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Novotel Geelong, VIC

Wound dressings: The oldest medical device in human history, but is the scientific evidence base proportionate?

Professor Amit Gefen

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AUSTRALIAN WOUND & SKIN ALLIANCE

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Declaration of Financial Interests or Relationships

Speaker's name: Professor Amit Gefen

The speaker reports multiple interfaces with the wound care industry in the fields of preventative and treatment dressings as well as skin protectants

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AUSTRALIAN WOUND & SKIN ALLIANCE

Wound dressing: The most ancient medical device

How are wound dressings currently being evaluated in laboratory testing for predicting their real-world clinical performance?

Failure of wound dressings in exudate management

Clinical practice

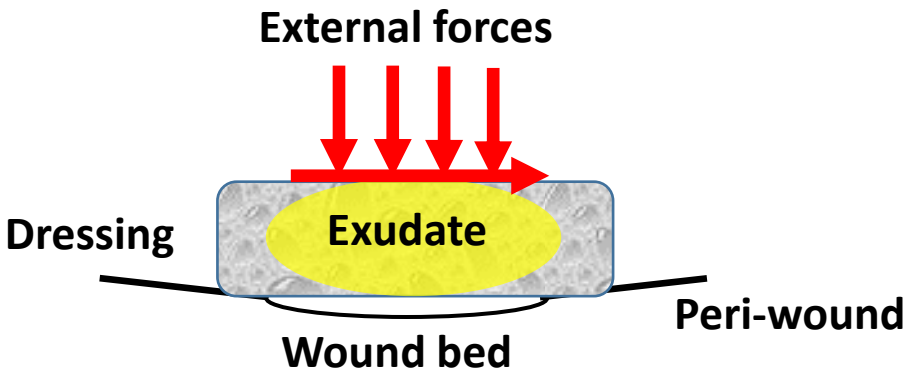
Saturation of a dressing applied to an exuding wound: the gap between clinical judgment and laboratory testing

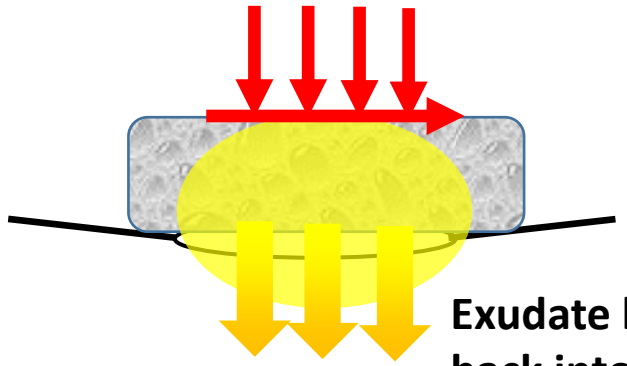
Authors:
Amit Gefen and Nick Santamaria

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.

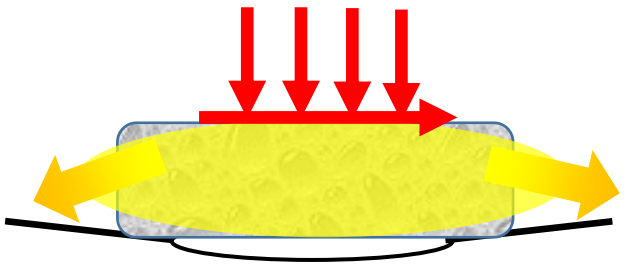
***Amit Gefen** is Professor of Biomedical Engineering, Department of Biomedical Engineering, Faculty of Engineering, Tel Aviv University, Israel; **Nick Santamaria** is Professor of Nursing Research School of Health Sciences, University of Melbourne, Melbourne, Victoria, Australia*

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





Exudate leakage back into the wound bed



Exudate leakage onto peri-wound skin

Gefen & Santamaria *Wounds International* 2021

Dressing failure in clinical settings typically relate to inadequate exudate management

WHS Wound Healing Society

How Should Clinical Wound Care and Management Translate to Effective Engineering Standard Testing Requirements from Foam Dressings? Mapping the Existing Gaps and Needs

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Significance: Wounds of all types remain one of the most important, expensive, and common medical problems, for example, up to approximately two-thirds of the work time of community nurses is spent on wound management. Many wounds are treated by means of dressings. The materials used in a dressing, their microarchitecture, and how they are composed and constructed form the basis for the laboratory and clinical performances of any advanced dressing.
Recent Advances: The established structure/function principle in material science is reviewed and analyzed in this article in the context of wound dressings. This principle states that the microstructure determines the physical, mechanical, and fluid transport and handling properties, all of which are critically important for, and relevant to the, adequate performances of wound dressings.
Critical Issues: According to the above principle, once the clinical requirements for wound care and management are defined for a given wound type and etiology, it should be theoretically possible to translate clinically relevant characteristics of dressings into physical test designs resulting specific metrics of materials, mechanical, and fluid transport and handling properties, all of which should be determined to meet the clinical objectives and be measurable through standardized bench testing.
Future Directions: This multidisciplinary review article, written by an International Wound Dressing Technology Expert Panel, discusses the translation of clinical wound care and management into effective, basic engineering

DOI: 10.1089/wound.2021.0173

Gefen et al. *Advanced Wound Care* 2022

Mass transport performance

- Excess exudate removal
- Moisture control
- Gas transmission

All the above performance measures can be determined in a bioengineering laboratory setting

Dressing failure scenarios

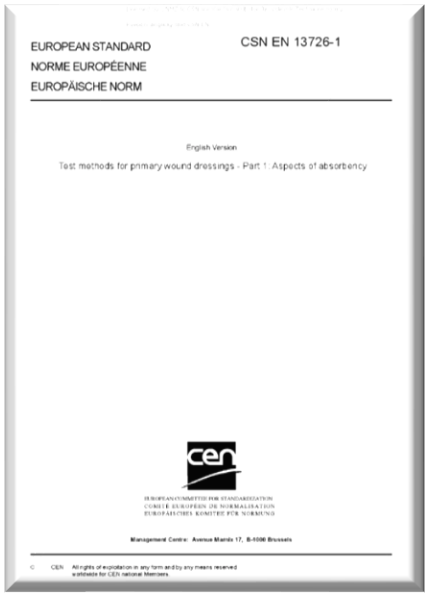
- Premature detachment
- Exudate accumulation
- Development of infection

Clinical and financial outcomes

- Impeded healing
- Wound necrosis
- Poor cost-effectiveness

What is NOT taken into account in existing tests?

