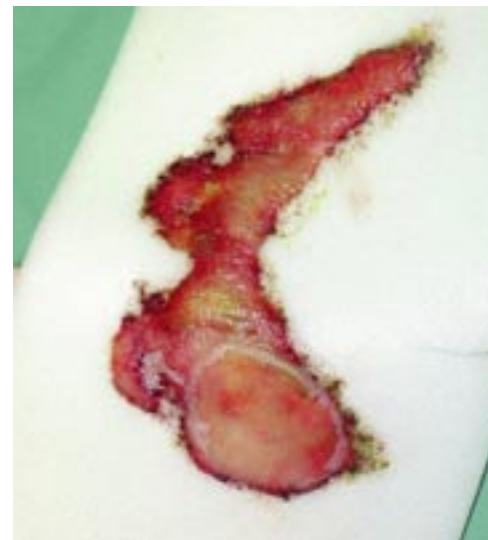


Exudate-handling mechanisms of the Cutimed® Siltec range of foam/film dressings

Steve Thomas B.Pharm. Ph.D. F.R.Pharm.S.



S. THOMAS B.PHARM. PH.D. F.R.PHARM.S., MEDICAL DEVICE CONSULTANT, MEDETEC

Exudate-handling mechanisms of the Cutimed® Siltec range of foam/film dressings

Introduction

The effective management of wound exudate is one of the key performance requirements of the 'ideal dressing',¹ and an important element of wound bed preparation.²⁻⁴

For most exuding lesions, this involves maintaining a moist environment at the wound surface and the removal of excess fluid from peri-wound skin to prevent maceration or erosion by the proteolytic enzymes commonly found in exudate from chronic wounds such as leg ulcers. In the treatment of relatively superficial wounds, an absorbent pad or sheet is usually applied which spans the wound and overlaps onto the surrounding healthy tissue. In the case of self-adhesive products this results in the production of a sealed chamber in which fluid accumulates before it is taken up by the dressing.

The wear time of a dressing is largely determined by its absorbent capacity. Once this is exceeded, the dressing becomes saturated and therefore ineffective. There also exists the possibility that strikethrough will occur, potentially facilitating the movement of microorganisms into or out of the wound, and representing a potential source of infection or cross infection.

Whilst it is possible to enhance the absorbency of a dressing by increasing its size or thickness, this will also increase its bulk and weight when wet, making it uncomfortable and impractical to wear. The possibility also exists that as healing progresses and exudate production diminishes, a very absorbent dressing will allow the wound to become too dry, which in turn may lead to problems of desiccation and adherence.

Manufacturers of dressings have sought to overcome these problems by combining absorbent materials, such as foams, with a semipermeable backing layer commonly made from a semipermeable polyurethane film or a thin sheet of closed cell polyurethane foam. Wound fluid is initially taken up by the absorbent component of the dressing but some subsequently evaporates away through the back thus extending its useful life. The film also serves as a bacterial barrier preventing strikethrough and reducing the risk of bacterial contamination. Together, the absorbency and permeability of a dressing determine its Fluid handling Capacity (FHC).

The permeability of the backing layer to moisture vapour will have a marked effect upon dressing performance. A very permeable film will increase evaporative loss and enhance the FHC but may permit excessive drying in a lightly exuding wound. A film of limited permeability will maintain a moist healing environment but do little to enhance the total fluid handling properties of the dressing. This issue has been addressed by the development of films the permeability of which changes according to their state of hydration. The performance of a foam dressing bearing a moisture reactive film backing layer has been described previously.⁵

This paper describes the results of a testing programme undertaken by the Surgical Materials Testing Laboratory (SMTL), an independent accredited test facility, of a new family of foam dressings, designed for the treatment of more superficial wounds which include intelligent film technology.

Test materials

The dressings included in the study are identified in Table 1 and described briefly below.

