Saturation of a dressing applied to an exuding wound: the gap between clinical judgment and laboratory testing


Authors:
Amit Gefen and Nick Santamaria

It is well established that a moist, but not wet, wound bed is conducive to healing. However, evaluating the ability of a dressing to induce such conditions in the wound bed, while also preventing leakage and minimising maceration of the periwound skin, remains a challenge. Clinical measurements of the fluid handling performances of wound dressing products are not feasible due to the considerable variability among patients, wounds, methods of practice and wound-care protocols. Accordingly, laboratory tests are often used by industry and academia to eliminate these variabilities and evaluate the fluid handling performances of wound dressings in controlled setups and under pre-set test conditions. Clinicians, product engineers, healthcare administrators, regulatory and reimbursement bodies all depend upon reliable, reproducible, robust and cost-effective testing methods and their outcomes for adequate decision-making processes. The purpose of this educational article is to describe currently recognised gaps between real-world, clinically relevant conditions pertaining to the use of dressings, versus the simplifications (or sometimes, oversimplifications) made in existing testing standards commonly employed by industry and university laboratories to evaluate dressing performances. The authors further propose here several practical ways to bridge these gaps. Specifically, improved testing standards should represent: (1) real-world scenarios of fluid flow into a dressing, which only occurs through the wound contacting layer; (2) the biophysical properties of wound exudates managed in clinical practice and in particular, the viscosity of these fluids, which may deviate substantially from that of water or saline solution; (3) compressive and shear mechanical forces that may act on a dressing and cause it to release absorbed fluids; (4) instructions for use and recommendations for the frequency of dressing changes, as they are provided by manufacturers.

***Amit Gefen** is Professor of Biomedical Engineering, Department of Biomedical Engineering, Faculty of Engineering, Tel Aviv University, Israel; **Nick Santamaria** is Professor of Nursing Research School of Health Sciences, University of Melbourne, Melbourne, Victoria, Australia*

It is well established that a moist, but not wet, wound bed is conducive to healing (Bishop et al, 2003; Wounds International, 2019), however, evaluating the ability of a certain dressing to induce such optimised conditions in the wound bed while also preventing leakage from the dressing and minimising maceration of the periwound skin remains a major challenge. Clinical measurements of the fluid handling performances of wound dressing products are not feasible, as there is vast variability among patients, wounds, methods of practice and wound care protocols. Even wounds with a similar aetiology are likely to differ substantially by size and depth, shape, microbiological status, presence or absence of infection, amount and rate of released exudate and its viscosity, wound temperature, pH and other relevant biophysical and biochemical conditions. Accordingly, laboratory tests are used by industry and researchers in academia to eliminate the

biological variability and evaluate the fluid handling performances of wound dressings in controlled setups and under pre-set test conditions (British Standards Institution 2002a; 2002b; Atkin et al, 2015; Hasatsri et al, 2018; Thomas and Uzun, 2019). Clinicians, product engineers, healthcare administrators, regulatory and reimbursement bodies critically depend upon reliable, reproducible, robust and cost-effective testing methods and their outcomes for an adequate decision-making process. Hence, contemporary testing standards for wound dressings should correctly evaluate the fluid handling performances of the tested dressings and importantly, must approximate the relevant real-world clinical conditions pertaining to the use of the dressing products that they assert to test.

What is a state of 'saturation' of a wound dressing?

'Saturation' is a term that is often being used by both wound care clinicians and bioengineers in the context of how wound dressings function, to describe a condition where a dressing contains a considerable amount of exudate. However, while clinicians may often use a descriptive, qualitative language and describe a dressing as 'saturated' to simply indicate that a dressing is wet, engineers would typically use this word in its formal, strict and quantitative meaning. That is, engineers would say that a dressing is 'saturated' when it has reached the level of exudate absorption where each of the dressing materials (or layers) and the entire dressing structure are filled completely with fluid, so that no more fluid can be absorbed anymore.

The difference between the qualitative ('wet') and quantitative ('full absorption') inferences is fundamental. Where a 'wet' dressing may still absorb additional exudate, a fully saturated dressing cannot absorb any additional fluid and even the slightest amount of extra fluid will spill over from the dressing to the environment, i.e., onto the periwound skin or back into the wound bed where such excess fluid will pool.

