the risk of maceration of the peri-wound area and further wound deterioration, leading to an overall improved patient health status and quality of life (e.g., due to pain, exudate leakage and malodor) and reduced care time and costs in clinical practice.[45-47]

6.2 | A contemporary laboratory testing method for studying the fluid handling of dressings

In the aforementioned context, we describe herein the fluid handling performance data of commercial wound dressings obtained using a contemporary wound simulator, which builds on existing literature and the theoretical knowledge described above. The main goal is to illustrate the applicability of this clinically relevant wound simulator under standardized, reproducible laboratory testing that is suitable for direct implementation by industry and regulators as well as for decision-making by healthcare procurers. The current wound simulator was designed to allow objective delineation of wound dressings performance parameters and identify conditions where certain wound dressings may fail to sufficiently manage exudate. Given the limitations of existing fluid handling tests, the new wound simulator represents a considerable improvement relative to current test methods, particularly with respect to the fluid handling test methods in the EN 13726 standard. Specifically, the wound simulator, named the fluid handling test equipment (FLUHTE; Figure 3A), was designed to mimic the cylindrical shape of the lower leg and is positioned vertically to encompass the effect of gravity on the spreading of exudate within the absorbent materials of the dressing under investigation.[16–18] Importantly, the current FLUHTE wound simulator allows control of several well-recognized factors

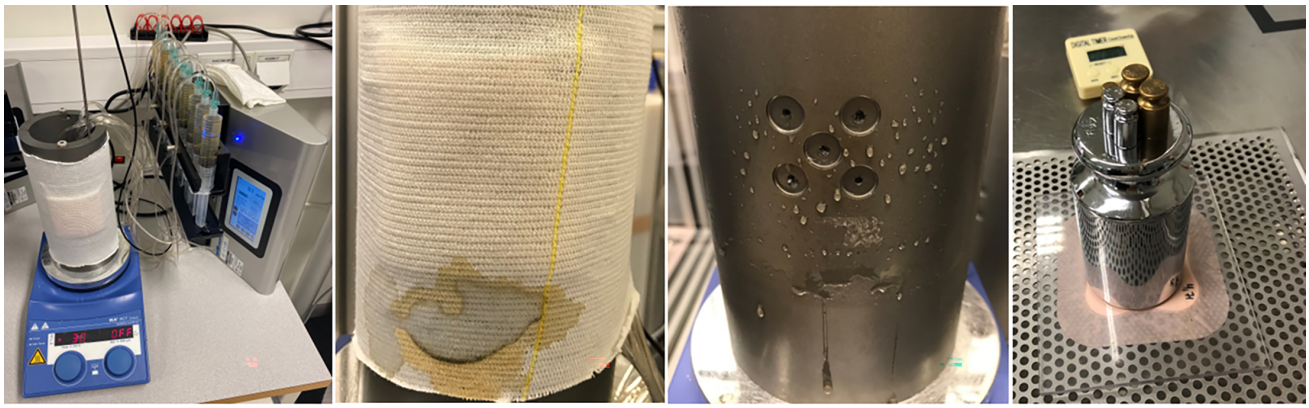


FIGURE 3 The FLUHTE (acronym for 'fluid handling test equipment') wound leg simulator with its heating plate and computer-controlled syringe pump (A). Examples of fluid handling after simulated use for 24 h at a flow rate of 0.75 mL/h is shown, demonstrating leakage of simulated wound fluid (SWF) to the secondary bandage by dressing F (B), pooling of SWF (0.34 g) on the leg model after removal of dressing E (C) and a retention test of dressing post simulated use at 40 mmHg (D).

affecting the fluid handling properties of dressings, for example, the ambient and wound temperatures, relative humidity and the associated evaporation from the tested dressing, the exudate flow rate, gravitational force directing the flow to the lower region of the dressing, compression bandaging and the specific composition and viscosity of the SWF (Figure 2). For a more detailed, technical description of the FLUHTE wound simulator and relevant experimental results demonstrating differences in fluid handling performance, see Appendix 6 and Figures 4, 5.

7 | SUMMARY AND CONCLUSIONS

This article extensively reviews and analyzes the theory and practice of evaluating the fluid handling performance of foam-based wound dressings. Emphasis is placed on understanding engineering structure–function relationships and employing contemporary laboratory testing methods. The 'foam' dressings category is hence dissected to highlight diverse product performances and challenges. Quantitative analysis and mathematical formulations in the set of Appendices address the effects of various factors on absorbency and fluid handling. While the EN 13726 testing standard is a starting point, it has considerable limitations, necessitating more advanced methods. The FLUHTE wound simulator is therefore introduced, and its superiority in assessing bordered foam dressings is demonstrated. Future FLUHTE applications may explore other dressing types, clinical scenarios and combinations with treatments. We consider FLUHTE superior to EN 13726 because FLUHTE focuses on better aligning laboratory measurements of fluid handling with real-world clinical outcomes while remaining practical for industry use; the latter distinguishes FLUHTE from recent academic research in the field.[16,17] Finally, we acknowledge the close, collaborative efforts required from clinicians, bioengineers and regulators to establish new, comprehensive laboratory test methods, criteria for medical claims, realistic SWFs and standardized metrics to improve confidence in dressing efficacy and related wound care quality of life and cost-effectiveness measures.

