Evaluating Current *in-vitro* Assays for Assessing Fluid Handling Properties of Dressings and their Clinical Relevance

Sarah Aickin, Michelle DelBono, Sharon Lindsay, Priyesh Mistry, Rachael Clark, Breda Cullen
Systagenix Wound Management, Gargrave, UK

Let's Comfort™

LET'S HEAL™

ABSTRACT

Introduction
Wound care dressings have advanced in recent years; notable features of modern dressings include maintenance of a bacterial barrier while still retaining breathability of the dressing. Numerous *in vitro* assays have been developed and are widely used within the healthcare industry to evaluate these properties in existing and prototype dressings, but exactly how clinically relevant are these assays? This study aims to review the clinical relevance of current *in vitro* assays used to evaluate the fluid handling capabilities of dressings.

Methods
Numerous *in vitro* test methods were reviewed to ascertain their clinical relevance in assessing various physical properties of a range of dressings. These methods included the European Standards for measuring moisture vapour transmission rate (MVTR) assay, the Wound Care Research for Appropriate Products (WRAP) assay for measuring strikethrough and an in-house simulated leg model assay based on the WRAP model.
The MVTR assay involved adding water in a static, closed system, whereas both the simulated leg model assay and WRAP assay involved adding simulated wound fluid (SWF) (with blue dye for visualisation) under continuous flow conditions to mimic an exudating wound. Briefly, the MVTR assay involved saturating test dressings in water for 24 hours prior to calculating the MVTR. By comparison, the WRAP assay and simulated leg model assay enabled the continuous perfusion of SWF through the dressings; dressings were placed either horizontally (WRAP assay) or vertically (simulated leg model assay) to mimic a wound site on a patient.

Results
Experimental procedures were reviewed; notable limitations of the MVTR method included an inability to assess the fluid handling capabilities of test dressings under continuous flow conditions over a period of time corresponding to dressing wear-time. Results for each assay were collected and tabulated. ALLEVYN® Adhesive and ALLEVYN® Gentle Border had the highest MVTR out of all dressings tested. However, when using the WRAP model, strikethrough was only observed for ALLEVYN® Adhesive and ALLEVYN® Gentle Border. When assessed using the simulated leg model assay, Tielle® Plus was found to distribute the SWF evenly across the dressing, whereas "pooling" of fluid along the bottom edge of the dressing was noted with ALLEVYN® Adhesive.

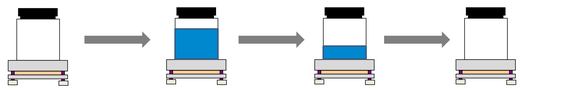
Conclusions
A more comprehensive assessment of the fluid handling characteristics of dressings can be determined when a range of test systems are used compared with relying upon only one method. In addition, it is important to recognise the differences in experimental design when assessing dressing performance. For example, while ALLEVYN® dressings had the highest MVTR out of all dressings tested, they were also the only dressings that showed strikethrough at 24 h when assessed under continuous, "real-life" conditions. While the MVTR assay may provide data on the amount of water evaporated from a saturated dressing, this system does not adequately reflect an exudating chronic wound environment. The WRAP assay and simulated leg model assay enabled the assessment of the fluid handling properties of dressings under continuous flow conditions, thus mimicking an exudative wound over a period of time that corresponds to dressing-wear time. In addition, the leg simulation model indicated that SWF was not distributed evenly with ALLEVYN® Adhesive – ultimately this may compromise the integrity of the dressing over time.

OBJECTIVE

- To gain a more comprehensive understanding of dressing performance using a range of test methods.

Paddington Cup Method (BS:EN 13726)

- **Total Fluid Handling: MVTR and Absorbency**

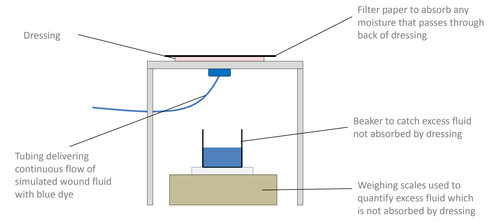


1) The dry "Paddington Cup" with sample is weighed *weight = a*
2) The "Paddington Cup" with sample + water is weighed *weight = x*
3) After storage the apparatus is weighed again, *weight = y*
4) Water is drained and the apparatus weighed *weight = b*

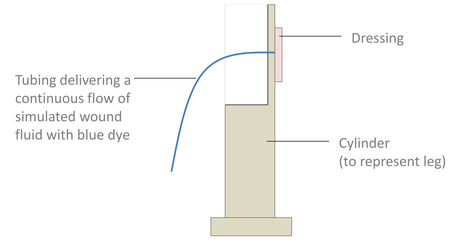
MVTR = *x-y /storage time/ area*

Absorbent Capacity = *b-a /storage time/ area* **Total Fluid Handling = MVTR + Absorbent Capacity**

