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Comparing test methods for moisturevapor transmission rate (MVTR) for vascular access transparent semipermeable dressings

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Abstract

Background: Catheter insertion sites are commonly covered by transparent film dressings, offering protection of the insertion site from external contaminants and securement of the catheter while allowing site observation through a clear window. Currently, there is considerable focus on creating IV film dressings with ever-increasing moisture vapor transmission rates (MVTR) to prevent the accumulation of moisture under the film and reduce the risk of infection. These increasingly high MVTR IV dressings are often promoted as superior to IV dressings with lesser MVTR values.

Methods: Since there are different methods to determine MVTR, we chose to test a series of commercially available dressings with two standard methods to compare the results and better understand the information provided by this measurement. We used European Standard EN 13726 to test the MVTR of seven different IV dressings with two different methods (upright and inverted).

Results: We measured a range of MVTR values from 773 to $2838 \, g/m^2/day$ for the upright method and from 845 to $30,530 \, g/m^2/day$ for the inverted method for the seven IV dressings tested. Three dressings showed statistically different MVTR values with the two test methods.

Conclusions: The MVTR test method (upright or inverted) used and considered for IV dressing product selection matters because the results obtained can be very different. We suggest that the upright method is better suited for IV dressings because they are not in constant contact with fluid. We conclude that the inverted method alone is not adequate to compare IV dressings.

Keywords

Moisture vapor transmission rate, MVTR, film dressings, IV dressings, EN13726

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Introduction

Catheter insertion sites are covered to protect the site from external contaminants and to stabilize the catheter. Initially, gauze and tape dressings were employed for this purpose. The practice was later changed to use transparent film dressings because they allow for the visualization of the site, protect the site from external contaminants, help secure the catheter, and also help reduce the number of dressing changes.

The early research literature following this change in practice contains examples of clinical studies where transparent film dressings led to higher skin colonization and signs of local infections around catheter sites than gauze and tape dressings.^{1,2} This most likely happened because the first generation of film dressings had been developed to provide a moist environment to promote wound healing, a benefit evidenced by the research from Winter³ and

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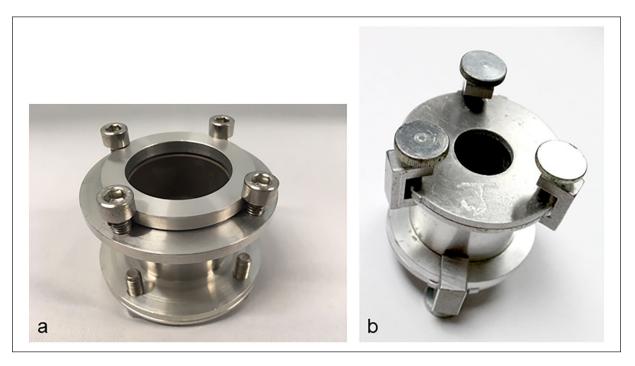


Figure 1. (a) Standard Paddington cup. The film dressing is clamped across the open annular plate which provides a 10 cm² area for evaporation. A volume of 20 ml is used. (b) Modified cup used in this study (3.14 cm² area for evaporation; a volume of 10 ml is used).

Water is added to the cup leaving a 5 ± 1 mm air gap at the top of the cup (shown in upright position).

first published in 1962. Such dressings were possibly too occlusive for IV dressing applications and sometimes allowed for the accumulation of fluid under the dressing, increasing the risk of infection. To address these concerns, films with higher permeability to moisture were developed specifically with the IV site application in mind. The permeability of various films to moisture can be measured in the laboratory setting and is expressed as the Moisture Vapor Transmission Rate, or MVTR. It is typically measured in grams per square meter per day (g/m²/day). "High MVTR" transparent dressings were introduced in the early 1990s. The expectation was that fluid accumulation and bacterial regrowth under these newer dressings would be minimized, thus reducing the risk of catheter-related infection.

Later literature reveals that clinical studies done with such higher MVTR dressings in fact led to the same^{5,6} or even lower⁷ infection rates than gauze and tape dressings. In 1997, a meta-analysis concluded that "transparent polyurethane dressings do not increase the risk of central venous catheter-related bloodstream infections." It is now well established that film dressings are the best technology to care for IV sites (versus gauze and tape), and this is reflected in the current guidelines of various professional organizations. ^{9,10}

Assumptions have been made that continuing to further increase the MVTR of IV dressings would lead to additional benefit but there is no clinical evidence to support this. "High MVTR" is defined by laboratory bench data

and standard methodology includes two methods (upright and inverted) referring to whether the film dressing tested is in contact with vapor or water. Validated, standardized test methods do exist for the laboratory testing of MVTR (EN 13726, 11 ASTM E-9612), but it is not unusual to see published MVTR values without a clear description of which method was used, or stating that a "modified" method was used without much discussion of the potential impact of the modifications on the reported results. 13,14 The purpose of this study is to compare the results obtained with the two standard methods on seven commercially available IV film dressings. Based on these results, we discuss test method relevance for product selection.