In real-world conditions, wound dressings, such as multi-layered foam dressings, very seldom reach a fully saturated condition during use; in practice, dressings will be changed by the healthcare professional long before they reach true saturation (as per its engineering definition). This is because modern wound dressings are designed to spread absorbed exudate within the dressing structure (some multilayered dressings have a specific 'spreading layer' included in the layered design for this purpose), so a dressing may appear to contain more fluids than it actually contains, which serves as a safety measure (Nicolson et al, 2018; Alvarez et al, 2021).

Moreover, most manufacturers recommend dressing changes when or before the exudate reaches the edges (borders) of the dressing, as a dressing may leak prior to becoming saturated, e.g., if being subjected to unintentional compression that squeezes absorbed exudate from the dressing outwards; a situation which the instructions for use are typically designed to avoid. In other scenarios, some dressings may leak even if they do not reach a saturation state, due to gravity forces acting on the absorbed exudate or where a certain spreading pattern within the dressing develops, which causes leakage with movement of the patient. Leakage may also be indicative of dressing design deficiencies. The latter form of leakage is often seen in ambulant patients with venous leg ulceration (Caprini et al, 2013).

The concept of undisturbed wound healing is important to mention when discussing the optimal frequency of dressing changes (Berg et al, 2019). The goal of undisturbed wound healing is to not increase the wound bed and periwound irritation, overly cool or dry the wound bed or potentially expose it to environmental pathogens by over-frequent dressing changes (Dabiri et al, 2016). Optimising the dressing change frequency contributes to improving the quality of life of patients and allows them to have as normal a life as possible (Anderson, 2010; Berg et al, 2019).

Dressing manufacturers have generally adopted this concept, which is often reflected in the instructions for use provided with the dressing products. Indeed, a review of the online instructions for use of available wound dressings, using the search words "instructions for use" and "saturation" and "wound" and "dressing", indicated that the majority of manufacturers recommend that a dressing be changed when the exudate is visible through the backing film, or when the exudate had reached an edge of the dressing or wound pad, or a certain distance from these borders *[Figure 1]*. Some manufacturers also include a 'change indicator' or an 'exudate progress monitor' on the backing film of their dressings, to visually indicate when a dressing change is warranted.

With that said, we have identified several anecdotal examples where mainstream manufacturers indicate that a dressing should be changed when it becomes saturated, which is likely the result of misuse of the term 'saturation', where the intention was simply to note that the dressing should be changed when it appears

to be wet. Of note, instructions for use should avoid the term 'saturation' as a descriptor for when a dressing needs to be changed, since this term has a specific physical and engineering meaning, as defined above. For example, for foam dressings, 'saturation' implies that the entire cumulative volume of the porous voids, which facilitates the absorption capacity of the dressing structure, has been fully exploited. A saturated state of a dressing is clearly unwarranted in clinical practice, as it may cause pooling of exudate within the wound cavity, leakage from the dressing, periwound skin maceration or their combination.

It is, therefore, unreasonable, from both a bioengineering and a clinical perspective, to recommend clinicians to change a dressing only when the dressing already appears to be 'saturated'. More precise, scientifically justified wording — possibly referring to the pattern or the extent of the fluid spreading as shown on the external surface of the dressing — should be used for guiding clinicians in this regard.

In addition to the clinical practice of changing dressings before they begin to leak and as an extra safety measure, the engineering design of modern wound dressings should never allow a dressing product to reach saturation, as the backing film (external surface) of all modern wound dressings should be made of breathable materials. This design feature has been integrated in dressings to continuously release a portion of the absorbed fluid to the environment as vapour. The rate of moisture vapour transmission through the backing film of a dressing is, therefore, a key characteristic which has a fundamental influence on the fluid balance at the wound bed and the overall fluid management performances of the product (Lachenbruch and VanGilder, 2012; Xu et al, 2016).

Laboratory work has established that marked differences exist between dressing products in terms of moisture vapour transmission rates, which affect the fluid handling capacity (Thomas et al, 2011; Zehrer et al, 2014).