EN 13726-1 Test methods for primary wound dressings - Part 1: Aspects of absorbency


EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

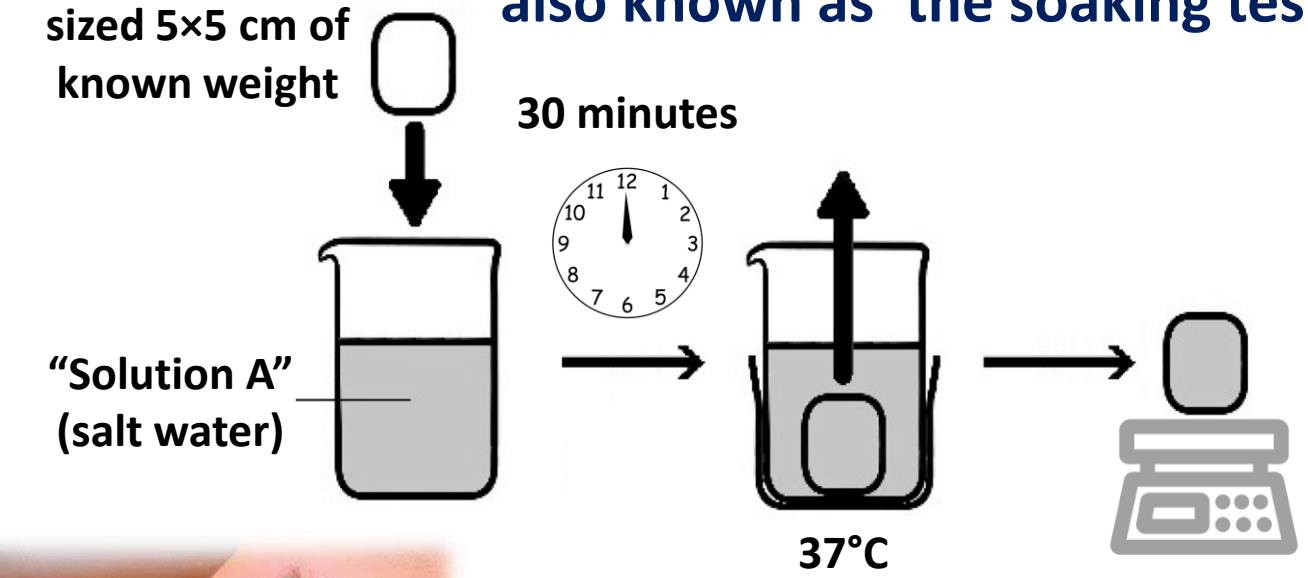
CSN EN 13726-1

English Version

Test methods for primary wound dressings - Part 1: Aspects of absorbency

cen

"Free-Swell Absorptive Capacity" also known as 'the soaking test'



