Received: 11 January 2024 | Revised: 28 January 2024 | Accepted: 2 February 2024

DOI: 10.1111/iwj.14787

IWJ WILEY

LETTER TO THE EDITOR

Little news is good news? What is missing in the recently published EN 13726:2023 test standard for wound dressings

Dear Editors,

Test standards are essential for evaluating medical devices by establishing consistent criteria and methodologies, ensuring reliable performance and effectiveness and facilitating product comparisons and regulatory compliance. We focus this letter on the recently revised EN 13726:2023 test standard for assessing the performance of wound dressings in laboratory evaluations, with emphasis on fluid handling (Figure 1).[1–3] We identify here disparities between the laboratory testing methods outlined in the updated standard[3] and real-world clinical practice. Specifically, soaking dressing specimens in salt solution until rapid saturation does not accurately replicate clinical dressing functionality, and there are also implications of using a nonbiological test fluid in these evaluations.[1] Solely relying on EN 13726:2023 methods for procurement decisions could compromise care quality, especially for advanced foam dressings, which may not perform similarly in clinical settings.[1] We recommend a holistic decision-making approach based on published evidence, encompassing advanced bioengineering research, validated clinically relevant test methods, clinical experience, practice judgement and cost-effectiveness analyses. This context calls for further improving the EN 13726:2023 to better align it with clinical realities, as detailed below.

Wound dressings play a crucial role in fluid handling, which is essential for positive clinical outcomes. This involves absorbing wound fluids, maintaining a moist environment and promoting tissue repair.[1] The European standard EN 13726, first published in 2002[2] and updated in 2023,[3] sets benchmarks for laboratory evaluations of dressings, focusing, for example, on absorption and moisture control.[2,3] The 2023 revision, titled 'Test methods for wound dressings. Aspects of absorption, moisture vapor transmission, waterproofness, and extensibility' measures the Free Swell Absorptive Capacity and Fluid Handling Capacity of dressings (in Annex B and E) which indicate consistent performance.[3] Clinicians and hospital administrators then use these test data for decision-making, but often tend to overinterpret the results. In this context, the clinical relevance and limitations of the revised standard[3] must be critically considered, especially in view of the impact on quality of life of patients.[1]

The fluid handling capacity measure for dressings and its limitations: The fluid handling capacity (FHC) measurement for dressings, detailed in Annex E of the updated standard,[3] has notable limitations. The FHC quantification combines fluid absorbency (ABS) and moisture vapour loss (MVL) from dressings with waterproof backing. In the test, a dressing is weighed, placed on a Paddington cup (Annex M[3]) saturated with 30 mL of liquid for 24 h and then reweighed to calculate the ABS and MVL. The total of the ABS and MVL gives the FHC, expressed in grams/cm^2/24 h.[3] While this method allows for reproducible results, which is important for quality control across batches, the rapid saturation of the dressing specimen oversimplifies the clinical reality, possibly reducing the real-world applicability. Clearly, industry test standards pertaining to medical devices, including those in EN 13726:2023[3] inevitably possess limitations. It is neither feasible nor practical to encompass the full complexity of a variety of potential clinical scenarios within a single test method that is designed to achieve reproducibility across different laboratories and ease of implementation.

With that said, in wound care, dressing performance relies on many diverse factors like patient characteristics, wound stages and healthcare practices. Laboratory tests, while quantitatively informative, often do not replicate real-world conditions. This dilemma is central in test development, where simplicity is favoured for practicality and standardization, as seen in EN 13726:2023.[3] However, simplicity can distance tests from reality, a notable issue in EN 13726:2023 fluid handling tests (Annex B to E).[3] These tests, particularly the Free swell absorptive capacity test (Annex B), involve saturating dressings, a method that is easy in laboratories but unrepresentative of actual use. The standard itself notes unrealistic outcomes, for example, fluid trapping leading to artificially