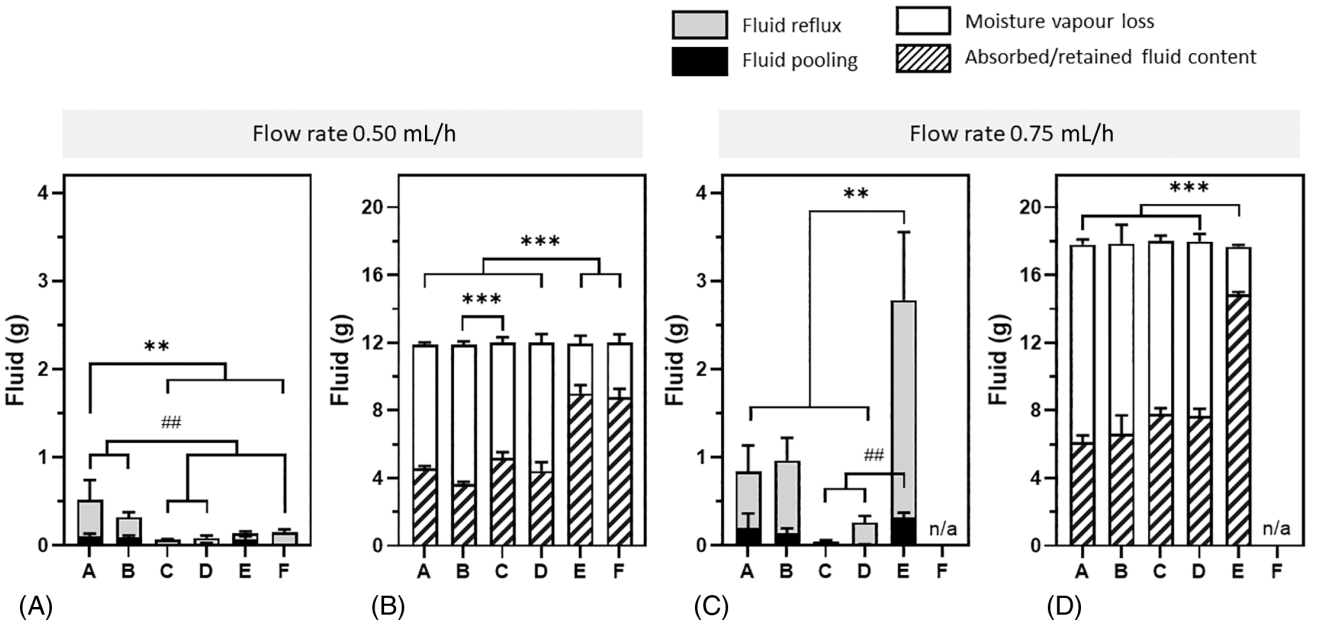


FIGURE 4 Fluid handling properties of six wound dressings marked 'A' to 'F', measured by means of the FLUHTE (acronym for 'fluid handling test equipment') wound leg simulator after simulated use for 24 h at a testing ('wound surface') temperature of 30°C. The flow rates were either 0.5 mL/h (panels A, B; $n = 4$ specimens per dressing type) or 0.75 mL/h (panel C, D; $n = 3$). Grey bars indicate fluid reflux; black bars indicate fluid pooling; white bars indicate moisture vapour loss (MVL); and hatched bars indicate absorbed or retained fluid content (FC). Error bars show the standard deviations from the mean values. One-way analysis of variance followed by Tukey pairwise comparisons was conducted to compare the fluid handling performance metrics of the tested dressings A–F in the FLUHTE apparatus. Horizontal brackets indicate that the dressing products underneath the bracket are significantly different. ** indicates significant differences in fluid reflux ($p \leq 0.01$); ## indicates significant differences in pooling ($p \leq 0.01$); *** indicates significant differences in both MVL and FC data ($p \leq 0.001$); n/a indicates dressing failure in fluid handling under the FLUHTE test due to leakage from the tested dressing product (for product F).

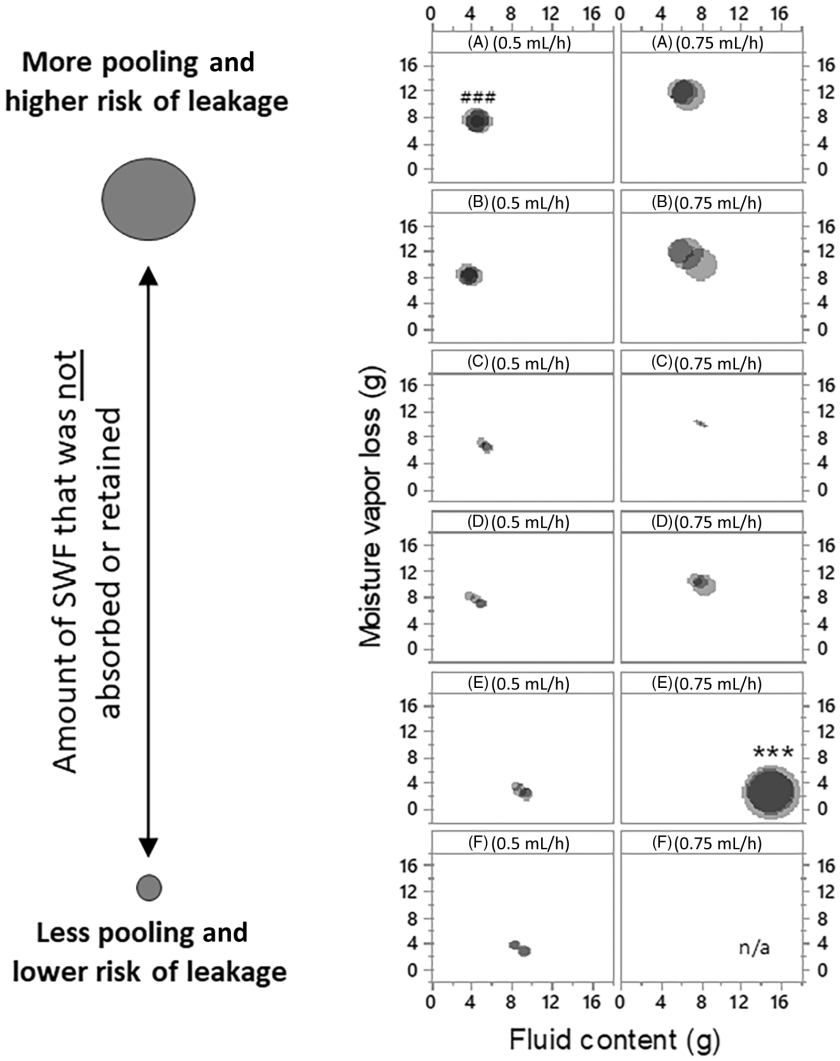


FIGURE 5 Fluid handling properties of six wound dressings marked 'A' to 'F' after simulated use for 24 h on the FLUHTE (acronym for 'fluid handling test equipment') wound leg simulator, at a 'wound surface' temperature of 30°C and flow rates of either 0.5 mL/h (left column; $n = 4$ specimens per dressing type) or 0.75 mL/h (right column; $n = 3$). The area of each bubble in the bubble plots is proportional to the total amount of fluid that was not absorbed or retained by the relevant dressing (A–F) with the position indicating moisture vapour loss on the *y*-axis and absorbed or retained fluid content on the *x*-axis. One-way analysis of variance followed by Tukey pairwise comparisons was conducted to compare the mean areas. ### indicates significant differences between product A versus C to F ($p \leq 0.01$); *** indicates significant differences between product E versus A to D ($p \leq 0.001$); n/a indicates dressing failure in fluid handling under the FLUHTE test due to leakage from the tested dressing product (F, for the 0.75 mL/h flow rate). SWF, simulated wound fluid.