Methods

MVTR was determined under controlled conditions by exposing the dressings to either moisture vapor or direct contact with water and was calculated by the mass differential detailed within EN 13726 Part 2.¹¹ This standard defines MVTR as the "permeability of materials to the passage of water molecules from the skin contact side to the external atmosphere under controlled conditions of humidity and temperature" and describes test methods for the determination of MVTR of permeable film dressings but does not contain performance requirements. These experiments were conducted in an apparatus commonly called a Paddington Cup (Figure 1).

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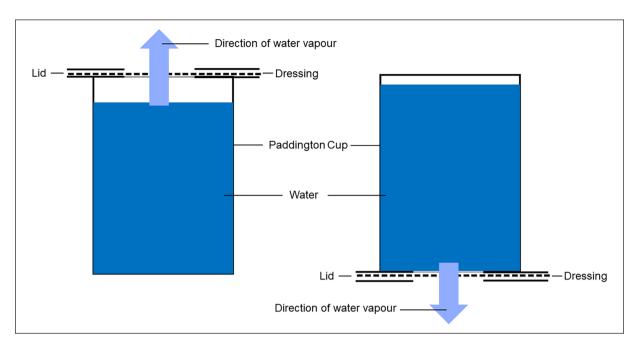


Figure 2. Left: Test method EN 13726-2:2002 section 3.2: Paddington cup in the upright orientation. The standard states that this test is intended for the evaluation of the MVTR of a wound dressing when in contact with water vapor (upright method). The standard specifies this test method as being appropriate for "thin film dressings." Right: Test method EN 13726-2:2002 section 3.3: Paddington cup in an inverted orientation. The standard states that this test is intended for the evaluation of the MVTR of a waterproof wound dressing when it is in contact with liquid (inverted method).

EN 13726-2:2002¹¹ section 3.2 covers the MVTR of a wound dressing when in contact with water vapor (upright cup method), and section 3.3 covers the MVTR of a wound dressing when in contact with liquid (inverted cup method). These test methods are described in Figure 2.

The sealed cups were placed in an incubator at 37°C. The test only measured a section of the film, not the whole dressing and did not include any soft cloth/reinforcement (often called "bordered") area in the results.

We compared the results obtained from EN 13726 Part 2 sections 3.2 and 3.3 (e.g. vapor contact vs liquid contact) on several transparent film dressings intended for IV sites: Dressing A: 3MTM TegadermTM I.V. Advanced Securement Dressing (3M Company); Dressing B: 3MTM TegadermTM I.V. Transparent Film Dressing with Border (3M Company); Dressing C: 3MTM TegadermTM HP Transparent Film Dressing (3M Company); Dressing D: ClearFilm I.V. dressing (Richardson Healthcare); Dressing E: Leukomed I.V. film (BSN Medical GmbH); Dressing F: IV3000 Ported $7 \text{ cm} \times 9 \text{ cm}$ (Smith and Nephew); and Dressing G: SHIELD SorbaView Window Dressing, Medium (Centurion). The testing was performed on five replicates. The test method complied with EN 13726; however, the following deviations were reported by the independent test laboratory (1) Testing was performed at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ rather than $\pm 1^{\circ}$ C as stated in the standard. (2) The dressings were tested using a smaller aperture (2 cm diameter rather than 3.57 cm) test cylinders (Paddington cups) with 10 ml of fluid (rather than 20 ml), ensuring an air gap of 5 ± 1 mm at the top of the cup. Note: The change in area was made to accommodate Dressing E, which was too small to fill the standard area. These deviations from the standard method are not expected to change the measured MVTR values (reported in g/m²/24h) because MVTR is calculated by multiplying the amount of water evapourated (in g) by a correction factor to report per square meter. If the area of evapouration is smaller than what is used in the standard method, the correction factor is adjusted accordingly. Finally, with a smaller area of evapouration, less fluid is needed. (3) The MVTR testing in contact with liquid was performed over 24 h (the standard method gives a range of $18-24\,h$, to be recorded $\pm5\,min$).

Swelling was determined qualitatively by cutting a piece of each type of dressing and clamping it between metal rings. Each sample was placed in a clear petri dish and exposed to 1 ml of water on the adhesive side for various periods of time. Petri dishes were covered between observation time points to minimize evaporation. Observations are reported in Figure 3.