Product	Manufacturer
Allevyn non-adhesive	Smith and Nephew
Allevyn Compression	Smith and Nephew
Allevyn Gentle	Smith and Nephew
Allevyn Gentle Border	Smith and Nephew
Biatain Adhesive	Coloplast Ltd
Biatain non-adhesive	Coloplast Ltd
Biatain Soft Hold	Coloplast Ltd
Cutimed Siltec	BSN medical GmbH
Cutimed Siltec B	BSN medical GmbH
Cutimed Siltec L	BSN medical GmbH
Gentleheal standard (now Cutimed Siltec)	Ossur (now BSN medical GmbH)
Medifoam	Biopol Ltd
Mepilex	Mölnlycke Healthcare
Mepilex Border	Mölnlycke Healthcare
Tielle	Johnson & Johnson Ltd
Versiva	Convatec Ltd

Table 1: Wound dressings included in study

Sheet dressings

Allevyn non-adhesive consists of a sheet of polyurethane foam bonded to a highly permeable moisture-reactive polyurethane film backing layer.

Like Allevyn non-adhesive, Allevyn Compression, previously known as Cutinova Foam, also consists of a sheet of polyurethane foam bonded to a highly permeable moisture-reactive polyurethane film backing layer. The foam layer in Allevyn Compression contains super-absorbent particles imbedded within its structure that are intended to enhance the ability of the dressing to absorb and retain a significant amount of wound exudate even when subjected to pressure. The inner, wound-contact surface, of the dressing is inherently tacky, which facilitates application of the dressing beneath compression bandages but enables the dressing to be easily removed from sensitive skin.

Allevyn Gentle consists of a sheet of polyurethane

foam bonded to a highly permeable polyurethane film backing layer. The wound contact surface of the dressing is coated with a perforated soft gel layer which ensures that the dressing stays in intimate contact with the periwound skin but permits easy pain-free removal. Allevyn Gentle Border has a perforated silicone layer which extends to the dressing border.

Biatain non-adhesive is a polyurethane film/foam laminate, Biatain Soft Hold similarly consists of a polyurethane film/foam laminate but is coated with an apertured adhesive wound contact layer. Biatain adhesive, consists a of foam-film laminate without an adhesive layer but with a border bearing a hydrocolloid adhesive.

Cutimed Siltec (previously Gentleheal Standard) consists of a sheet of polyurethane foam containing super-absorbent particles contained in receptacles created on the outer surface of the foam which is bonded to a highly permeable film backing layer. The wound contact surface is a silicone layer. Cutimed Siltec L, designed for use in light to moderately exuding wounds, is similar to the above but the foam layer is thinner, increasing the conformability of the dressing. Cutimed Siltec B is a bordered version of Siltec L with enhanced adherence properties on the margin.

Medifoam comprises highly absorbent hydrophilic polyurethane foam with a semipermeable film backing.

Mepilex consists of a polyurethane foam sheet bonded to a polyurethane membrane with a wound contact layer of soft silicone. Mepilex Border also has a perforated soft silicone wound contact layer bonded to an absorbent core which consists of three components, a thin sheet of polyurethane foam, a piece of nonwoven fabric and a layer of superabsorbent polyacrylate fibres. The core is located centrally upon a larger piece of polyurethane film and is held in place by the perforated silicone adhesive layer that extends to the outer margins of the dressing.

Tielle is a multi-layered dressing consisting of a thin sheet of hydrophilic absorbent polyurethane foam applied to the centre of thin polyurethane foam membrane coated with a polyurethane adhesive. A piece of nonwoven fabric located between the foam island and the adhesive backing acts as a wicking layer and facilitates uniform dispersion of exudate throughout the absorbent layer.

Versiva is not a foam dressing as such, but consists of a layer of sodium carboxymethyl-cellulose fibres located centrally upon a larger piece of a thin sheet consisting of a polyurethane foam/film laminate. The patient contact surface of the dressing is coated with a perforated layer of a hydrocolloid adhesive that extends to the outer margins. The dressing absorbs and interacts with wound exudate to form a soft gel trapping wound fluid and preventing lateral leakage or backflow into the wound even under compression.

Test methods and results

Fluid Handling Capacity

The dressings were examined using different test systems in order to characterise their performance. The absorbency and moisture vapour transmission rates of each were determined on five samples of each using the Paddington Cup technique described in European Standard BS EN 13726-1:2002. This test determines the absorbency and permeability of the dressing when in contact with liquid.