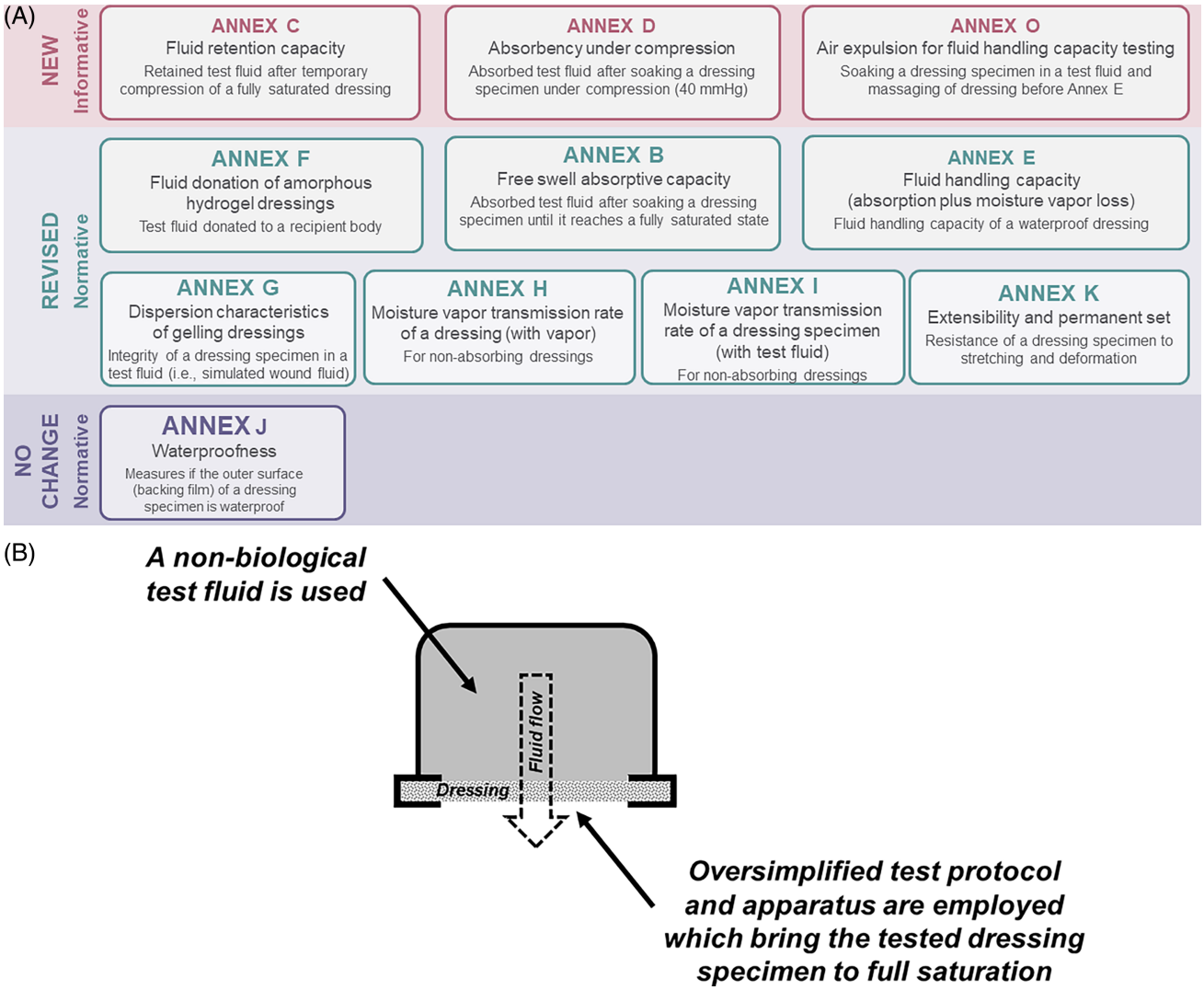

FIGURE 1 (A) Summary of the (new) 'informative' versus normative test methods detailed in the EN 13726:2023 test standard.[3] 'Informative' methods are methods that did not pass an interlaboratory validation process, called a 'round-robin' or laboratory proficiency test process in experimental methodology. (B) The clinical relevance of the EN 13726:2023 fluid handling capacity test is seriously questioned due to use of an oversimplified test method as well as a nonbiological test fluid.