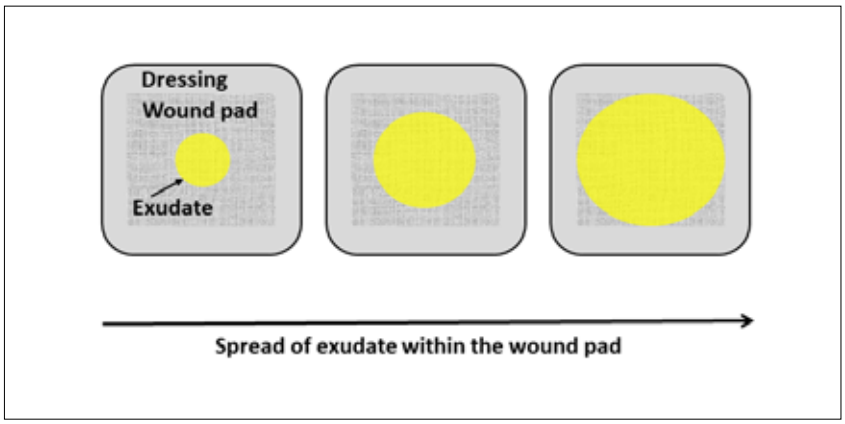
Why are traditional testing protocols for fluid handling of dressings limited?

The classic testing standard for evaluating the absorption performances of wound dressings is EN 13726-1 "Test methods for primary wound dressings — Part 1: Aspects of absorbency" (British Standards Institution, 2002). The above testing standard has been described in numerous publications reporting the performances of commercially available wound dressings and novel dressing designs developed in academic settings (e.g., Boateng et al, 2008; Atkin et al, 2015; Lee et al, 2016; Mennini et al, 2016; Hasatsri et al, 2018). For example, the free-swell absorptive capacity of a dressing is measured by cutting a square sample of the dressing material, weighing the dry sample and then immersing and incubating it in artificial exudate for a given time period, following which the wet dressing specimen is reweighted and the gain in mass of the dressing is subsequently calculated.

The artificial exudate used in these absorbency tests is 20 ml of a solution of sodium/calcium chloride containing 142 mmol/litre of sodium ions and 2.5 mmol/litre of calcium ions, which is known in the industry as 'Solution A'. The test method EN 13726-1 further refers to the use of an excess amount of this Solution A, which is 40-times more than the weight of the specimen itself (i.e., the fluid volume is not fixed).

The testing method described above is far from being representative of the real-world conditions and clinically relevant scenarios under which a wound dressing is required to function (when applied to an actual wound of a patient). First, the above test configuration infers that fluid is entering the dressing specimen from all directions (due to the immersion), as opposed to a clinically relevant scenario in which wound exudates will always enter the dressing only from and via the wound contact layer (i.e., the wound-facing aspect of the 'wound pad'). Secondly, Solution A which is used as the test fluid is not representative of biological wound fluids with respect to composition (including protein contents) and as a result, does not simulate the rheology (viscosity) of real-world wound exudates.

As viscosity is a fundamental parameter affecting the rate and extent of fluid flow into a dressing structure and the potential escape of fluids from the dressing when it is subjected to forces and as a result is deformed, considering only a watery fluid appears to be an oversimplification of the test method. Solution A is only representative of a limited range of wound exudates having a serous (watery) nature and accordingly, a test that only considers Solution A fails to approximate real-life clinical practice (Lustig et al, 2020; Lustig and Gefen, 2021). New testing methods need to better approximate the actual composition of wound exudates that can range from a watery serous state to ones that can be highly viscous and composed of variety of wound debris, proteins,