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CONFLICT OF INTEREST STATEMENT

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

DATA AVAILABILITY STATEMENT

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

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ENDNOTES

[1] Wound exudate is not to be confused with 'transudate', which is a fluid caused by imbalances in pressure within blood vessels, characterized by low protein levels and a clear appearance; transudate is typically linked to non-inflammatory conditions like heart failure or liver disease.

[2] There is a complex interplay between physicochemical factors in the exudate of the specific wound and exudate management by a given applied dressing, for example, the pH of the exudate affects the solubility, chemical activity and physical properties of solubilized constituents such as proteins, which in turn affects the exudate viscosity, and hence the fluid handling performance of the dressing in use.[15]

[3] Protein adsorption into a dressing may, for example, affect the surface properties and topography of the dressing materials over time, which is sometimes referred to as 'host fouling'.[19]

[4] The surface energy of a fluid is defined as the sum of all the intermolecular forces that are on the surface of the said fluid, that is, the net effect of all the attraction or repulsion forces of the molecules in the fluid. The surface tension property of a liquid relates to its surface energy and is defined as the energy (in Joule) needed to create 1 m^2 of a new liquid–gas interfacial area. Generally, an exudate liquid with a lower surface tension will wet the wound pad of a dressing more easily.[30]

[5] The original EN 13726 standard cover test methods for primary wound dressings. The industry recognized, however, that a number of test methods included in the original documents needed revision to ensure that the test results remain relevant to modern dressing design. A revised version of the standard has therefore been produced to supersede the original document. This revised version EN 13726:2023 *Test methods for wound dressings—Aspects of absorption, moisture vapour transmission, waterproofness and extensibility* was made available by CEN on the 20 September 2023. URL: CEN - CEN/TC 205 (cencenelec.eu).

[6] For example, the surface tension of milk, which is a protein-rich, but not highly viscous fluid falls in the range of 44–60 mN/m at 20°C whereas that of water is 72 mN/m at room temperature.[35]

[7] In this regard, the pH level affects the isoelectric point of proteins and thereby, their 'stickiness'.

[8] The longest dressing wear times are associated with podiatry settings.[50]

[9] For example, in multilayer dressings, foams may be combined with nonwoven cellulose fluff and/or with superabsorbent layers.[13,52]

[10] The pore gradient in a foam is a measure of the extent by which the pore size distribution is continuous and uniform along a certain orientation. For example, a foam can be made with graded porosity so that the size of pores increases (or decreases) from the surface to the depth of the specimen.

[11] Advanced bordered dressings with silicone adhesive often use the same silicone in (i) and (iv).

[12] The agreed regulatory route for these dressings is that they help control bacteria within the dressing and from entering the wound and should be used in conjunction with antibiotic in infected wounds.

[13] It should be noted that Darcy's theory assumes that the porous materials in a dressing are already fully wetted (i.e., the transient effects of how a new, dry dressing initially absorbs exudate cannot be described using Darcy's theory). Likewise, gravity and external forces (e.g., from compression bandaging) and capillary action, which also influence the spreading of fluid in a dressing are not included in this analytical-mathematical description[18] (Lusting & Gefen, 2022). Lastly, Darcy's law does not consider the evaporation of fluid to the environment.[16,17]

[14] This supports the addition of antiseptic agents to biological test fluids used in laboratory performance evaluations of wound dressings, such as bovine or horse serum-based fluids, to eliminate bacterial growth and thereby better control the viscosity of the test fluid.

[15] The wound temperature range reported in the Gethin et al.[74] article for pooled data from seven reviewed studies (as opposed to the temperature mean values reported therein) was 25.1–35.3°C (for 176 patients).

[16] The EN 13726 test specifies a maximum test duration of 48 h (and a shorter possible test period of 24 h), but in clinical practice, wound dressings are used for up to 7 days. Moreover, the FC is most likely overestimated in the EN 13726 test due to rapid reach to a fully saturated state of the dressing (which does not necessarily occur clinically), whereas critical information about leakage and pooling cannot be acquired.

[17] Darcy's law is applicable for relatively slow-moving flows and does not account for gravity; in order to account for gravity effects, a more complex model called the Darcy-Forchheimer flow model (which contains a correction term for gravity) should be used,[98] but this topic is considered out of scope here.

[18] Converted to SI units, 1 Darcy is equivalent to 9.869233×10^{-13} m^2 or 0.9869233 μm^2; this conversion (the non-

rounded numbers relate to the conversion from atmospheres to bars) is usually approximated as 1 μm^2.[101]

[19] Available upon a reasonable request from authors, BS, AS and EN are the computer-aided design files of the technical drawings and the workshop specifications for producing a FLUHTE wound simulator as described above, as well as the list of equipment to control or measure additional relevant parameters, for example, the pressure under an applied compression bandage and dressing weight changes during an experiment (for MVL calculations).