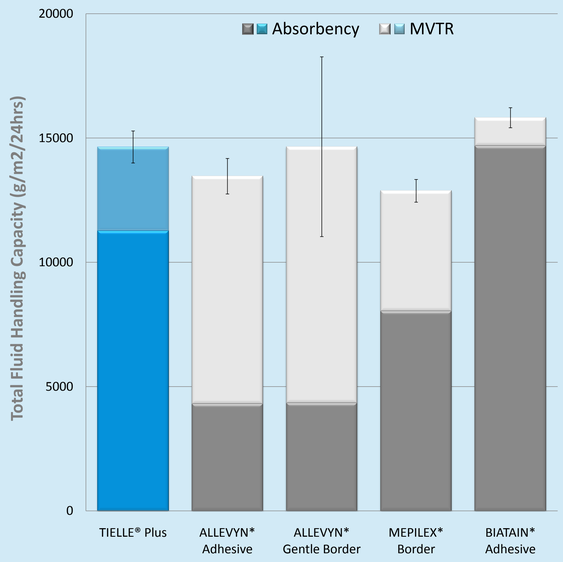
WRAP Model: Wound Care Research for Appropriate Products



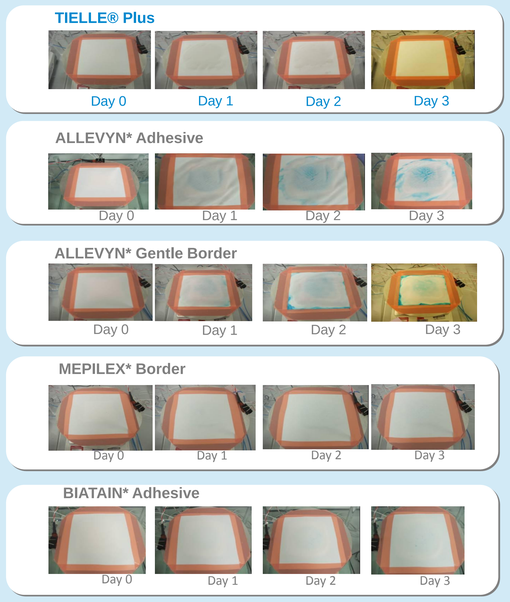
Vertical leg model



RESULTS: Total Fluid Handling



RESULTS : Strikethrough of fluid to filter paper through back of dressing after 24hrs



RESULTS: Fluid absorption after 24hrs by dressings when applied vertically to a leg model

ADVANTAGES

- Recognised standard test method
- Easy to calculate total fluid handling capacity of a saturated dressing (absorbency and MVTR)
- Provides quantitative data

DISADVANTAGES

- Only centre of the dressing is tested
- Total fluid handling data represents maximum values
- Not clinically representative

ADVANTAGES

- Continuous flow of SWF is more clinically relevant than Paddington cup method
- Good model to evaluate dressing strikethrough
- Provides quantitative data

DISADVANTAGES

- Technically more difficult to setup than Paddington cup method
- Does not demonstrate how dressing will handle fluid on a vertical leg

ADVANTAGES

- Continuous flow of SWF is more clinically relevant than Paddington cup method
- Demonstrates how dressing may handle fluid on a vertical leg
- Visual assessment of dressing fluid handling ability

DISADVANTAGES

- Technically more difficult to setup than Paddington cup method
- Only qualitative results obtained
- Does not provide individual MVTR and absorbency data

CONCLUSIONS

- By using a range of test systems to evaluate dressing performance, a more comprehensive understanding of how these moist wound healing dressing handle fluid has been established.
- The Paddington cup standard method would suggest that all the dressings tested provide a similar ability to handling fluid, however both other methods suggest that in a more clinically relevant situation these dressings have varying abilities to handle fluid, with TIELLE® Plus and TIELLE® Max providing superior fluid handling abilities in all methods.
- Dressings tested using the Paddington cup method all showed a high fluid handling capacity, however TIELLE® Plus achieved this through high absorbency rather than high MVTR; Some of the dressings tested with high MVTR also showed strikethrough, which could compromise the dressing performance.
- Dressing indicated for use on venous leg ulcers were tested for fluid handling on a Vertical leg model. TIELLE® Max and TIELLE® Plus both showed superior fluid handling when compared to other dressings, which showed pooling of fluid at the edge of the dressing even after 24 hours.

* These products are trademarks of their owners

Systagenix