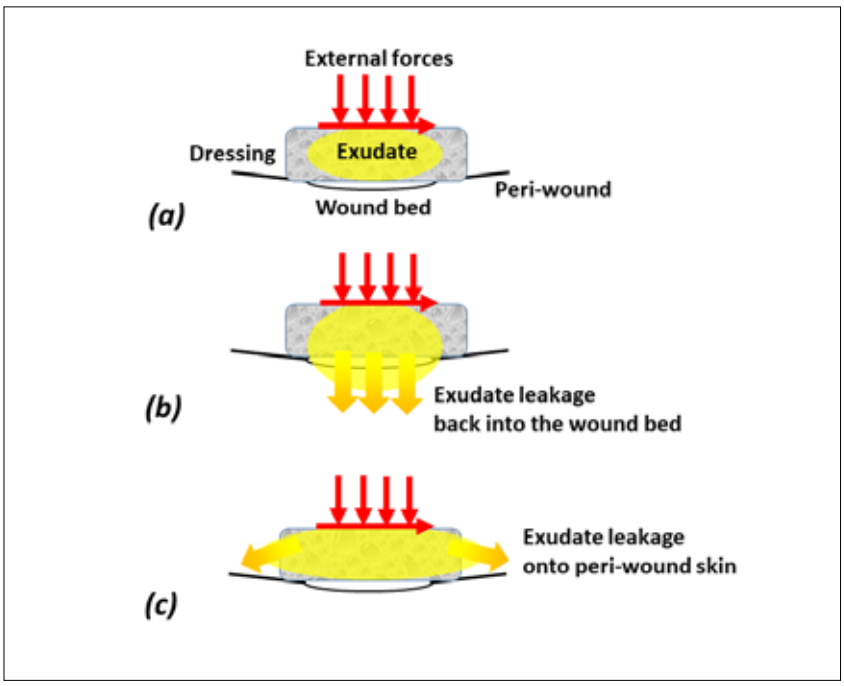


Figure 1 (top). The spread of exudate in a wound dressing: (a) The majority of manufacturers recommend that a dressing be changed when the exudate is visible through the backing film, or when the exudate has reached the edge of the dressing or wound pad or at a certain distance from these borders, as exemplified in this sketch. From left to right: the exudate is relatively far from the wound pad borders and so there is no need to change the dressing; the exudate approaches the wound pad edges and hence, changing the dressing should be considered and; the exudate has reached the wound pad edges and therefore, the dressing needs to be changed. This illustration represents most of the available instructions for use of wound dressing products.

Figure 2 (above). Fluid retention in a dressing under mechanical forces: Certain dressing products may theoretically demonstrate good retention of fluid even under mechanical forces (a), or contrarily, backflow through the wound contacting layer (b) or side-flow through the borders of the dressing (c), or a combination of the latter two forms of malfunction.

cells, bacteria and in some cases pus (Lustig et al, 2020).

When clinically applied, multi-layered foam and other types of dressings are subjected to directional flow from the wound bed into the wound contact layer of the dressing. Such directional flow (from just one dressing aspect, i.e. the wound-facing aspect of the dressing) would be characterised by a different absorption rate (and, therefore, duration where saturation is achieved) with respect to a case where the fluid flows from every face of the dressing, as in the aforementioned 'soaking tests'. Importantly, testing wound dressings under directional flow conditions considers the clinical mode of application of a dressing, for example, with regards to dressings which are applied to cover the wound bed and are thereby exposed to directional flow from the wound bed aspect only.

Furthermore, many advanced wound dressings are made of multiple layers, each with a specific role in the absorption or retention process. These layers are made of different materials with distinct permeability properties and, therefore, the fluid penetration and absorption into the different dressing layers when absorption progresses from the wound contacting layer into the deeper layers of the dressing does not necessarily occur at equal rates across the layers. If a dressing is soaked in fluid and brought to a fully saturated state, information on the extent of absorption in each of the individual layers of the dressing and how it has progressed with time cannot be obtained.

Moreover, as many manufactures recommend that dressings be changed when the exudate is at or near the edges of the wound pad, as observed when examining the backing film, testing dressings at their fully saturated state falls outside the commonly recommended use guidelines, particularly for multi-layered foam dressings.