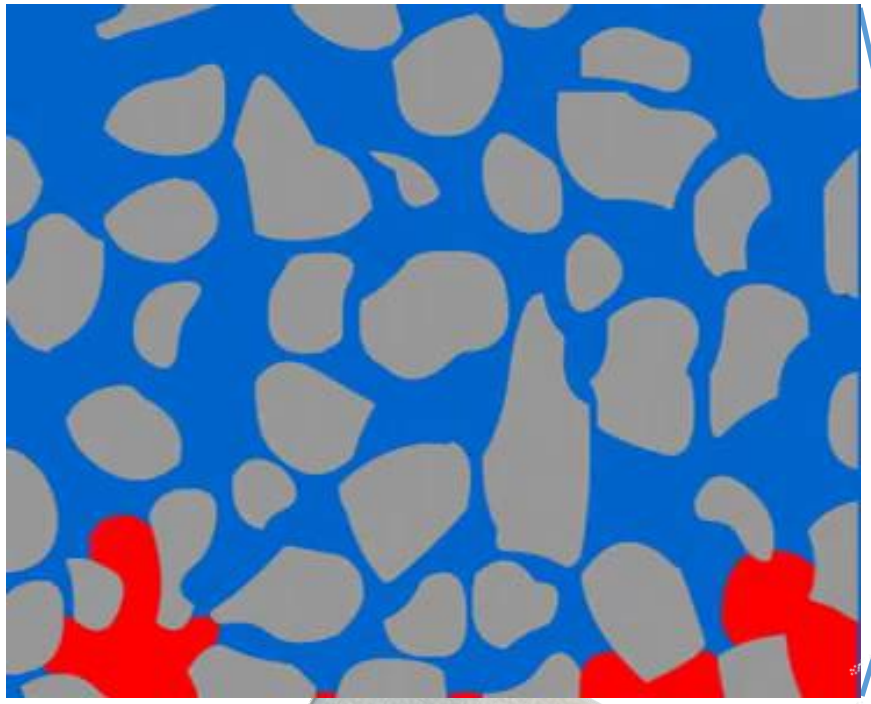
It is as simple –

and as simplistic

– as a tea dunk,

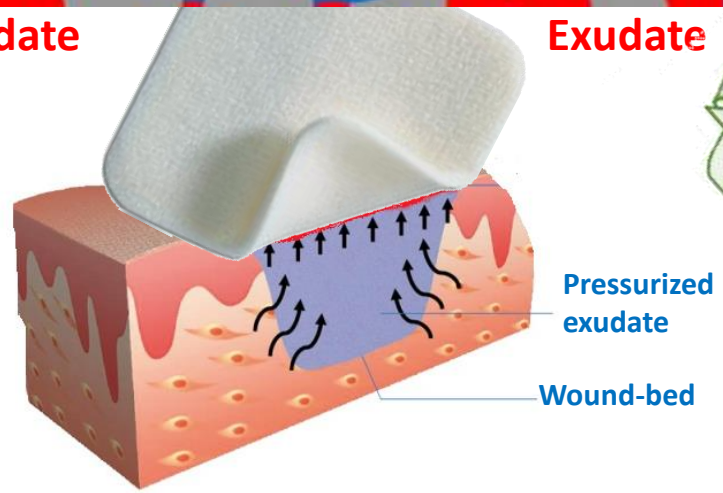
but lacks any clinical relevance!

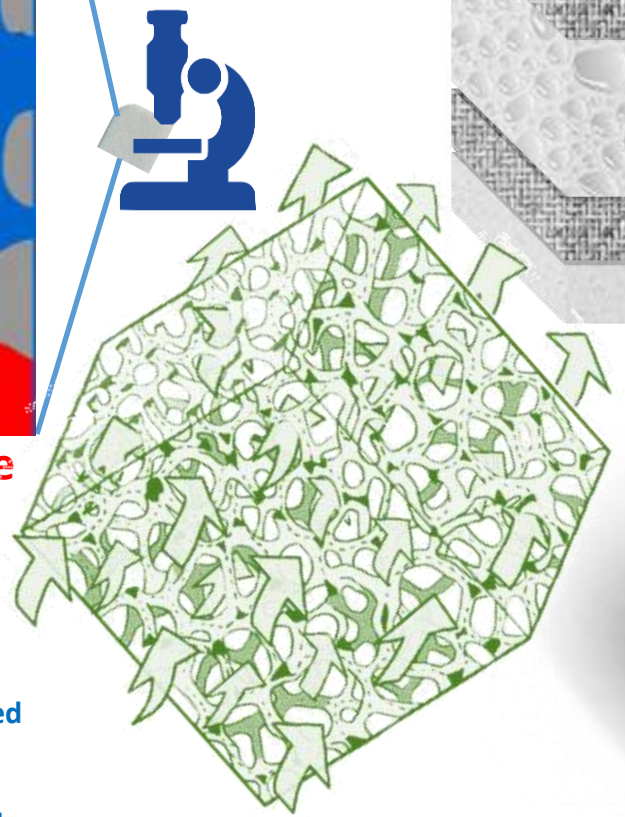
Directionality: In real-world clinical settings, wound dressings always absorb exudate from their wound pad surface (only), not from all sides