Full experimental details for this test method have been provided elsewhere,⁶ but it may be summarised as follows. A sample of dressing of known weight is cut to shape and applied to the upper flange of a Paddington Cup, a modified Payne Cup, and fixed securely in place with the retaining ring. The appropriate volume of 'Solution A' is then added to the cup which is securely sealed, weighed and placed, with the liquid in contact with the foam, in an incubator capable of maintaining an environment of $37 \pm 2^\circ\text{C}$ and a relative humidity below 20% for a period of 24 hours.

At the end of this time the cup is removed from the incubator, allowed to equilibrate to room temperature and reweighed. From these results, the loss in weight due to the passage of moisture vapour through the dressing is determined by difference. The base of the cup is then removed and any free fluid remaining in the cup that has not been absorbed by the dressing is allowed to drain away. The cup is then reweighed once again and the weight of fluid retained by the dressing calculated (Figure 1, 2).

In the case of two of the products examined, Tielle and Biatain, a degree delamination occurred within the structure of the dressing which resulted in some test solution becoming trapped between the layers. This was regarded as an artefact, caused by the test method and something that would not occur during normal use of the dressings concerned. The problem was easily resolved by slitting the dressings inside the Paddington Cup to allow the trapped fluid to escape before the final weighing.

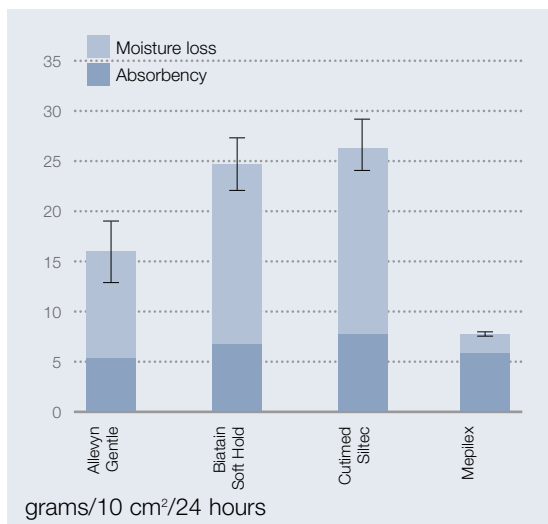


Fig. 1: Fluid handling properties of foam dressings

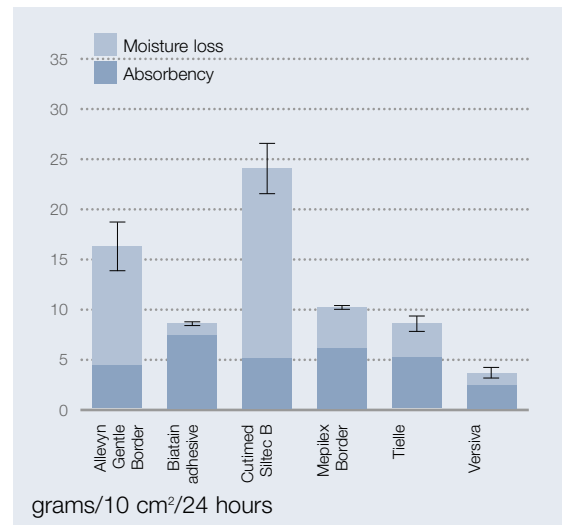


Fig. 2: Fluid handling properties of bordered foam dressings

Effect of moisture on permeability of film backing

The effect of the presence of liquid upon the permeability of the film components of the dressings was determined in a more dynamic fashion in a second study in which a Paddington cup containing a sample of dressing was placed upon the pan of a top loading balance inside the environmental chamber. The change in weight of the cup was monitored electronically for 48 hours, and these data used to construct a graph which showed the time-related changes in the weight of the cup caused by the loss of fluid through the dressing. This test was first conducted with the foam in contact with the liquid and three replicate results were obtained for each product from which the average values obtained at each time point were calculated. The test was then repeated with the cups placed upon on the balance in the inverted position so that the fluid was not in contact with the dressing.

The MVTR after 24 hours of each dressing was determined from the slopes of the linear portions of each graph and the results are shown in Figure 3.