It follows from the above points that if a testing protocol ignores the time course of absorption (swelling) of a tested dressing and only examines the end-point of the swelling process, where the dressing is fully saturated, the information about the rate of swelling is also lost. Specifically, in the testing standard EN 13726-1, which subtracts the weight of the dry dressing specimen from the weight of the fully-saturated dressing to evaluate absorbency, the rate of mass and volume gain in the dressing specimen remains unknown. Since the swelling of dressing materials in a real-world scenario, i.e. on and within a wound cavity, always occurs against the resilience of the contacting tissues (i.e. semi-confined swelling conditions, not free swelling apply), the rate of the swelling will determine the corresponding rate of build-up of pressures on the wound bed.

From a clinical perspective, if dressings are

changed frequently, a fully-saturated dressing state may never be reached and, therefore, the clinical frequency of dressing changes must be weighed against the swelling rate of the dressing (not just the weight gain due to fluids absorbed at the end of the test). It should also be considered that if the wound bed appears to be stiffer, e.g., as in indurated or oedematous wounds or where localised fibrosis is present, a dressing with a high swelling capacity may induce elevated mechanical stress concentrations in the wound bed (which may build up quickly or slowly, depending on the specific function of the dressing materials) (Lustig and Gefen, 2021). If formed, such wound bed stress concentrations and adverse stress fields are likely to compromise the microvascular function and damage re-epithelialisation and thereby, delay the healing (Flynn, 2010). None of these physiologically and clinically relevant phenomena are represented by the current EN 13726-1, derived testing standards and similar test methods.

Neglecting the effects of reaction forces on an applied dressing is a major limitation of existing test methods that are based on the EN 13726-1 protocol since, in real-world conditions, dressings are rarely able to swell freely (Lustig and Gefen, 2021). Firstly, in a real-life scenario, a dressing is physically constrained by the perimeters of the wound bed, periwound skin and its adhesion/anchoring to the skin beyond the wound margins. A dressing responds to these confined conditions by developing swelling forces (or swelling pressures, which are the swelling forces per unit area), due to the growing pressure on the wound bed as the dressing absorbs exudate (Höhne and Tauer, 2014). Engineers define swelling forces or pressures as the loads under which no more swelling can occur (Zhang et al, 2020). In view of this definition, it is reasonable to assume that the larger the extent of free swelling, which is observed in tests such as EN 13726-1, the greater the dressing-wound swelling pressures that are to be expected under more realistic, semi-confined swelling conditions.

Given that the swelling pressures under semi-confined swelling conditions (as would happen within a wound cavity) are expected to represent the mechanical pressures that a swollen dressing would apply on wound bed tissues, it is worthwhile to conduct laboratory testing of semi-confined swelling of dressings. Such semi-confined swelling tests should include measurements of the lateral swell pressures on a simulated wound bed surface (made of a synthetic elastic material), or equivalent measures indicating the expected loading state on the wound bed. In other words, the dressing should be applied to a deformable simulated wound geometry, as opposed to be allowed to swell freely. In such new testing configuration, the intensity of the mechanical loading applied on the simulated wound bed by a progressively swelling dressing would depend not only on the free-swelling volumetric expansion or gained dressing weight, but also on the resilience (i.e., elastic properties) of the (simulated) wound bed tissues in resisting the contact pressures from the inflating dressing structure.

According to Hooke's law, the steady-state pressures applied by the swelling dressing on the wound bed would be proportional to the stiffness of the wound bed tissues. This paradoxically suggests that dressings that perform well in a free-swelling test (i.e., swell considerably) are likely to be the ones that also contribute to increased pressures on the wound bed, particularly if the wound bed tissues are relatively stiff, which would then lead to mechanical stress concentrations in the wound bed, possibly compressing the neo-vasculature and compromising the healing process (Guo et al, 2018; Lustig and Gefen, 2021).

In addition, bodyweight loads causing reaction forces from a support surface, or any external object (e.g., clothing, bedsheets, other medical device such as compression stockings etc.) may further load the dressing, the wound bed and periwound skin in compression, tension and shear or any combination of these. Such forces distort a dressing and may cause it to release the fluids accumulated in its microstructural voids back into the environment. One could consider, for example, a patient with a category-3 or category-4 cavity sacral pressure ulcer where the multi-layer secondary dressing over the wound is exposed to significant bodyweight forces as the patient changes their position (Lustig et al, 2020). While the patient lying on the dressing is not ideal, it is often seen in real clinical settings and as such, further brings in to question the utility of the testing method described in the EN 13726-1 and similar standards and protocols.