high absorbency figures.[3] Also, many wound dressings leak before full saturation, meaning clinicians often change them earlier, a scenario not considered in Annex B-D.[3] In addition, breathable backing films in dressings evaporate exudate and thus may prevent saturation, an aspect overlooked in the revised standard.[3]

Advanced foam dressings, in particular, are designed to stay sub-saturated through their structure and usage instructions.[1,4] They are meant to be replaced *before* full saturation, with some having built-in replacement indicators or specific instructions for use to avoid leakage and potential wound deterioration.[1,4] However, the EN 13726:2023 standard, particularly in its Annex C,[3] tests dressings at full saturation under compression, a scenario unlikely in clinical practice. This test further overlooks fluid migration within the dressing during compression, a crucial aspect of dressing performance.[3] Moreover, the Free swell absorptive capacity test (Annex B) in the standard[3] also diverges from clinical realism, not accounting for directional flow of exudate from the wound into the dressing, allowing flow from multiple sides which is not a condition encountered in practice. This approach further misses the key issues of exudate leakage and pooling under the dressing, which are common clinical concerns.[3] Additionally, the test fluid indicated in the standard, named 'Solution A',[3] is a simplistic, nonbiological salt solution lacking the biophysical properties of wound exudates such as viscosity and wettability that are crucial for realistic interactions with dressings.[1] These discrepancies between the EN 13726:2023 standard[3] and clinical reality highlight the need for caution in interpreting its results for wound care decision-making.[1,5]

Informative versus *normative annexes*: When considering the application of the test methods outlined in EN 13726:2023[3] and interpreting their results, it is crucial to recognize that the revised standard adopts a two-tiered approach to test methods, encompassing both normative and informative annexes (Figure 1A). The normative methods (specifically Annexes B, E, F, G, H, I, J and K) serve as well-established protocols for evaluating wound dressings claiming compliance with EN 13726:2023, ensuring consistent product quality measures.[3] These methods offer repeatability and reliability in performance measurements through rigorous validation, ensuring credibility and reproducibility. In contrast, the informative annexes in the EN 13726:2023 standard discussed here[3] (i.e., Annexes C, D and O in the EN 13726:2023 standard[3]) provide supplementary information and guidance on assessing dressing performance. However, their value and applicability are significantly constrained by a lack of rigorous validation. According to Annex A (titled *Rationale for Revision for EN 13726 Parts 1–4*), Annexes C and D are informative methods as 'inter-laboratory experiments have shown unexplained variation, especially between laboratories', indicating a lack of successful round-robin (In experimental laboratory work, a round-robin design involves multiple laboratories sequentially performing the same experiments under a standardized protocol to assess reproducibility of the results. This collaborative approach, distributing the workload among participants, helps identify sources of variation and ensures reliability and consistency of experimental methods across different entities.) validation (presumably applying to Annex O as well, given its informative classification). Classifying a test method as 'informative' underscores a need for caution when interpreting and applying outcomes obtained using the said method. Hence, while informative methods may provide additional insights, their outcomes should not supersede well-established data obtained through normative testing. It is essential to exercise discretion when utilizing informative test results and prioritize insights derived from validated, normative methods. Investigating the association between unexplained outcome variations and the test protocol outlined in Annex O, *Air expulsion for fluid handling capacity testing*, we present our recent laboratory findings for a specific non-bordered foam dressing to exemplify the problem (Figure 2). As the name indicates, Annex O is performed before the testing of FHC (as detailed in Annex E of[3]). Of note, application of Annex O requires that the dressing under evaluation has previously demonstrated failure in adequately absorbing the test fluid according to Annex E alone, causing dry spots to be observable on the base of the dressing following a preceding 24-h FHC test. Moreover, it is crucial to highlight that if applying Annex O, both sets of data