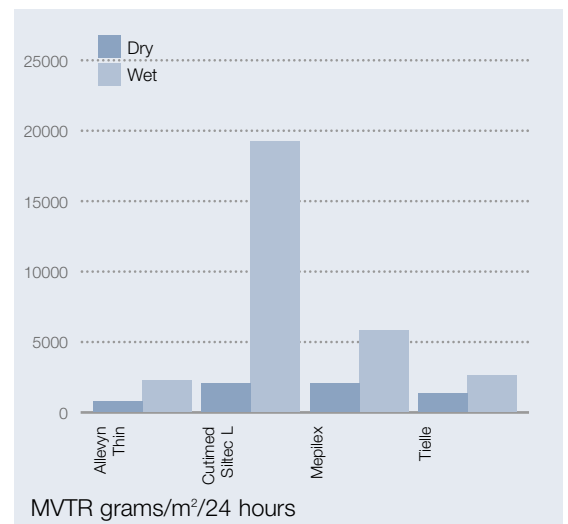


Fig. 3: Permeability of dressings dry and wet

Simulated clinical testing

A selection of foam dressings was tested using a procedure developed by SMTL which seeks to reproduce, so far as is practicable, the clinical use of a dressing. The method differs from those previously described, because it examines the ability of an intact dressing to take up liquid from a moist simulated wound surface, rather than the ability of a small piece of dressing to absorb large quantities of fluid applied to it in the form of a bolus.

This technique, known as the WRAP method, has been described in detail elsewhere.^{7,8} In summary it consists of a temperature-controlled test rig in which an appropriate test solution is presented to an absorbent cellulose disc placed in intimate contact with the dressing under examination at a predetermined rate, typically 1.0 ml/hour. The test may be conducted in the presence or absence of a compressive force, typically 40 mmHg, simulating that which is produced beneath a compression bandage. The moisture vapour lost through the dressing during the test is also recorded and by subtracting this value from the total weight of fluid taken up by the test sample it is possible to determine the weight of fluid retained within the structure of the dressing itself.

As test solution is only presented to the test sample at the rate of 1ml/h, the maximum weight of exudate that the dressing is exposed to during a 48 hour test period is 43 grams, the remaining 5 grams is retained within the test apparatus.

Any suitable test solution can be used, but for the purpose of the present study new born calf serum was chosen to replace Solution A which is normally employed. The temperature of the testing platform was set to 37°C.

Three samples of each product were tested in this way which showed good repeatability for all products with the exception of Medifoam dressing tested in the presence of compression. Two additional samples of this product were therefore examined.

The results of this test are interesting. In the absence of compression, Figure 4, Allewyn, Biatain, Cutimed Siltec and Medifoam all successfully coped with virtually all the fluid presented to them over a 48 hour period but Allewyn Compression and Mepilex although obviously permeable to moisture vapour, failed to demonstrate significant fluid retention under the conditions of test.

In the presence of compression (Figure 5), once again Allewyn, Biatain and Cutimed Siltec were able to cope with all the fluid presented to them but the performance of the Medifoam was reduced by compression. Somewhat surprisingly, Mepilex performed better when compressed but Allewyn Compression still failed to show evidence of significant fluid uptake.