[20] Horse and human sera are similar in terms of the primary structure of albumin,[126] a dominant factor affecting the exudate viscosity as well as in some other circulating plasma proteins, for example, clotting factors and immunoglobulins, but differences do exist, such as in the solubility of human versus horse fibrinogens.[127,128]

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APPENDIX 1

DARCY'S LAW APPLIED TO WOUND DRESSINGS

Darcy's law, which describes the flow of viscous fluids in porous media, is a useful approximation. According to Darcy's law when applied to a single-layer foam dressing of thickness L, the rate of exudate flow Q from the high-pressure region in the wound bed to the low-pressure region in the core of the dressing (typically the retention layer in multilayer dressings) is proportional to the cross-sectional area of the dressing A times the pressure difference ΔP between the wound facing and the external dressing surfaces, and inversely proportional to the viscosity of the exudate fluid η:

$$Q = \frac{kA}{\eta L}\Delta P, \qquad (A1-1)$$

where k is the permeability constant of the specific foam.[17] This permeability, commonly measured in units of Darcy, is governed by the effects of the physical and structural features of the porous foam material, such as its density and porosity, the shape of the pores and level of pore-to-pore interconnectivity, and potential directionality features that may exist in the microarchitecture.[99,100] A medium with permeability of 1 Darcy permits a flow of 1 cm^3/s of a fluid with viscosity 1 Cp (1 mPa s) under a pressure gradient of 1 atm/cm acting across an area of 1 cm^2.[18] For water flowing through polyurethane foams, the permeability k was found to be in the range of 3200–4900 Darcy.[102]

Darcy's law and the permeability property k are fundamentally important for understanding the function of all wound dressings and bordered foam dressings in particular. Firstly, Darcy's law indicates that the wound bed itself affects the performance of the dressing, through the viscosity of the exudate η and pressure of exudate release from the wound-bed ΔP. The latter, pressure gradient (ΔP), is affected by the capillary pressure in the wound, by changes in the surface permeability of the dressing determining the surface resistance to the inflow as the dressing absorbs the exudate and by the level of the seal at the dressing-skin interface (Figure 2). In addition, the characteristics of the specific dressing applied on the wound may affect the level of exudation, for example, a porous dressing applied on a wound may promote more exudation with respect to a relatively compact dressing, hence the wound pathophysiology responds to the presence of the dressing.[103] With that said, the inverse physical relationship between the flow rate and viscosity in Equation (A1-1) provides some important insights, as follows.

Relatively low viscosity of the exudate fluid (and likewise, a high-pressure gradient, e.g., due to high capillary pressure) will result in a greater flow rate through the dressing structure. For a particular wound and applied dressing with certain η and ΔP characteristics, it is the permeability of the specific foam material in the dressing k that will determine the rate of exudate flow into the dressing and, therefore, the absorbency performance. However, advanced bordered foam dressings are made of multiple material types, and in such dressings, it is possible to refer to an effective permeability of the layered construct (constituted by the permeability properties of all the materials in the dressing structure together), termed the average permeability. Let us assume, for example, that a (simple multilayer) bordered foam dressing contains three material layers: (i) a wound-facing absorbent foam layer with thickness L_1, (ii) a spreading layer (also termed distribution layer) with thickness L_2 and (iii) a retention layer with thickness of L_3, and each of these layers has its specific permeability k_i. For a steady state, non-gravitational flow of exudate from the wound bed, the flow rate Q should be constant and the total pressure drop ΔP must equal the sum of the pressure drops across all the three layers:

$$\Delta P = \Delta P_1 + \Delta P_2 + \Delta P_3. \qquad (A1-2)$$

Defining the average permeability k_{avg} as the permeability causing the pressure loss ΔP across the entire dressing construct and replacing the pressure gradient component for each layer with the corresponding Darcy's law term for the specific layer yields:

$$\frac{Q\eta L}{k_{avg}A} = \frac{Q\eta L_1}{k_1 A} + \frac{Q\eta L_2}{k_2 A} + \frac{Q\eta L_3}{k_3 A}. \qquad (A1-3)$$

Now cancelling the identical parameters and rearranging terms, and recalling that $L_1 + L_2 + L_3 = L$:

$$k_{\text{avg}} = \frac{L}{\frac{L_1}{k_1} + \frac{L_2}{k_2} + \frac{L_3}{k_3}}. \quad (\text{A1}-4)$$

The above derivation can be generalized to an n number of dressing layers, for which case the average permeability k_{avg} is:

$$k_{\text{avg}} = \frac{\sum_{i=1}^{n} L_i}{\sum_{i=1}^{n} L_i / k_i}. \quad (\text{A1}-5)$$

The above relationship demonstrates how the absorbency of foam dressings depends on both the geometry (thickness) and materials (permeability) of each layer in the dressing. For example, let us assume a hypothetical 3-layer dressing for which the absorbent and spreading layers each have a thickness t (mm) and permeability C (Darcy), whereas the retention layer has a thickness of 2 t and permeability of 2C; in this case, substituting the parameters in Equation (A1-4) yields that the average permeability of the dressing is 1.33C. If, however, the design of this hypothetical dressing is modified to make it thinner (e.g., to improve its flexibility and conformability), by reducing the thickness of the retention layer to t, then k_{avg} becomes 1.2C, that is, 50% reduction in the thickness of the retention layer decreases the average permeability of the dressing by 10%. Now assuming that the design modification does not only involve reduction in the thickness of the retention layer but also replacing the material of that layer with a different material with improved permeability of 4C. In this case, the k_{avg} returns to the initial level of 1.33C because the increased permeability of the new retention material compensates for the reduction in thickness of this layer, and so, the whole dressing can be made more flexible and conformable without compromising its absorbency performance. Another important implication of the above derivations, based on Darcy's law, is that the dressing layer with the lowest permeability has the most influence on the amount of exudate that eventually reaches the core of the dressing (the retention layer) and which can therefore be retained in the dressing. To illustrate this phenomenon, let us now examine another hypothetical dressing in which the spreading layer is made of a nonoptimal material (e.g., due to a flawed design) with permeability of 0.1C, whereas all the other layers have permeability of C, and for simplicity, let us further assume that the layers all have the same thickness t. The average permeability in this case will be 0.25C, that is, closer to that of the spreading layer with the poor permeability than to that of the other layers.