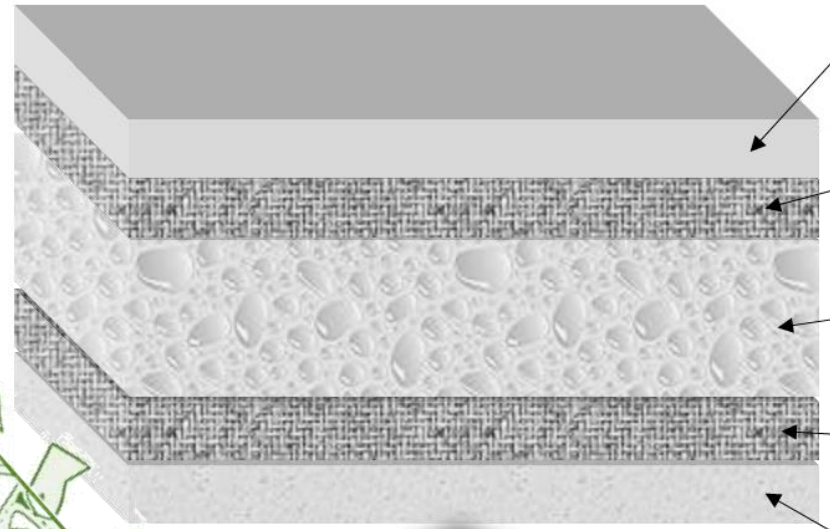
Exudate

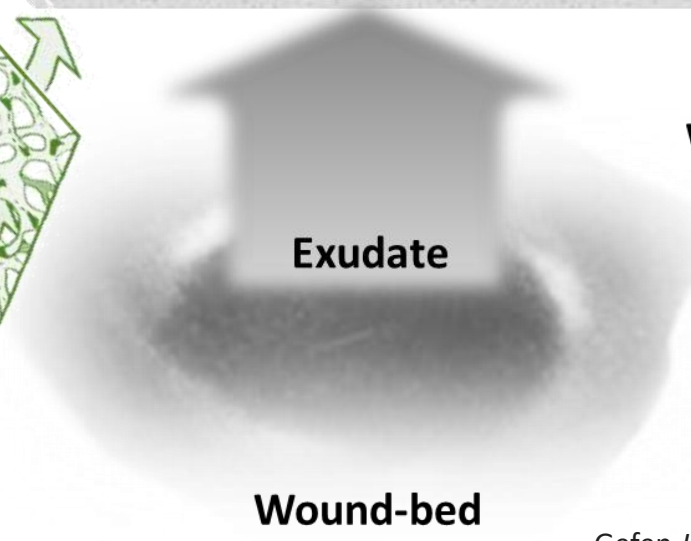
Exudate





Flow is directional in the 3D microstructure



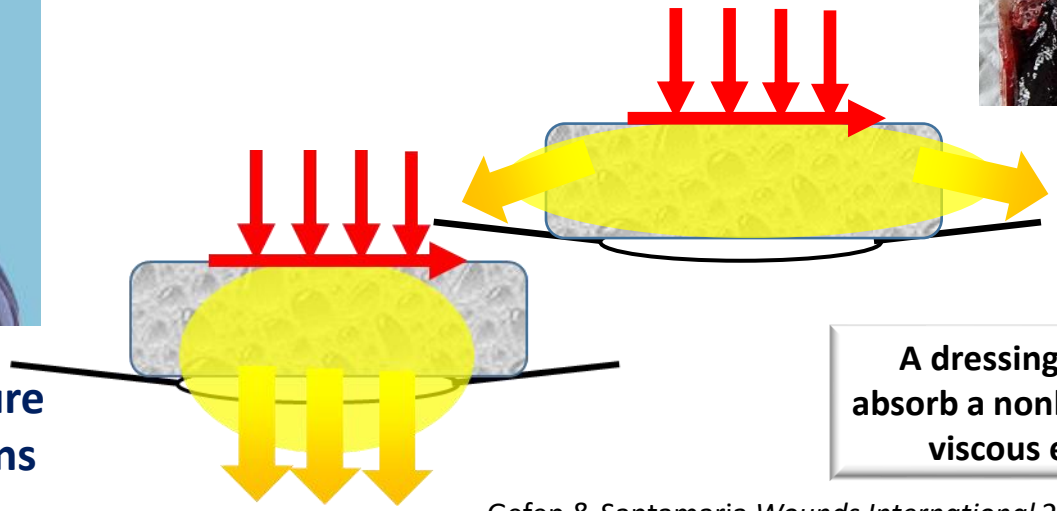


Gefen *Journal of Wound Care* 2021
Gefen et al. *Advanced Wound Care* 2022

Effects of exudate viscosity

Viscous fluids (exudates included) flow s.l.o.w.l.y

but the passages in the microstructure of dressings are narrow, which means that if the exudate is too viscous:



Dressings failing to absorb hematic viscous exudates

A dressing failing to absorb a nonhemorrhagic viscous exudate

Gefen & Santamaria *Wounds International* 2021
Gefen et al. *Advanced Wound Care* 2022

The important of composition of test fluids

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ORIGINAL ARTICLE

IWJ WILEY

The importance of the simulated wound fluid composition and properties in the determination of the fluid handling performance of wound dressings

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Abstract

Effective fluid handling by wound dressings is crucial in the management of exuding wounds through maintaining a clean, moist environment, facilitating healing by removing excess exudate and promoting tissue regeneration. In this context, the availability of reliable and clinically relevant standardised testing methods for wound dressings are critical for informed decision making by clinicians, healthcare administrators, regulatory/reimbursement bodies and product developers. The widely used standard EN 13726 specifies the use of Solution A, an aqueous protein-free salt solution, for determining fluid-handling capacity (FHC). However, a simulated wound fluid (SWF) with a more complex composition, resembling the protein, salt, and buffer concentrations found in real-world clinical exudate, would provide a more clinically relevant dressing performance assessment. This study compared selected physicochemical parameters of Solution A, an alternative, novel simulated wound fluid (SWF A), and a benchmark reference serum-containing solution (SCS) simulating chronic wound exudate. Additionally, FHC values for eight advanced bordered and non-bordered foam dressings were determined for all three test fluids, following EN 13726. Our findings demonstrate a close resemblance between SWF A and SCS. This study highlights the critical importance

Abbreviations: BSA, bovine serum albumin; FHC, fluid handling capacity; SCS, serum-containing solution; Sol A, Solution A; SWF A, simulated wound fluid A.

Anna U. Svensby and Erik Nygren contributed equally to this work.

	Component	SWF A
Salts	Sodium chloride, NaCl	110 mM
	Calcium chloride, $CaCl_2$	2.2 mM
	Potassium chloride, KCl	2.7 mM
	Magnesium chloride, $MgCl_2$	0.5 mM
Protein	Bovine serum albumin (BSA), protease-free, lyophilised fraction V, purity ≥98.5%	34 g/L
Buffers	Potassium phosphate, KH_2PO_4	1.3 mM
	Sodium bicarbonate, $NaHCO_3$	20 mM

SWF A= **new simulated wound fluid**
SCS= serum-containing solution
Sol A= traditional solution A