The greater the fluid mass that has been absorbed in a dressing, the more likely it is that mechanical forces will cause these fluids to be released or to leak. Hence, it is critically important to test wound dressings under mechanical loading in their non-saturated (sub-saturated) state, to assess whether the absorbed fluids would remain in the dressing or be

transported out of the dressing under a certain level of force (Vuolo, 2004; Lustig et al, 2020; Lusting and Gefen, 2021). Moreover, if fluid leaks out of a dressing under the effects of mechanical forces, it is important and clinically relevant to understand whether the leakage occurs through the wound contact layer (i.e., backflow into the wound bed) or through the borders of the dressing (which may lead to periwound damage and maceration).

Certain products may theoretically demonstrate good retention of fluid even under mechanical forces, or contrarily, backflow through the wound contacting layer or, side-flow through the borders of the dressing, or a combination of the latter two forms of malfunction that have the potential to increase intra-wound pressures and/or increase the potential for microrganisms to enter the wound space via the leakage track *[Figure 2]*. All these important and clinically relevant parameters are currently not represented in existing testing standards including the current EN 13726-1 and the derived reported testing protocols.

Finally, a soaking test such as the EN 13726-1 protocol ignores the process of evaporation through the dressing. While other sections in the aforementioned standard (Section 3.3 Fluid Handling Capacity; British Standards Institution, 2002) address moisture vapour transmission, the moisture vapour transmission cannot be studied separately and independently from the absorption behavior of a dressing — these two phenomena are fundamentally coupled.

Specifically, immediately after the initial fluid uptake into the dressing structure has occurred, the evaporation of the fluid through the backing film of the dressing strongly affects the fluid management in the dressing over time (McColl et al, 2007). Under real-world conditions, there is continuous evaporation of fluid from a wet dressing to the environment. Complete immersion of a dressing in fluid, as in the currently used testing protocols, does not allow evaporation of fluid to ambient air through the backing film of the dressing. Water loss from a normal skin is ~250 gm^{-2}/day at 35°C, however, in lack of the protective effect of intact skin, the amount of water loss from a wound bed extensively increases to 5,000 gm^{-2}/day (Kamoun et al, 2017). These water loss data indicate that dressings should possess a relatively high water-vapour permeability to allow exudate to leave the wound surface, in order to prevent degradation and maceration. Also, for any relative humidity value ($0 \leq RH \leq 1$), evaporation of exudate from the wound bed can only occur when the wound bed temperature is greater than the ambient temperature (the exudate saturation pressure increases monotonically with the wound temperature). Dressings will be able to influence the evaporation rate from the wound depending on their specific thermal properties (e.g., their thermal conductivity; Gefen, 2021). However, the evaporation rate through a dressing structure would still depend on the ambient temperature and humidity. All of these complex wound-dressing interactions with the environment that relate to evaporation are lost in the oversimplified, currently used soaking-test types.

Summary and conclusions

There is an urgent need to replace the traditional testing standards for wound dressings with improved testing standards that should reflect: (1) real-world scenarios of fluid flow into the dressing, i.e., only through the wound contacting layer; (2) the biophysical properties of wound exudates managed in clinical practice and in particular, the viscosity of these fluids which varies and may deviate substantially from that of water or saline (i.e. 'Solution A'); (3) compressive and shear mechanical forces that may act on a dressing and cause it to release absorbed fluids; (4) instructions for use and recommendations for the frequency of dressing changes provided by manufacturers.

Vice versa, instructions for use provided by manufacturers should conform to clinical practice, avoiding the term 'saturation' which has a specific physical and engineering meaning and implications as a descriptor for when a dressing needs to be changed. A saturation state of a dressing is clearly unwarranted in clinical practice. Overall, it appears that existing testing standards for wound dressings are not suitable for many dressing products, particularly for multi-layered foam dressings. The authors strongly believe that new, dedicated, scientifically sound and clinically valid testing methods need to be developed for wound dressings. WINT

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