APPENDIX 2

THE RELATIONSHIP BETWEEN PROTEIN CONTENTS AND VISCOSITY OF A BIOLOGICAL FLUID

The theoretical foundation for the relationship between protein contents and viscosity of a biological fluid is Einstein's theory, namely, $\eta = \eta_0(1 + 2.5\phi)$, where η_0 is the viscosity of water and ϕ is the volume fracture of the solute; however, this linear relationship rapidly loses accuracy for protein-rich fluids. Theoretical analyses comparing the above Einstein's equation to more complex models indicated that Einstein's theory is accurate for fluids with protein suspensions of up to 3% vol %.[104] Hong et al.[105] demonstrated that for representing the viscosity of bovine serum that contains an increasing amount of albumin, Einstein's equation becomes substantially inaccurate for albumin concentrations above 180 mg/mL. However, Krieger–Dougherty's equation,

$$\eta = \eta_0 \left(1 - \frac{\varphi}{\varphi_m}\right)^{-[\eta]\,\varphi_m}, \quad (\text{A2}-1)$$

where φ_m is the maximum volume fraction of the protein molecule, commonly taken as 0.6–0.7, and $[\eta]$ is a constant set to 2.5 and was appropriate for calculating the η of the albumin-supplemented serum for a range of albumin concentrations between 100 and near 300 mg/mL. Throughout this range, the viscosity of the serum with the added albumin climbed exponentially from 2 to 120 Cp.[105] With that said, the works of Trengove et al.[26] and James et al.[106] indicate that the total protein concentration in human exudate is lower than the nonlinearity threshold found by Hong et al.,[105] that is, the total protein does not exceed 72 mg/mL even for infected wounds[106] which indicates that Einstein's equation may be a sufficient approximation to characterize the viscosity of most wound exudates depending on the protein level ϕ. Accordingly, substituting the Einstein's equation in Darcy's law (Equation (A2-1)) yields:

$$Q = \frac{kA}{\eta_0(1 + 2.5\varphi)\,L}\Delta P, \quad (\text{A2}-2)$$

demonstrating that with the increase in protein concentration, the flow rate into the dressing decreases.

In order to combine the effects of the exudate protein concentration and exudate temperature in Darcy's law, we recall that the viscosity of water at 30 and 33°C are 0.8 and 0.75 Cp, respectively (www.engineeringtoolbox.com). The viscosity of water within the aforementioned temperature range can therefore be linearized based on the above values and approximated as $\eta_0 = 0.8–0.0166(T - 30)$ Cp, where T is the wound-bed temperature in °C ($30°C \leq T \leq 33°C$). This linearized term can be substituted into Equation (A2-2) to account for the effect of the wound-bed temperature coupled with the influence of the solute (protein and bacterial) volume fraction ϕ. If this is performed, and since a rise in the wound-bed temperature T within the 3°C pathophysiological range will act to decrease the value of the denominator term in Equation (A2-2), an increase in the wound-bed temperature is predicted to increase the flow rate into the dressing. With that said, given that a relatively narrow, 3°C range of wound-bed temperature variation is expected, the influence of the protein contents and bacterial load in the exudate on its viscosity is predicted to be stronger than that of the wound temperature (Equation (A2-2)).

APPENDIX 3

THE RELATIONSHIPS BETWEEN ABSORBENCY, THE FOAM POROSITY AND EXTERNAL FORCES

The permeability of individual dressing layers (and therefore, the average permeability of the dressing) relates to the microstructure of the material and, in particular, to the porosity Ø (total fraction of the spaces in the solid polymer in the foam, which ranges from zero to unity) and to the interconnectivity in the microstructure. This relationship is often described in the literature as[107–108]:

$$k = C_* \frac{Ø^{n+1}}{(1-Ø)^n}, \qquad (A3-1)$$

where n (typically set as $n = 2$[109]) and C^* are empirical parameters related to the range of shapes of the pores, the interconnectivity and the tortuosity (defined as the ratio of an actual flow path length to the straight distance between the ends of that flow path; for all practical porous materials, this tortuosity factor is greater than unity[110]) of the microarchitecture.[111] Substituting Equation (A3-1) into Equation (A1-1) (Darcy's law) and setting $n = 2$ yields[109]:

$$Q = C_* \frac{Ø^3}{(1-Ø)^2} \frac{A}{\eta L} \Delta P, \qquad (A3-2)$$

which elucidates that the microarchitecture of the foam determines the flow rate through, and thereby the absorbency of each layer in a foam dressing, again highlighting the influence of the specific materials and manufacturing process on the absorbency outcomes. The porosity Ø of foams can be evaluated based on processing of electron microscopy micrographs, optical microscopy images or using laser scanning-based techniques,[100,112] yet the C^* parameter should be determined (calibrated) experimentally. In addition, the polymer chemistry in the specific foam affects the fluid handling properties due to, for example, capillary forces and swelling, for which the mathematical descriptions are outside the scope of this work.

Foam materials in dressings are highly porous and typically have porosity values Ø of 0.95 to 0.98.[113,114] Even the slight deviation in the porosity of foams, for example, due to variant industrial processes between manufacturers, will impact the permeability and thereby the fluid handling properties of foam dressings. For example, Equation (A3-2) indicates that due to the power-law nature of the porosity term, the change of permeability resulting from the change in porosity (to $Ø_1$ from a baseline of Ø), assuming no change to the shape of pores and tortuosity, is:

$$\frac{\Delta k}{k} = \left[\frac{Ø_1^3}{(1-Ø_1)^2} - \frac{Ø^3}{(1-Ø)^2}\right] \Big/ \frac{Ø^3}{(1-Ø)^2} = \frac{Ø_1^3(1-Ø)^2}{Ø^3(1-Ø_1)^2} - 1. \qquad (A3-3)$$

This latter Equation (A3-3) exemplifies the absurd in generalizing foam dressings as a 'category' and considering all the products belonging into this category as equal. Specifically, let us utilize Equation (A3-3) to demonstrate the consequences of a deviation in a manufacturing process between two hypothetical foam dressing manufacturers using the same polyurethane solid for their foaming process and targeting exactly the same range of pore shapes, but deviating by just 0.5% in the resulted mean porosity, so that one manufacturer obtains $Ø_1 = 96.5\%$ and the other $Ø = 97\%$. The above Equation (A3-3) predicts that the foam of the first manufacturer with the just slightly lower 96.5% porosity will have permeability that is 28% lower (!) than that of the manufacturer producing the foam with the 97% porosity. The $\Delta Ø = 0.5\%$ manufacturing tolerance level in the above example is minor with respect to the product-to-product differences among commercial foam dressings. For example, Lee et al.[100] studied apparent densities ρ_a of four silver-containing

foams used in different commercial dressings and reported a range of 0.12–0.25 g/cm^3, which (assuming solid polyurethane polymer density of $\rho_s = 1.2$ g/cm^3[115] and using $Ø = 1 - (\rho_a/\rho_s)$) translates to mean porosities of 0.79 to 0.9; this is a considerably wide range of inter-product variability in porosities, which must result in an even wider range of fluid handling performance metrics as the above theory stipulates.