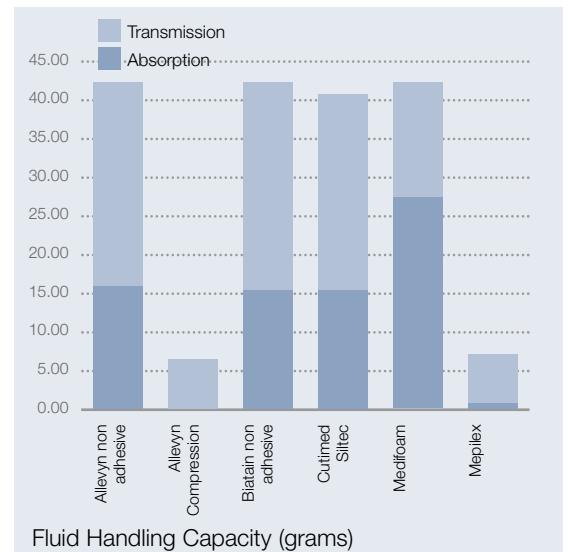


Fig. 4: WRAP test results, dressing not under compression

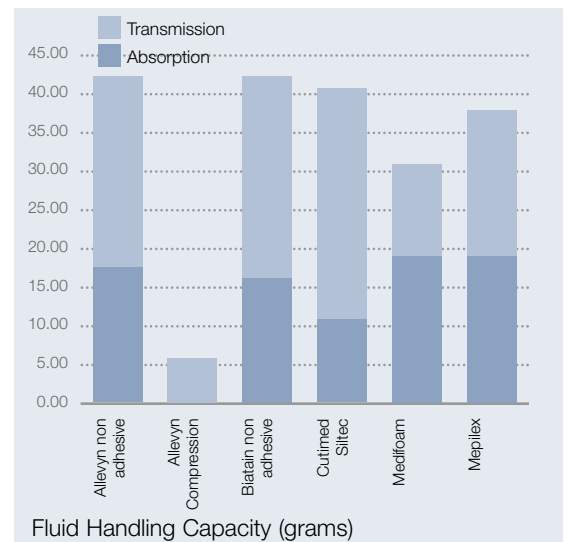


Fig. 5: WRAP test results, dressing under compression

The fact that Mepilex appears to absorb better when compressed is probably due to the presence of the relatively hydrophobic perforated silicone wound contact layer which prevents intimate contact between the absorbent core of the dressing and the simulated wound surface. The application of compression improves this contact, enabling the dressing to take up liquid.

The poor performance of Allewyn Compression cannot be explained in this way, as the results achieved are consistent with those obtained in an earlier unpublished study using the Paddington Cup method.

Summary and interpretation of results

The principal findings of this study and the conclusions which may be drawn from the study are as follows.

Fluid handling properties of sheet dressings

- The results of the Paddington Cup tests indicate that most of the foam products examined were broadly similar in terms of their **absorbency**, ranging from about 5 - 7 g/10 cm²/24 hours with **Cutimed Siltec and Biatain Adhesive having the highest values**.
- More significant differences were evident in terms of their permeability which varied from around 1 to 20 grams.
- Very marked differences were also noted in the effects of hydration upon the permeability of the film backing of the four selected dressings. Only one of the products examined, **Cutimed Siltec L, showed a pronounced switching effect in the presence of moisture, increasing in permeability** from 1800 to 19000 g/m²/24 hours. However it is anticipated that all the dressings in the Cutimed range which utilise the same backing film would possess this property.
- **The importance of the ability to react to changes in the local wound environment can hardly be overstated.** Although a standard non-switching film with a very high MVTR might provide a similar level of performance to the Cutimed range in the presence of significant

levels of wound exudate, as healing progressed and exudate production diminished it is possible that a very permeable standard film would allow the wound to become excessively dry and thus the benefits of moist wound healing would be lost. This would be much less likely to occur if the permeability of the film reduces as the wound surface becomes progressively drier.

Results of WRAP tests

- The results of the Wrap testing indicate that under the conditions of test, five of the eight products examined were capable of dealing with all of the fluid presented to them in the absence of a compressive force.
- Allevyn Compression and Mepilex failed to absorb fluid in the absence of compression, possibly due to surface tension effects, but under compression Mepilex did become absorbent although Allevyn Compression still failed to demonstrate significant absorbency in this test system.
- The application of compression appeared to reduce the absorbency of most but not all the dressings examined.
- Under the conditions of test the **Cutimed Siltec was able to cope with all the fluid applied to it even in the presence of relatively high levels of compression** equivalent to that normally provided in the treatment of venous disease.

Limitations of test system

The Fluid Handling Capacity values determined using the Paddington Cup technique are obtained using a circular piece of dressing approximately 3.5 cm in diameter with an effective area of 10 cm². This might suggest that the FHC of an intact dressing measuring 10 cm x 10 cm is actually ten times the figure determined in this way. In practice, however, this would not provide an accurate estimate of a dressing's clinical performance for a number of reasons.

Firstly the absorbency figures produced by the Paddington Cup method probably provide an inflated estimate of the true value because the dressings is not subjected to any significant pressure during the course of the test.