A statistical analysis using SAS 9.4 (SAS Institute, Cary NC) was performed to evaluate the significance of the differences in the results obtained with the two MVTR test methods for each dressing tested (post hoc comparisons of differences in MVTR by method within samples using Tukey's test).

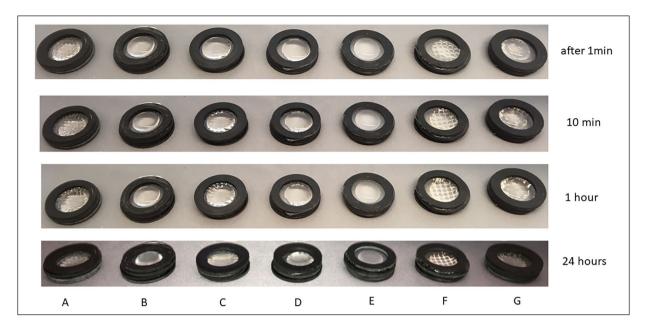


Figure 3. Swelling behavior for each type of dressing when exposed to water on adhesive side over time, up to the duration of the MVTR assay.

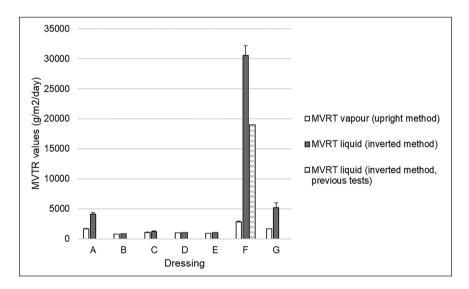


Figure 4. Mean MVTR value (±standard error) of dressings A–G tested using both methods of EN 13726-2:2002. Because of the fact that the Paddington cup was found empty at the end of the test for Dressing F using the inverted method, Dressing F is displayed with both the value obtained in this assay (30,000) and the value obtained in a previous assay by the same test laboratory (19,000), which matches the published manufacturer's value. Statistical analysis of data: for the upright method, all dressings were significantly different from each other except for the following three paired comparisons: A–G, C–D, and D–E. For the inverted method, the majority of dressings were different from each other except for the following seven paired comparisons: A–G, B–C, B–D, B–E, C–D, C–E, and D–E. When comparing for each dressing the MVTR values obtained by both methods, the difference was statistically significant for Dressings A, F, and G.

Results

The inverted cup method (EN 13726-2:2002 section 3.3) consistently gave MVTR values that were greater than the values obtained with the upright method (EN 13726-2:2002 section 3.2), as seen in Figure 4. This

difference was statistically significant for Dressings A, F, and G (Table 1). In addition, we compared the values obtained for all dressings within each test method (21 comparisons in total for 7 dressings, for each method). For the vapor method (upright), all dressings were

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Dressing	MVTR liquid (inverted method)	MVTR vapor (upright method)	Difference Calculation between MVTR test methods (liquid—vapor) ^a	t Value	p Value
A	4089	1682	2407	7.58	<0.0001
В	845	773	72	0.23	0.8224
С	1225	1079	146	0.46	0.6465
D	1047	976	71	0.22	0.8238
E	1031	936	95	0.30	0.7668
F ^b	30,530	2838	27,692	87.23	< 0.0001
G	5164	1644	3520	11.09	< 0.0001

Table 1. Statistical analysis of differences in MVTR by test method within dressings using Tukey's test.

^bAnalysis made with the MVTR value of 30,000 for Dressing F (the analysis cannot be done with the 19,000 value published by others since we do not know the variability of that data set).

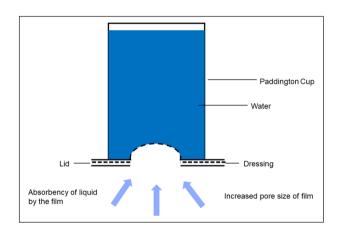


Figure 5. Illustration of the concave effect observed due to the development of a vacuum over time and its impact on vapor transmission. As water is lost from the Paddington cup over the test period, and air does not travel through the film, a vacuum develops and leads to film deformation. This is observed in both the upright and inverted methods, but to different extents with different materials, depending on their stretchability, and depending on their MVTR (and thus the amount of evaporated water).

significantly different from each other except for the following three paired comparisons: A-G, C-D, and D-E. For the liquid method (inverted), the majority of dressings were different from each other except for the following seven paired comparisons: A-G, B-C, B-D, B-E, C-D, C-E, and D-E.

We observed that over time, all samples in both methods develop a concave shape, to various extents. Figure 5 illustrates this phenomenon.