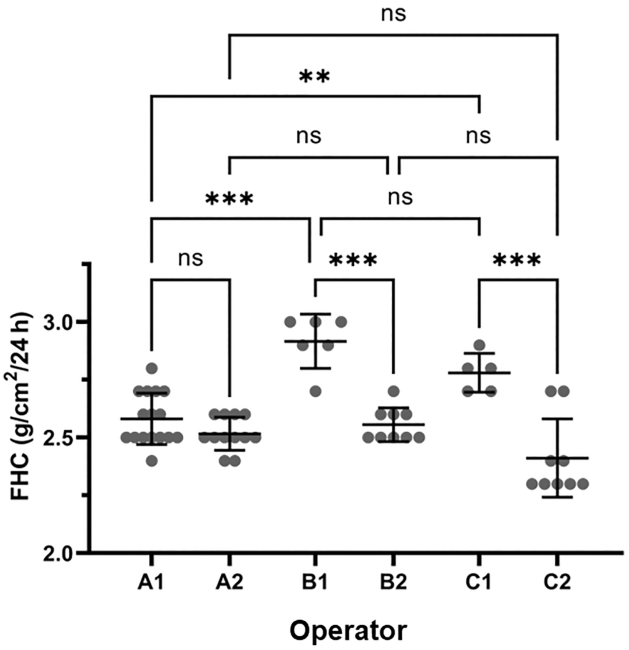

FIGURE 2 Inter-operator and intra-operator variability in fluid handling capacity (FHC) outcomes associated with Annex O of EN 13726:2023.[3] Three independent operators (A, B and C) followed Annex O in combination with Annex E as detailed in EN 13726:2023[3] to evaluate the FHC of a certain commercial foam dressing. A first set of experiments, with FHC outcomes labelled A1, B1 and C1 resulted in statistically significant differences between A1, B1 and C1 (in a one-way analysis of variance followed by Bonferroni post-hoc multiple pairwise comparisons). This prompted a review and modification of the laboratory instructions for performing Annex O in an attempt to reduce the observed variability; the primary modification was harmonization of the air massaging technique, with operator A adopting the technique used by operators B and C. The FHC outcomes from a second set of experiments conducted in accordance with these revised instructions are labelled A2, B2 and C2. Statistical differences emerged between B1 and B2, as well as between C1 and C2, while no such differences were observed between A1 and A2. Additionally, the FHC outcomes A2, B2 and C2 were statistically similar. Data are shown as means (centre lines) with error bars depicting the standard deviations. Each repetition is depicted as a circle, ** $p < 0.001$, *** $p < 0.0001$ and ns, not significant.

resulting from Annexes E and O must be reported together.[3] The initial phase of the combined test (Annexes E and O) involves expelling air and replacing it with a test fluid. This is achieved by using a plunger to massage the dressing from its wound-contacting side. It is important to emphasize that this procedure does not simulate the natural entry of exudate into a dressing in clinical practice. Our results demonstrate that the FHC outcomes obtained when applying Annex O with E are susceptible to considerable variations apparently related to both inter-tester and intra-tester differences (Figure 2). We suspect that massaging the tested dressings

practically forces the FHC measurements to reflect the MVL of a fully saturated dressing right from the beginning of the test, disregarding the time factor in fluid absorbency and the coupled MVL, thus making the test clinically irrelevant.