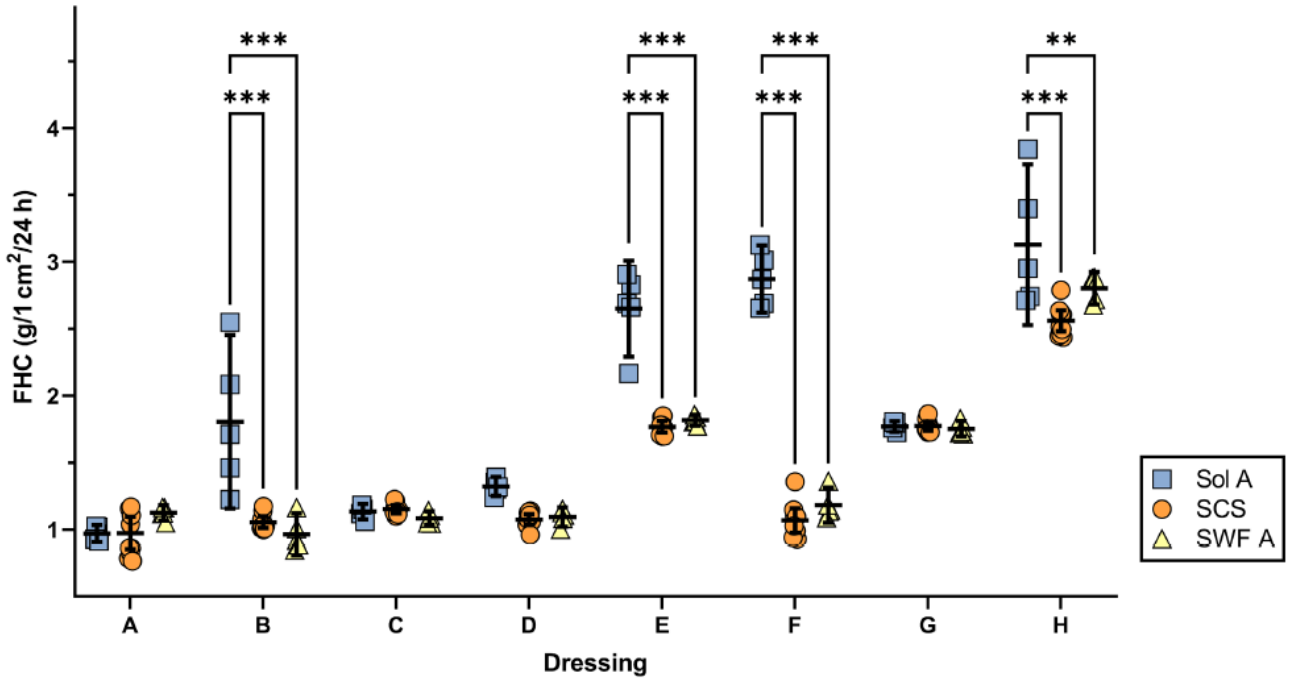
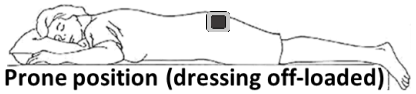


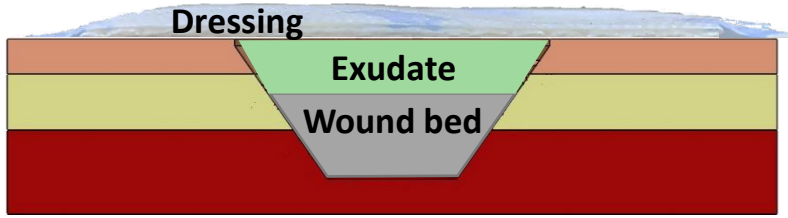
FIGURE 2 Fluid handling capacity (FHC) data (showing the mean and 95% confidence intervals) for the eight tested wound dressings
Svensby, Nygren, Gefen et al. *International Wound Journal* 2024

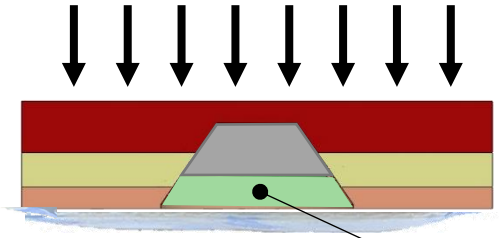
Dressing orientation with respect to the gravity vector

Gravity



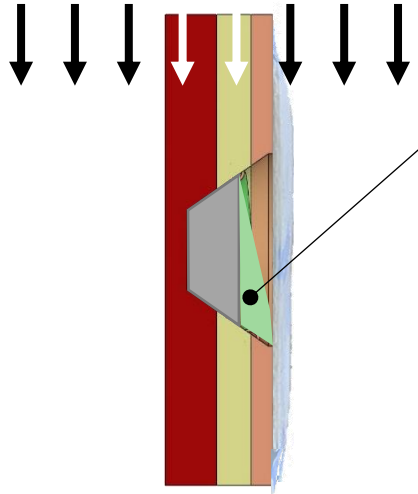
Prone position (dressing off-loaded)



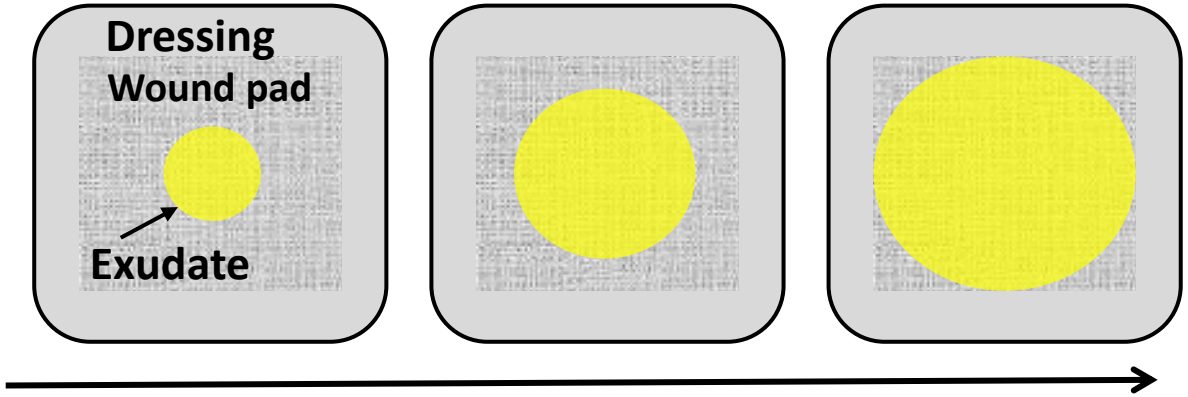


Supine position (dressing non off-loaded)