We observed that the Paddington cup was empty at the end of the inverted cup test method for Dressing F. This finding could not be explained by the test laboratory. This suggests that the MVTR value obtained was therefore probably underestimated. However, previous testing without this problem had given an MVTR value of 19,000 for this dressing by the same test lab and as reported by the manufacturer in their previous product literature. The

value of 30,000 is therefore questionable, but in this and previous tests the MVTR (inverted method) of Dressing F remains significantly higher than all other dressings tested (both values are displayed on Figure 4 to illustrate this).

We also observed that sample G absorbed a significant amount of water and obviously swelled during the test; samples A and F demonstrated this behavior but to a much lesser extent. The swelling assay showed that the different dressing materials do not all absorb water or swell to the same extent (Figure 3).

Discussion

Our results have shown a range of MVTR values from 773 to 2838 g/m²/day for the upright test method (film in contact with water vapor) and from 845 to 30,530 g/m²/day for the inverted method (film in contact with liquid water) for the seven IV dressings tested. The differences between methods for a given film dressing ranged from 71 to 27,692 g/m²/day. When dressings were compared on the basis of their MVTR values within each test method (resulting in 21 paired comparisons), most dressings were significantly different from each other except for three paired comparisons with the upright method and seven paired comparisons for the inverted method, illustrating that these methods do not consistently correlate with each other for how they rank dressings. In addition, three dressings (A, F, and G) showed a statistically significant difference in results when comparing the two test methods. This clearly illustrates that any correlation that may exist between these test methods is not consistent among dressings (Figure 4). Therefore, comparing several dressings based solely on their inverted MVTR value does not provide the full picture. Similarly, comparing dressings by providing their MVTR values without specifying which method was used is at best incomplete information, since using the inverted method values would suggest that the products are very different from each other but the upright method values would indicate much more similarity. We suggest that the upright method is the correct one to use for

^aStandard error (SE): 317; degrees of freedom (DF): 56.

IV dressings because they do not come in contact with significant amounts of wound exudate. This recommendation is now also specifically stated in a new draft version of standard EN 1372615 published in January 2021 and intended to supersede the current 2002 version used in our experiments. This is significant because if this new draft standard is accepted, it will invalidate several MVTR values currently listed for IV dressings in the product literature provided by manufacturers and create a need for new comparative testing. We postulate that as long as the MVTR value (upright method) of a dressing is sufficient to prevent accumulation of moisture under the dressing, any increase in this MVTR value will not bring additional benefits. The questionable result for Dressing F could be due to a leak in that cup (although this was not reported by the operator), or to the fact that the swelling of this dressing causes inconsistency and makes the MVTR test less reproducible for this dressing. The new draft standard includes changes in methodology and states that "Modifications to previous methods have been implemented to more closely simulate clinical use of the wound dressings and to eliminate artefacts introduced by the technical methods which would not be expected in the clinical setting" (p. 69), and that "The technical issues now inherent in the standard mean that the usefulness of some of this data is questionable, and in fact can be misleading" (p. 73).

"High MVTR" is defined by laboratory bench data, which does not necessarily correlate with actual dressing performance in a clinical setting. For example, it does not take into account clinically important performance factors such as how well the adhesive adheres to the skin, how long it maintains its adhesion, and how gentle it is when the dressing is removed. The dressing behavior on the skin depends on how much fluid needs to be handled, which is influenced by the activity of the eccrine sweat glands and by the transepidermal water loss (TEWL) of the patient. The dressing behavior of the patient.

Clinicians have access to a range of IV dressings that vary based on size, shape, method of application, and level of adhesion to suit their patients' requirements. MVTR is another parameter that can differentiate among the dressings available in the market today. Many factors influence the MVTR of the dressing such as the construction materials of the film, the film thickness, the presence of a reinforcing soft cloth area, and the adhesive used and its pattern. However, an optimum MVTR level for IV dressings has not been determined by consensus guidelines.

The guidance found in the literature for desirable MVTR values is very limited. In an article focused on wound healing, the authors state that occlusive, or moisture-retentive dressings (defined by a MVTR of 35 g/m²/h, or 840 g/m²/day) provide faster healing. ¹⁸ Earlier versions of the British Pharmacopoeia ^{19,20} set a minimum level of 500 g/m²/24h to define "permeable plastic dressings and tapes," and in those documents, "permeable plastic wound

dressing" is defined as "an absorbent pad attached to a piece of permeable plastic adhesive tape so that a suitable adhesive margin is left." The presence of the absorbent pad makes those dressings different from the typical IV dressings discussed in our work. The British Pharmacopoeia has since removed sutures and dressings, to be covered in the European Medical Device Regulation. Finally, in a review on dressings for catheter sites, Jones⁴ suggests that an MVTR ranging from 400 to 900 g/m²/day is adequate to cope with the normal evapouration loss from skin but adds that however, excess sweating may lead to moisture buildup. According to the epic3 guidelines, there is no standard minimum requirement, or optimal value for MVTR, as long as the dressing is truly "semi-permeable" and that it is "changed if moisture collects under the dressing." It would therefore be logical to suggest that any MVTR high enough to prevent accumulation of fluid under the IV dressing is adequate and that further increases in MVTR will not bring additional benefits.