Secondly the MVTR component of the FHC determined during the laboratory tests is measured under atypical conditions in that the humidity gradient across the test sample, which determines the rate of moisture vapour transmission, is much higher than normally occurs in practice. When applied to a wound the humidity beneath the dressing will normally be very high but the humidity at the outer surface will vary. Nevertheless this will almost

always be considerably higher than the 20% used in the laboratory test. This means that in practice the passage of moisture vapour through the dressing will be substantially reduced compared with experimental values which once again will tend to overestimate the performance of the dressing. Changes in environmental temperature may also affect dressing performance as will the effect of gravity which will tend to cause exudate to pool at the lowest point of a leg ulcer dressing for example.

The WRAP test, which also contains a simulated wound with an area of 10 cm², is believed to address at least some of these criticisms and provide results which are more clinically relevant, at least in terms of absorbency, for an intact dressing is tested under varying degrees of compression.

The WRAP results obtained in the current study confirm that when test solution is presented to them at a constant rate over a 48 hour, some 10 cm x 10 cm dressings are capable of handling at least 25 grams of test fluid and possibly more.

In a clinical situation, the ratio between wound area and dressing size is extremely important but

generally poorly appreciated. For example if a dressing measuring 15 cm x 15 cm, having an area of 225 cm², were to be applied to a wound with approximate dimensions of 10 cm x 10 cm and an area of 100 cm², the area of the wound would equate to 44% of that of the dressing.

In contrast, if a dressing measuring 10 cm x 10 cm with a total area of 100 cm² were to be applied to a small wound measuring approximately 3 cm x 4 cm with an area of 12 cm² the area of the wound would equate to only 12% of the area of the dressing. The difference in the ratio between wound area and dressing in the two examples cited means that in relative terms there is four times the amount of absorbent material present to take up exudate and four times the area of film to enable moisture vapour transmission.

Clinical relevance of test data

For the reasons outlined above, no laboratory-based study can do no more than provide a broad indication of the ability of a dressing to cope with wound exudate in vivo, and provide a comparison between different dressings. Nevertheless, an attempt has been made to put the present findings into a clinical context using information on exudate rates from different wound types reported in a previous study,⁵ which suggested that third degree burns, donor sites, and unspecified granulating wounds generated between about 3.4 and 5.1 grams of exudate per 10 cm²/24 hours. Leg ulcers produced, on average, 5 grams per 10 cm²/24 hours but in some patients, possibly in the presence of infection, this rate doubled.

For the purpose of this exercise it is assumed that the dressings in question measure 10 cm x 10 cm and will be applied to wounds 25 cm² in area which will produce 12.5 ml of exudate in 24 hours.

Day	1	2	3	4	5
Exudate Produced	12.5	25	37.5	50	62.5
Allevyn Gentle Border	24	24	24	24	24
Allevyn Gentle	28	28	28	28	28
Biatain adhesive	40	40	40	40	40
Biatain Soft Hold	32	32	32	32	32
Cutimed Siltec	39	39	39	39	39
Cutimed Siltec B	26	26	26	26	26
Cutimed Siltec L	28	28	28	28	28
Mepilex	31	31	31	31	31
Mepilex Border	32	32	32	32	32
Tielle	27	27	27	27	27
Versiva	13	13	13	13	13

Table 2: Estimate of performance considering only absorbency

Assuming both wounds were exuding at the same rate, calculated as g/cm²/24 hours, a dressing applied to the small wound should in theory last four times as long as an identical but larger dressing applied to the bigger wound before it became saturated with exudate assuming that fluid is spread rapidly and uniformly throughout the absorbent area. This difference may also tend to lead clinicians to conclude, incorrectly, that the larger wound is exuding more heavily than the smaller one.

In practice, however, the results of an earlier ultrasound study which monitored the fluid handling properties of a film-foam dressing⁵ suggest that not all products do handle fluid in this way which makes an accurate prediction of total capacity extremely difficult.

It is further assumed that in each case that the absorbent capacity of the entire dressing is half the theoretical maximum figure, i.e. five not ten times the value for 10 cm² determined in the Paddington Cup test during a 24 hour test period.