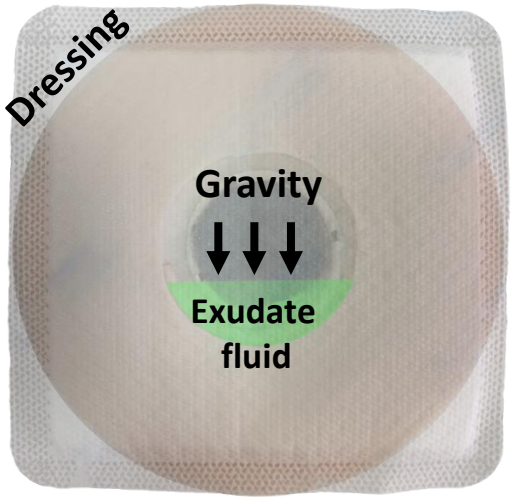
Exudate



Sims' position (dressing off-loaded)



Spread of exudate within the wound pad is approximately symmetrical

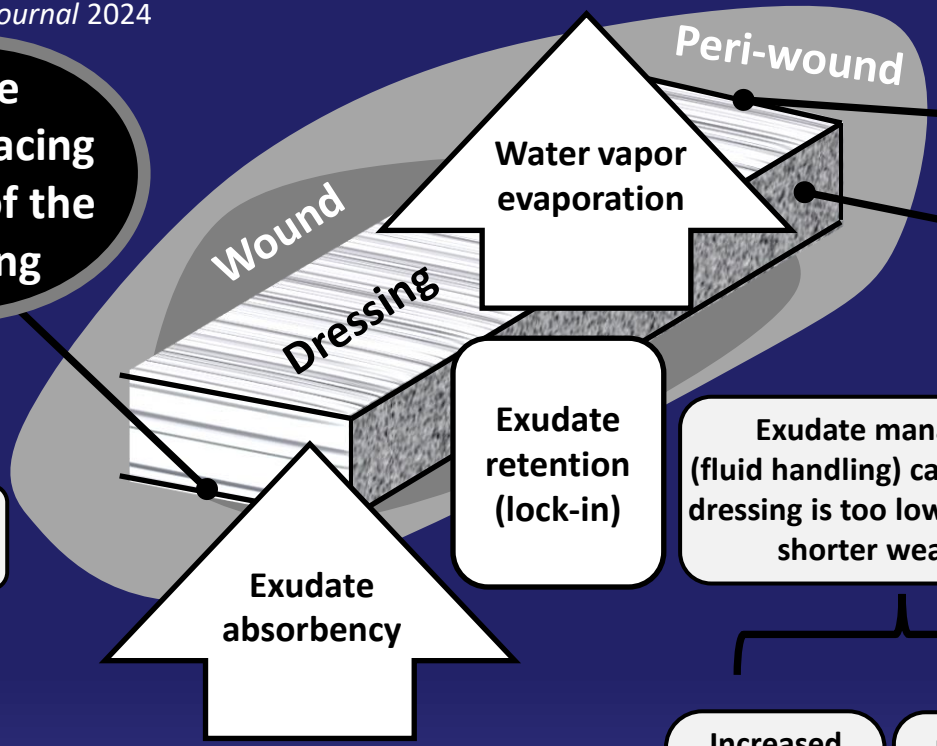


Spread of exudate within the wound pad is NOT symmetrical! The exudate is pulled downwards

Gefen & Santamaria *Wounds International* 2021
Orlov & Gefen *International Wound Journal* 2022

Complexity of the problem of fluid handling: Clinical & cost aspects

Gefen et al. *International Wound Journal* 2024



At the wound-facing surface of the dressing

- Exudate pooling under the dressing
  - Degradation of the wound-bed
  - Maceration of peri-wound skin
  - → Delayed wound healing, non-healing or deterioration
    - Risk of amputation or limb loss
    - Risk of osteomyelitis, sepsis or organ failure

Within the dressing

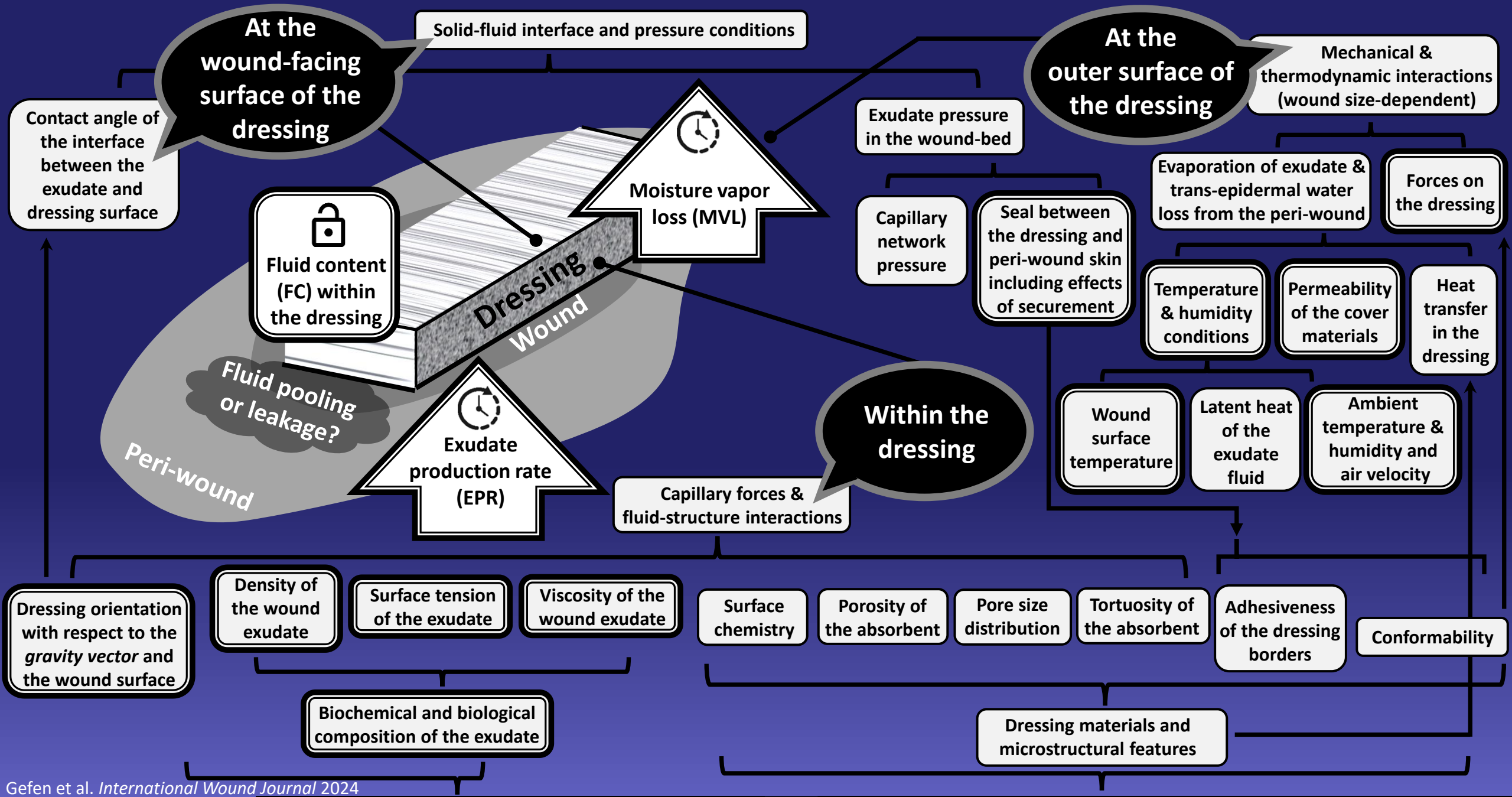
- Exudate management (fluid handling) capacity of the dressing is too low leading to a shorter wear time
  - Increased clinician time spent on dressing changes
  - Increased number of dressings needed
  - → Increased direct wound care costs