Procurement decisions and clinical relevance: A major concern arising from the implementation of the *Free swell absorptive capacity* and the FHC tests in the EN 13726 standard[2,3] is that the test results are eventually incorporated into procurement decisions, where higher FHC values are deemed better. This practice draws a striking analogy to purchasing high-speed cars in a world governed by strict speed limits. While products may excel in the EN 13726 laboratory test settings,[2,3] this does not necessarily reflect their exudate management performance in clinical practice when interacting with real exudates on actual wounds. Relying solely on simplified laboratory tests for selecting wound dressings in tender-driven markets overlooks critical real-world considerations, potentially compromising the clinical efficacy, the quality of care, the quality of life of patients and the cost-benefit outcomes of the selected treatment protocol and products. Alternatively, a holistic approach to the dressing selection process should be adopted. This approach should integrate various aspects of patient care, including more sophisticated, clinically relevant, contemporary laboratory methods and peer-reviewed bioengineering research reported in the literature for the specific products of interest. Relevant clinical experience and judgement, cost-effectiveness analyses and performance in core treatment outcomes should further be considered.[5–9]

More than 20 years have elapsed between the publication of the original version of the EN 13726 standard and its updated 2023 edition. Despite the significant progress made in wound healing research,[1,5–10] it is disappointing, in our view, that the changes made in the EN 13726 standard are so marginal. The minimal impact on the wound care research and development arena brought by the newly released version of the standard is, unfortunately, not good news, as the gap between the state-of-science of wound care and testing standards remains large and likely has even increased. To bridge the existing gaps between the EN 13726:2023 test methods[3] and the clinical performance of wound dressings, a process of improving the test methods for better clinical relevance is required. This involves additional advanced bioengineering laboratory research, typically conducted in academia, which is not constrained by the need to simplify the work to the extent typical of a test standard. Annex Q (titled '*Future work*') of EN 13726:2023[3] does leave some space for such improvements, with a promising optional avenue of substituting Solution A with more biologically representative simulated wound fluids, containing physiologically relevant protein sources to better simulate the fluid behaviours of wound exudates. Other factors need consideration as well, such as directional flow (as mentioned above); the influence of gravity on the flow regime from the wound (for wound-dressing interfaces that are inclined with respect to the horizon such as in treating venous leg ulcers); better representation of wound-dressing environments in terms of exudate flow volumes and rates; thermodynamic conditions; and potential bodyweight or external forces acting on the wound and dressing.

A call for improvement and future considerations: Research efforts aiming to establish connections between laboratory outcomes and the clinical performance of dressing products are paramount for advancing product efficacy and making evidence-based decisions that ultimately enhance the quality of life for patients in need of wound care. While this may be a long-term endeavour, it must be pursued as an incentive for ongoing methodological updates in standard development work, aligning them continuously with clinical observations and established wound care practices. As described here, the updated EN 13726:2023[3] has considerable limitations in representing the complexity of the clinical performance of dressings, and there is a pressing need for its further improvement towards better clinical relevance. Furthermore, we are concerned that the incorporation of immature, so-called 'informative' methods in the updated standard,[3] lacking acceptable round-robin validation leading to absence of recognized limitations, renders these methods unsuitable for rigorous product comparisons and evidence-based decision-making. The recognition of limitations in a test method, as detailed in this letter, does not diminish its importance. Instead, it underscores the need to place it in the context of clinical work and the spectrum of available resources from which evidence can be extracted. These resources range from academic bioengineering laboratory studies (both experimental and in silico) to clinical trials focusing on a pre-defined core outcome set.[1,5–10] Stakeholders in the wound care arena should be thoughtful in not relying solely on EN 13726[2,3] as their source of information for decision-making. They should strive for a delicate balance, recognizing the significance of laboratory techniques while remaining mindful of other types of peer-reviewed evidence as well as their available resources and other constraints. Embracing a holistic approach and a comprehensive framework that integrates various aspects of laboratory and clinical efficacy of dressing products and the overall quality of care, using core treatment outcomes which capture these variables altogether, is essential in this process.[1,5–10] Importantly, interpreting or attempting to draw conclusions from data generated using the EN 13726:2023 standard[3] must be approached with high caution and using other evidence in the

literature, as this standard still needs substantial improvements to represent the clinical reality of wound care.