In clinical settings, foam dressings are often exposed to transient or sustained mechanical forces, such as body-weight forces or compression bandaging over the dressing, which influences their effective porosity for fluid handling (as the pores condense or collapse under the external forces and the total reservoir for absorbency decreases). Assuming that a foam in a dressing can be described as isotropic, its relative density under uniaxial compression, where the strain ε is taken to be negative, is given as[102]:

$$\frac{\rho_a^*}{\rho_s} = \frac{\rho_{a,0}}{\rho_s}\frac{1}{(1+\varepsilon)(1-\nu\varepsilon)^2}, \tag{A3-4}$$

where $\rho_{a,0}$ is the initial density of the foam at 0% compression, ρ_a^* is the apparent density of the foam at a compressive strain ε and ν is Poisson's ratio of the foam. Recalling that $Ø = 1 - (\rho_a/\rho_s)$, Equation (A3-4) can be rewritten in terms of the porosity Ø* of the foam when strain applies:

$$\emptyset^* = 1 - \frac{1-\emptyset}{(1+\varepsilon)(1-\nu\varepsilon)^2}. \tag{A3-5}$$

Note that for $\varepsilon = 0$, Ø* = Ø. Now substituting Equation (A3-5) into Equation (A3-2) results in Darcy's law for compressed foams:

$$Q = C_*\left[1 - \frac{1-\emptyset}{(1+\varepsilon)(1-\nu\varepsilon)^2}\right]^3\left[\frac{(1+\varepsilon)^2(1-\nu\varepsilon)^4}{(1-\emptyset)^2}\right]\frac{A}{\eta L}\Delta P. \tag{A3-6}$$

The permeability of a foam subjected to external compression can therefore be formulated as:

$$k^* = C_*\left[1 - \frac{1-\emptyset}{(1+\varepsilon)(1-\nu\varepsilon)^2}\right]^3\left[\frac{(1+\varepsilon)^2(1-\nu\varepsilon)^4}{(1-\emptyset)^2}\right]. \tag{A3-7}$$

This facilitates the calculation of the change in permeability resulting from the application of compression on the foam:

$$\frac{\Delta k^*}{k^*} = \left\{\left[1 - \frac{1-\emptyset}{(1+\varepsilon)(1-\nu\varepsilon)^2}\right]^3\left[\frac{(1+\varepsilon)^2(1-\nu\varepsilon)^4}{(1-\emptyset)^2}\right] - \frac{Ø^3}{(1-Ø)^2}\right\}\Big/\frac{Ø^3}{(1-Ø)^2}$$
$$= \frac{(1-Ø)^2\left[1 - \frac{1-\emptyset}{(1+\varepsilon)(1-\nu\varepsilon)^2}\right]^3\left[\frac{(1+\varepsilon)^2(1-\nu\varepsilon)^4}{(1-\emptyset)^2}\right]}{Ø^3} - 1. \tag{A3-8}$$

Of note, in the absence of compressive strain, $\Delta k^*/k^* = 0$. Now considering, as an example, that a compressive strain of 10% is applied on a foam material of a dressing with undeformed porosity of 0.9[100] and Poisson's ratio of 0.2,[116] the expected reduction in permeability according to Equation (A3-8) is 13.6%. However, if the porosity of the undeformed foam would have been lower (as per the[100] study results), that is, 0.79 (assuming the same ν value), then the decrease in permeability due to external compressive forces would have been greater, 16.4%. Likewise, two foams with undeformed porosities of 0.9, one having $\nu = 0.25$ and the other $\nu = 0.35$, and both undergoing compression to 10% strain, are expected to exhibit decreases in permeability of 10.9% and 5.8%, respectively. In other words, identical mechanical forces will have distinct effects on the fluid handling of foam dressings containing different foam materials.

APPENDIX 4

CAPILLARY ACTION: SORPTIVITY AND ITS CONSTITUENTS

Capillary action is the movement of fluid within the spaces of a porous material due to the forces of adhesion, cohesion and surface tension. The ability of an absorbent dressing material to transfer a certain viscous fluid by capillary action is generally described as:[47,117]

$$V = AS\sqrt{t}, \tag{A4-1}$$

where V is the cumulative volume of the liquid absorbed through a cross-sectional area A of the absorbent material at time t, and S is the sorptivity of the absorbent material. This sorptivity S can be further formulated according to characteristics of the fluid, of the porous media and of the interaction, as[118]:

$$S = \left(d\sqrt{\frac{\gamma}{\mu}}\right)\left(\frac{\varepsilon}{1}\sqrt{r}\right)\left(\frac{\cos\theta}{2}\right), \tag{A4-2}$$

where d, γ and μ are the density, surface tension and viscosity of the fluid undergoing the capillary motion, respectively; ε is the effective porosity of the dry

absorbent material; λ is the average tortuosity of the absorbent material; r is the average pore radius; and θ is the contact angle of the interface between the liquid and pore walls. Noteworthy is that the three terms in the above formulation of the sorptivity correspond to parameters that are separately: (i) characteristic to the exudate fluid per se, that is, to patient-related and wound-related factors (in the left-hand side term); (ii) characteristic to the dressing microstructure only, that is, to dressing design-related and manufacturing-related factors (central term); and (iii) characteristic to the wound dressing interaction (the right-hand side term).