Additional considerations are presented here to put MVTR values in perspective. When a given material swells in contact with water, as observed with dressings A, F, and G, this likely causes an increase in pore size upon stretching of the material, which progressively and artificially increases the MVTR throughout the test period. The inverted method is therefore less reliable for those dressings because it puts them in direct contact with water, which induces the swelling. Even for materials that do not swell, the MVTR test, by design, leads to the development of a vacuum over time since water is lost from the Paddington cup and air does not travel through the film. The stretching of the materials in a concave shape (Figure 5) also leads to a deformation likely to cause an increase in pore size which can increase the MVTR value. Films with greater stretchability will distend more and be further affected. Therefore, these tests can at best estimate the MVTR of various dressings but do not provide the true MVTR experienced when a dressing is applied on skin. Other authors have shown that the conditions of temperature and humidity in a room will also affect the MVTR values of the dressing materials,²¹ suggesting that the environment of the patient will also impact the MVTR of the dressing.

There are a number of reasons why a minimum threshold for MVTR value has not been established for IV dressings. As mentioned previously, this threshold value depends on how much fluid needs to be handled, and this can vary between patients and over time, as well as with the ambient conditions. The amount of moisture on the skin is influenced by the activity of the eccrine sweat glands and by the TEWL of the patient. The eccrine sweat glands lead to active water loss through the skin (liquid phase), whereas TEWL, also termed insensible perspiration, is the passive diffusion of water vapor through the epidermis (gaseous phase) and does not involve the sweat

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glands. 17 TEWL has been determined to range from 120 to 240 g/m²/day.²² Sweat rates have been studied, typically during exercise, so published values²³ may not correspond to what is observed in patients with IV dressings but this parameter is expected to have considerable variability. Dressings for vascular access are designed to allow moisture vapor to pass through the dressing whilst providing a barrier to virus and bacteria, and typically perform that function adequately. Only certain extreme circumstances (such as diaphoresis or high ambient temperature and humidity) will lead to pooling of water on the skin surface, and then only typically for limited periods. The clinical performance of an IV dressing cannot be predicted simply by an MVTR value. The original concern regarding infection risk has been resolved since the late 1990's and several clinical studies have now confirmed this. 5-7,24 In today's practice, a high MVTR is more clinically relevant for wound dressings that are designed to be in contact with significant amounts of wound exudate during the use period, whereas the guidance for IV dressings is to remove and replace if and when any fluid accumulation is visible. All dressings tested in this study should be changed every 7 days or sooner if they are no longer intact or if moisture collects under the dressing, according to the guidance.

Manufacturers have a duty to ensure the claims made about their products are true and accurate. To this end, the test method should be clearly defined to enable end-users to fairly compare products. The MVTR value of dressings does not take into account clinically important factors such as how well the dressing adheres to the skin, how long it maintains its adhesion, and how gentle it is when the dressing is removed (to prevent skin damage). When health-care procurement staff support the "higher the MVTR the better" philosophy, they are excluding a range of products which not only are clinically adequate but could offer additional features and/or more cost-effective solutions.

Conclusion

MVTR is a laboratory test and is subject to artifacts that can vary among materials (e.g. swelling). Different standard methods to measure MVTR can give very different values for the same dressing and do not offer a complete picture of clinical performance. A new draft standard document teently published and intended to supersede the current EN 13726 issued in 2002 now specifies that the MVTR of IV dressings should be tested using the upright method. There is currently no clinical evidence indicating a correlation between a higher MVTR value and a lower rate of catheter-related infection for the IV dressings in use today. Current guidelines do not favor a type of transparent dressing over another for IV site applications and clinical practice should focus on choosing a dressing that will adhere well and provide good visibility to the IV site. We postulate

that as long as the MVTR value (upright method) of an IV dressing is sufficient to prevent accumulation of moisture under the dressing, any increase above this threshold value will not bring additional benefits. Guidelines recommend changing IV dressings at least every 7 days, 9 and all current commercially available IV dressings should be used with that recommendation in mind.

Author note

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