At the outer surface of the dressing (i.e., external leakage)

- Exudate leakage from the dressing to the surroundings
  - Malodors
  - Staining of clothing and bedsheets
  - Moisture in secondary wound care products
  - Risk of spread of infections increases
  - → Psychosocial impact on quality of life

- Additional healthcare resources consumed (e.g., clinical visits or hospitalizations)

Wound care clinical outcome-related implications & Cost-effectiveness-related implications (including outside wound care)

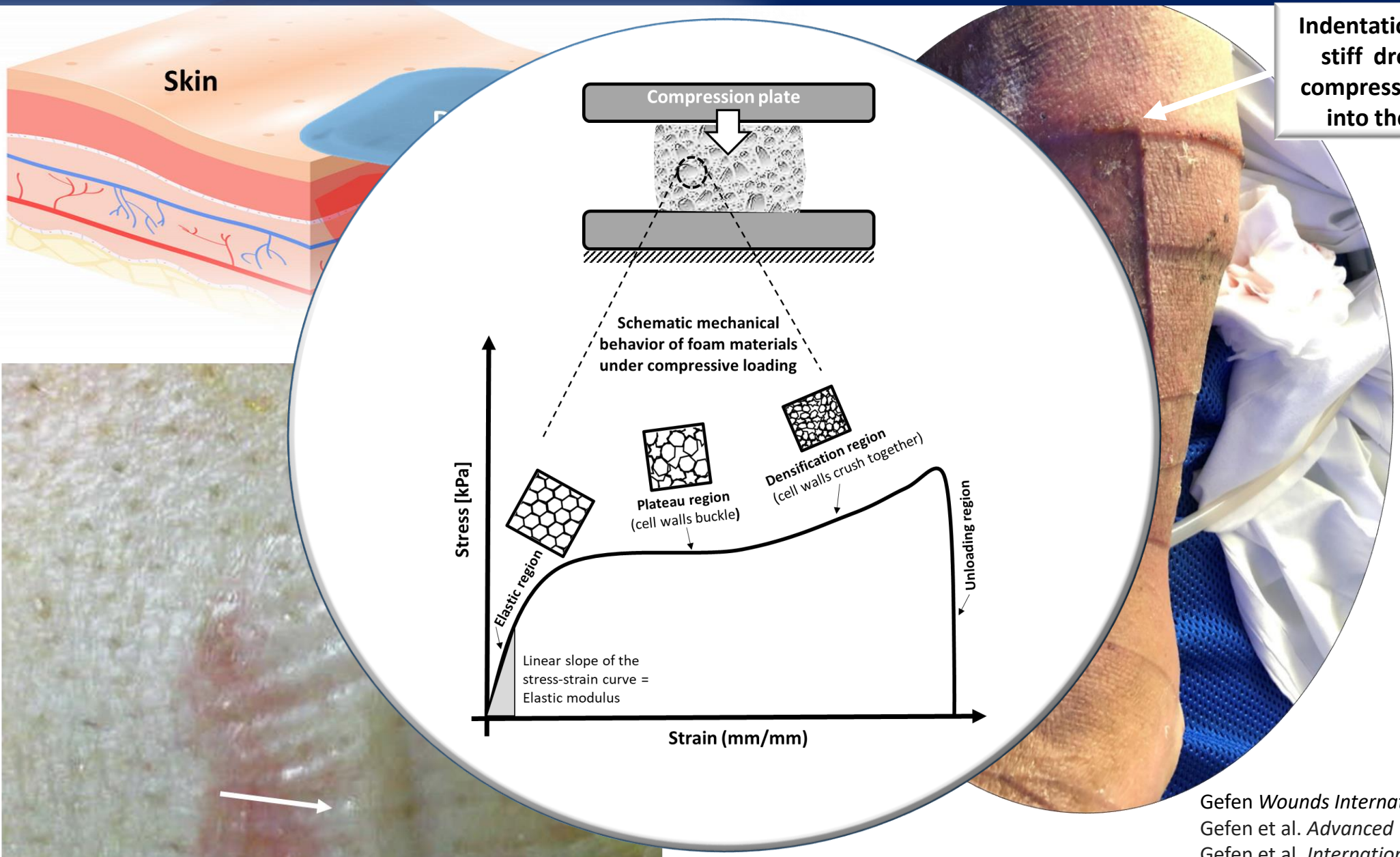


Gefen et al. *International Wound Journal* 2024

Measurable or controllable in laboratory wound models

Patient- and wound-related factors & Dressing design- and manufacturing-related factors