APPENDIX 5

THE EVAPORATION RATE FROM THE WOUND BED WITHOUT VERSUS WITH A DRESSING

For an open exuding wound without a dressing, the evaporation rate (ER) from the wound bed can be described using the Carrier equation[119]:

$$\mathrm{ER} = (K_1 + K_2 V_a) A_w \frac{\Delta P_{\mathrm{rs}}}{Y}, \qquad (\mathrm{A5}-1)$$

where A_w is the wound surface area, ΔP_{rs} is the difference between the fluid and room saturation pressures (Pa), Y is the latent heat of evaporation of the exudate fluid (Kj/kg), V_a is the velocity of the air parallel to the wound-bed surface (m/s) and K_1, K_2 are constants. Assuming an air velocity of zero (as in a building where the air is nearly stationary and the RH is typically >> 20%[120]), another form of the above equation is[121]:

$$\mathrm{ER} = K_3 A_w [P_e(T_w) - \mathrm{RH} \cdot P_e(T_a)], \qquad (\mathrm{A5}-2)$$

where P_e is the exudate saturation pressure at the wound-bed temperature $P_e(T_w)$ or at the ambient temperature $P_e(T_a)$, RH is the relative humidity and K_3 is a constant. For evaporation to occur from an open wound, the term in the square brackets needs to be positive, or $P_e(T_w) > \mathrm{RH} \cdot P_e(T_a)$. Accordingly, for any relative humidity value ($0 \leq \mathrm{RH} \leq 1$), evaporation from the wound bed can only occur when the wound-bed temperature is greater than the ambient temperature (which can be expected) because the exudate saturation pressure increases monotonically with the temperature. The above equation also defines an upper limit on the evaporation rate, depending on the ambient (temperature and humidity) conditions for a case where a dressing is applied onto the wound. Different dressings will be able to reduce the ER by variable extents depending on their material composition and thermal properties; however, the ER through the dressing would still depend on the aforementioned ambient conditions T_a and RH (Figure 3).

In the context of when a dressing is placed on the wound, there are two main conventional methods to measure the WVTR in a bioengineering laboratory[85,122]: The desiccant method and the water method. According to the desiccant method, the dressing is sealed to the top of a dish that is filled with desiccant and the dish is placed in an environment with high relative humidity. After a predetermined testing time, the amount of moisture that passes through the dressing, into the dish, is measured. The water method does the opposite, that is, the dish is filled with water and the dressing seals the dish and the apparatus is placed in an environment with low relative humidity. The amount of water in the dish is weighted after the test period to measure how much water vapour transferred from the dish during that time. The results from these two test types may not be consistent, and so, head-to-head comparisons of the WVTR between products should use a consistent test type.

Wu et al.[83] measured the WVTR of 14 commercially available wound dressings over 24- and 48-h periods and obtained a wide range of WVTRs (76–9360 g/m^2/24 h under forced air convection of 0.4 m/s). Interestingly, they found that the influence of a non-zero air velocity was not significant if the WVTR of the dressing was less than 880 g/m^2/24 h when measured under static air conditions. Wu et al.[123] then continued to study WVTRs of dressings in a clinical setting (on burns and VLUs) by utilizing an evaporimeter. Their results suggested that the evaporative water vapour loss from wounds depends mainly on the wound depth because VLUs had similar WVTR levels to full-thickness burns. Xu et al.[124] conducted in vitro and in vivo experiments using the water method to test polyurethane foam membranes with graded WVTRs and found that foams with a WVTR of approximately 2030 g/m^2/24 h did not affect the regular proliferation of epidermal cells and fibroblasts in a three-dimensional culture model and further allowed healing of skin in a mouse wound model. However, according to the work of Zehrer et al.[125] who studied the WVTRs of multiple foam-based dressings using both the desiccant and water methods, significant differences existed between the different foams of commercial dressings in terms of the WVTR. For the desiccant method, the WVTRs of the foams varied from 80 to 1620 g/m^2/24 h, whereas for the water method, the WVTR was significantly greater in all the foams included in their study and varied between 830 and 12 750 g/m^2/24 h. This vast variation in WVTRs of dressing materials is yet another example for the need

to standardize the testing and performance of wound dressing.

APPENDIX 6

TECHNICAL DESCRIPTION OF THE FLUID HANDLING TEST EQUIPMENT (FLUHTE) SYSTEM

Design of the FLUHTE wound simulator

The FLUHTE wound simulator unit is made of aluminium and has a half-cylindrical shape with outer and inner diameters of 100 mm and 76 mm, respectively, and a height of 20 cm. For the advanced fluid handling performance testing of wound dressings described here, two identical (half-cylinder) wound simulator units were assembled together to form a cylinder simulating a VLU aetiology on a 'leg'-like structure (Figure 3A). Each FLUHTE simulator unit is equipped with an irrigation region representing the wound area, from which a SWF can be released to simulate exudate secretion. To uniformize the fluid spreading in this 'wound' area, the irrigation region consists of five shallow circular recesses, of 10 mm in diameter and 1 mm in depth; a liquid inlet hole with a diameter of 2 mm is located at the centre of each recess, such that the SWF flows from the five inlets simultaneously (Figure 3C). This design allows evaluations of dressing products with an absorbent pad area of at least 5 cm in diameter. The surface temperature of the FLUHTE cylinder, set at 30°C based on reported wound temperature measurements in a large patient cohort as detailed in Section 3 (of the main text) and the literature cited therein, is controlled using a hot plate stirrer (RCT Basic, IKA®-Werke GmbH & Co. KG, Staufen, Germany) connected to a temperature sensor (mounted 5 cm from the top part of the FLUHTE). The surface temperature distribution over the FLUHTE wound simulator was evaluated using both an infrared temperature sensor and a contact temperature probe, and was verified to not deviate by more than ±0.5°C from the target 30°C surface temperature.[19]

The external temperature and humidity are also controlled, as the FLUHTE system is positioned in a climate laboratory room where these parameters are set as 23 ± 2°C and 50 ± 5%, respectively (according to the ISO 554:1976 standard). No external devices are used to increase the air velocity and thereby cause convection (which may influence the evaporation rate from the tested dressings).

To mimic the concentrations of protein observed in a real-world wound exudate content,[26] a SWF containing 50% horse serum solution (Håtunalab AB, Bro, Sweden) diluted with 50% 'Solution A' was used.[20] A syringe pump with 10 syringe units (Legato 200, KD Scientific Inc., Holliston, MA, USA, with Becton Dickinson Plastipak 20 mL Luer-LokTM syringes, Franklin Lakes, NJ, USA) was used to control the flow rate of the SWF into the FLUHTE system through plastic tubs with Luer Lok™ connectors (B. Braun Original Perfusor® Line Type IV-standard PVC, Melsungen, Germany). The syringe pump was calibrated in the 0.2–1.5 mL/h range per wound area size (of 10 cm^2).