ACKNOWLEDGEMENTS

Special thanks to Ms. Victoria Teng of Mölnlycke Health Care for organizing fluid handling capacity testing.

CONFLICT OF INTEREST STATEMENT

Author AG is a paid consultant for Mölnlycke Health Care (Gothenburg, Sweden).

DATA AVAILABILITY STATEMENT

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

Erik Nygren [1]
Amit Gefen [2,3,4]

[1]*Wound Care Research & Development, Mölnlycke Health Care AB, Gothenburg, Sweden*
[2]*Department of Biomedical Engineering, Faculty of Engineering, Tel Aviv University, Tel Aviv, Israel*
[3]*Department of Public Health and Primary Care, Skin Integrity Research Group (SKINT), University Centre for Nursing and Midwifery, Ghent University, Ghent, Belgium*
[4]*Department of Mathematics and Statistics, Faculty of Sciences, Hasselt University, Hasselt, Belgium*

Correspondence
Amit Gefen, The Herbert J. Berman Chair in Vascular Bioengineering, Department of Biomedical Engineering, Faculty of Engineering, Tel Aviv University, Tel Aviv 6997801, Israel.
Email: gefen@tauex.tau.ac.il

ORCID

Amit Gefen https://orcid.org/0000-0002-0223-7218

REFERENCES

1. Gefen A, Alves P, Beeckman D, et al. How should clinical wound care and management translate to effective engineering standard testing requirements from foam dressings? Mapping the existing gaps and needs. *Adv Wound Care (New Rochelle)*. 2024;13(1):34-52. doi:10.1089/wound.2021.0173
2. EN 13726-1. *Test Methods for Primary Wound Dressings - Part 1: Aspects of Absorbency*. European Committee for Standardization; 2002.
3. EN 13726. *Test Methods for Wound Dressings - Aspects of Absorption, Moisture Vapour Transmission, Waterproofness and Extensibility*. European Committee for Standardization; 2023.
4. Gefen A, Santamaria N. Saturation of a dressing applied to an exuding wound: the gap between clinical judgment and laboratory testing. *Wound Int*. 2021;12(2):20-26.
5. Gefen A, Alves P, Beeckman D, et al. Fluid handling by foam wound dressings: From engineering theory to advanced laboratory performance evaluations. *Int Wound J*. 2024;21(2):1-25, doi:10.1002/IWJ.14674
6. Santamaria N, Woo K, Beeckman D, et al. Clinical performance characteristics for bordered foam dressings in the treatment of complex wounds: an international wound dressing technology expert panel review. *Int Wound J*. 2023;20(9):3467-3473.
7. Raepsaet C, Alves P, Cullen B, et al. The development of a core outcome set for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds. *J Tissue Viability*. 2023;32(3):430-436. doi:10.1016/j.jtv.2023.04.008
8. Raepsaet C, Alves P, Cullen B, et al. Study protocol for the development of a core outcome set (COS) for clinical effectiveness trials of bordered foam dressings in the treatment of complex wounds. *J Tissue Viability*. 2022;31(4):625-629. doi:10.1016/j.jtv.2022.09.004
9. Raepsaet C, Alves P, Cullen B, et al. Clinical research on the use of bordered foam dressings in the treatment of complex wounds: a systematic review of reported outcomes and applied measurement instruments. *J Tissue Viability*. 2022;31(3):514-522. doi:10.1016/j.jtv.2022.05.005
10. Gefen A, Alves P, Beeckman D, et al. Mechanical and contact characteristics of foam materials within wound dressings: theoretical and practical considerations in treatment. *Int Wound J*. 2023;20(6):1960-1978. doi:10.1111/iwj.14056