What else can go wrong and is not currently being tested? Mechanical performance



Gefen *Wounds International* 2021
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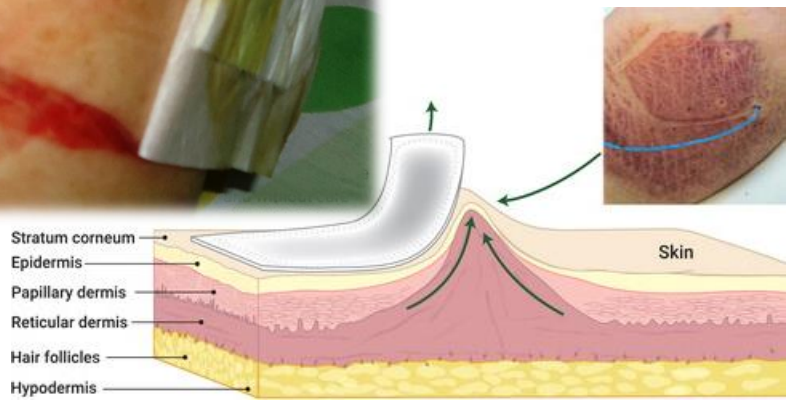
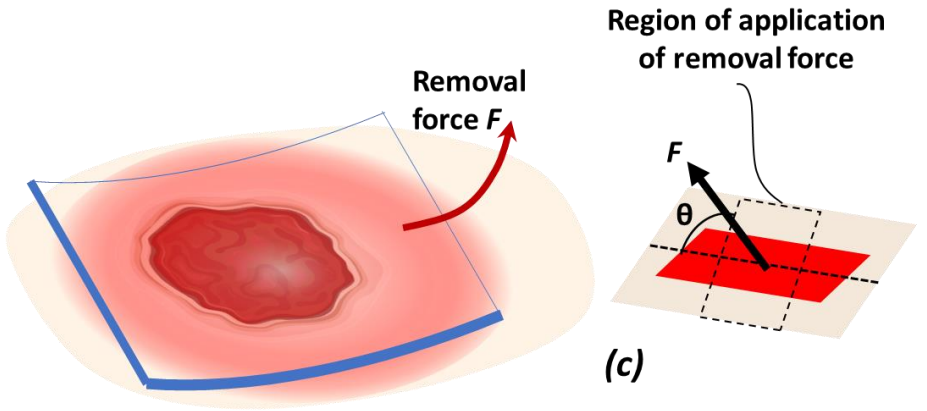
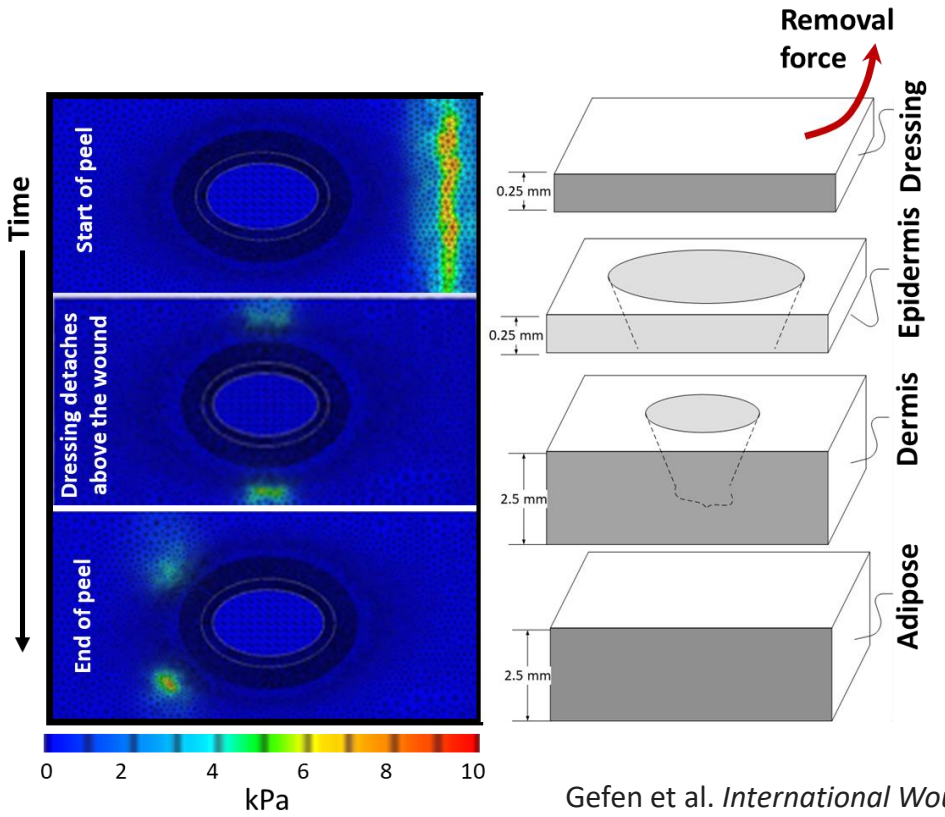
And what else can go wrong and is again not tested? Adhesive-related injuries

A medical adhesive-related skin injury (MARSI)



Barton *British Journal of Nursing* 2021





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