After applying the dressings, the FLUHTE system was covered with a standard lightweight secondary tubular dressing (without further constriction or compression). The pressure from that secondary dressing onto the FLUHTE surface was verified to be ~4 mmHg at baseline (time zero), by means of a pressure sensor (Kikuhime, ZiboCare, Horsens, Denmark). To assess the backflow component of leakage (as detailed in Section 6.2), the dressing was weighed post the simulated use (weight m_1) and then placed on a perforated stainless-steel plate with the wound pad of the dressing facing the plate. The plate had a thickness of 1.5 mm, evenly spaced circular holes with a diameter of 5 mm, and a total of 40% open area. A solid compression plate, larger than the dressing, was placed on the backing film side of the dressing, and weights exerting a pressure of 40 mmHg were applied for 30 s. Subsequently, the dressing was reweighed (m_2), and the backflow was calculated as the weight difference ($m_1 - m_2$).

The FLUHTE wound simulator was further designed to output quantitative fluid handling performance metrics for a tested dressing, including the absorbed and retained fluid content (FC) and the MVL, as well as commonly recognized dressing failure modes, for example, the exudate leakage or pooling observed clinically (illustrated in Figure 1). 'Leakage' was separated into three sub-parameters, namely external leakage (e.g., to a secondary bandage; Figure 3B), pooling of fluid residuals under the dressing at the time of removal (Figure 3C) and backflow (also known as reflux) observed at a retention test, simulating temporary external pressures that may be applied on the dressing during usage, as may occur in real-world clinical settings (Figure 3D), all of which are considered to indicate potential risk for wound degradation and/or peri-wound maceration based on published clinical literature.[95,96,129–132]

Application of the FLUHTE wound simulator to fluid handling performance evaluations

The fluid handling properties of six commercially available bordered foam dressings, all indicated for highly exuding wounds, were quantitatively evaluated and

compared by means of the FLUHTE wound simulator. All the currently tested wound dressings were used in the FLUHTE testing according to the instructions for use or the manufacturer's package inserts. The tested wound dressings were applied to the FLUHTE wound simulator and covered with the same secondary elasticated tubular bandaging to mimic normal wear and facilitate easy detection of external leakage. Two different flow rates, 0.5 mL/h and 0.75 mL/h per 10 cm^2, were used to apply 12 or 18 mL of SWF containing 50% horse serum solution (the detailed composition of the SWF is provided in Appendix 6) over a 24-h period, respectively. The chosen flow rates are well within the range reported in the literature (for clinical wound cases as well as for laboratory testing purposes) when scaled for the wound area size (10 cm^2): 0.17–0.50 mL/h,[106] 0.25–1.33 mL/h (Dealy et al., 2006)[133] and 0.13–1.17 mL/h.[134] Of note, currently, there is no widely accepted definition of what a 'normal' or 'high' exudate flow rate from a wound is, and no internationally accepted standard methods for measuring rates of exudate production in clinical situations and settings.[12] The results presented here are not intended for product comparisons, but rather, for demonstrating the applicability of FLUHTE, and hence, information that can be used to identify brands have been deleted.

Differences in fluid handling performance across dressing products identified by FLUHTE

The results generated by the FLUHTE system revealed considerable differences in the fluid handling performance between the six dressing products, manifested by both the quantitative metric outputs and the detection of commonly recognized dressing failure modes. External leakage to the secondary bandaging occurred for one product (product F) when the flow rate was 0.75 mL/h (Figure 3B). Quantitative comparisons of the fluid handling properties further demonstrated considerable differences between the six dressing products: Statistically significant higher levels of SWF pooling (i.e., amount of fluid in grams under the dressing) were observed for product A compared with C, D and F at 0.5 mL/h ($p \leq 0.01$); and for product E compared with C and D at 0.75 mL/h ($p \leq 0.01$) (Figure 4A,C).

In addition, significantly higher extents of backflow were observed in the retention tests for product A compared with products C to F at a flow rate of 0.5 mL/h ($p \leq 0.01$); and for product E compared with A to D at 0.75 mL/h ($p \leq 0.01$) (Figure 4A,C). Because external leakage may be considered as product failure already at the pre-clinical testing phase (also impairing the accuracy of fluid handling evaluations), the quantitative data for product F at 0.75 mL/h were excluded. Statistical analysis comparing the FC and MVL (separately) further revealed significant performance differences between the evaluated wound dressings (Figure 4B,D). At both flow rates, statistical significant lower mean FC ($p \leq 0.001$) and higher mean MVL ($p \leq 0.001$) were observed for four of the wound dressings (Figure 4B,D; products A, B, C and D). Of note, lower MVL values for products E and F may explain the above results, that is, products E and F have reached their limits at the higher flow rate (being unable to sufficiently evaporate the accumulated SWF).

The bubble plots in Figure 5 emphasize differences in the total amount of excess fluid that in real-world scenarios may cause deterioration of the wound and inflammation or maceration of the peri-wound skin. Specifically, Figure 5 illustrates how this excess fluid performance parameter relates to the FC within the dressing and the MVL, as the area of each bubble is sized in proportion to the total amount of pooling plus backflow and the X/Y-position indicate the FC and MVL, respectively. Statistically significant differences in the combined amount of fluid pooling and backflow were observed between product A versus C to F at a flow rate of 0.5 mL/h ($p \leq 0.001$) and between product E versus A to D at 0.75 mL/h ($p \leq 0.001$). Furthermore, it is evident when comparing products C or D to E that application of fluids at the (greater) flow rate of 0.75 mL/h over 24 h increased the fluid handling performance differences between the tested dressing products. In other words, the data generated by the FLUHTE wound simulator reveal that the flow rate is a critically important factor (not currently considered in the fluid handling test methods in the EN 13726 standard), the change of which leads to distinguished fluid handling performance across dressing products (Figures 4 and 5). Overall, the FLUHTE method and system appear to be more clinically relevant for objective, quantitative identification of performance parameters and conditions where certain wound dressings may fail to adequately manage the exudate compared with the simplistic tests included in the EN 13726 standard. Specifically, in contrast to FLUHTE, given that the EN 13726 standard does not directly quantify the amounts of a test fluid, which are not absorbed/retained in a tested dressing (i.e., that will potentially pool or leak out), the EN 13726 standard is not useful for distinguishing between dressing performance metrics on this critical aspect. A next potential step in the further development of FLUHTE would be to collect relevant clinical data and determine whether it rates dressings similarly to FLUHTE, which had already proved to be able to differentiate between fluid handling performance of different commercial dressings.