The contribution made by evaporation to the FHC is more difficult to estimate. According to the laboratory results the maximum permeability of Cutimed Siltec L approaches 20 grams/10 cm²/24 hours. If this value were to be used to calculate the FHC of an entire 10 x 10 cm dressing, it would equate to a figure of around 200 grams of exudate per day. In practice however there are numerous factors which will tend to reduce this value significantly. For this reason, a very conservative estimate of the contribution to FHC made by the permeability of the various products has been used when estimating potential wear times.

For the purpose of this report 50% of the experimentally determined value for the test sample has been used which is equivalent to 5% of the theoretical maximum permeability of the entire dressing.

The results have been expressed in tabular form. In each instance the predicted cumulative weight of exudate produced over a five day period is shown and these values are compared with those derived from the laboratory study adjusted as described. If the study predicts that the fluid handling capacity of the dressing exceed the exudate production on a particular day the table cell is coloured green. If exudate production exceeds the FHC, the table cell is coloured red.

Two tables have been constructed. Table 2 represents a conservative estimate of each dressing's performance as only the figures for absorption have been included; the contribution made to the FHC by the MVTR has been excluded. Table 3 is considered to represent a realistic prediction of dressing performance as it includes an estimate of the effects of MVTR.

Day	1	2	3	4	5
Exudate Produced	12.5	25	37.5	50	62.5
Allevyn Gentle Border	29	35	41	47	53
Allevyn Gentle	33	38	43	49	54
Biatain adhesive	40	41	41	42	42
Biatain Soft Hold	42	51	60	69	78
Cutimed Siltec	49	58	68	77	87
Cutimed Siltec B	36	45	55	64	74
Cutimed Siltec L	38	48	57	67	77
Mepilex	31	32	33	34	35
Mepilex Border	34	36	38	40	42
Tielle	29	31	32	34	35
Versiva	14	14	15	16	16

Table 3: Estimate of performance considering both absorbency and MVTR

Discussion

The ability of a dressing to manage exudate and prevent maceration during normal use is a major factor in determining its clinical acceptability. This study was undertaken to produce and interpret laboratory data which may be used to help assist with product selection by providing some broad guidelines on anticipated wear times for dressings intended for treating superficial wounds.

The results clearly illustrate that although the absorbency of a dressing is very important to its performance, moisture vapour permeability also plays a key role in determining its total Fluid Handling Capacity.

The very permeable nature of the Cutimed Siltec film meant that the dressing had the greatest FHC of all the dressings tested here. This would suggest that, compared with most of the comparators, the dressing is **likely to have the longest wear time** and/or the **lowest risk of skin maceration** for this type of dressing. Unfortunately, however, data generated by current standard tests greatly over estimates both the absorbency and MVTR of these types of dressings so in this study an attempt was made to adjust these data to figures which are more clinically relevant.

The results suggest for the sizes of both the wound and the dressing that have been chosen for this purpose most, but not all, of the products examined are predicted to provide an adequate level of exudate management for two days even in the absence of an MVTR effect. When this is included in the calculation, most dressings appear capable of lasting for a third day and in the case of dressings with a very permeable film, like the Cutimed Siltec

Author

Steve Thomas B.Pharm. Ph.D. F.R.Pharm.S., Medical Device Consultant Medetec
<http://www.medetec.co.uk/>

family and Biatain Soft-Hold, theoretical wear times of five days or even longer seem possible.

As previously described as wounds progress towards healing fluid production gradually diminishes potentially leading to adherence of the dressing to the wound surface. In these situations the inclusion of a film such as that used in the Cutimed Siltec range which has the ability to react to the changing conditions present with a wound must offer considerable practical advantages.

Statement by Author

This report was produced by the author for a professional fee as a medical device consultant and medical writer using test data generated independently by an accredited laboratory. The author had no involvement either with the choice of test methods employed, or the range of dressings included in the study and has no financial interests in any of the products concerned.

References

1. Thomas, S. (2008) *The role of dressings in the treatment of moisture-related skin damage*. World Wide Wounds
2. Vowden, K. and P. Vowden, *Wound Bed Preparation*. World Wide Wounds, 2002. <http://www.worldwidewounds.com/2002/april/Vowden/Wound-Bed-Preparation.html>
3. Sibbald, R.G., et al., *Preparing the wound bed 2003: focus on infection and inflammation*. *Ostomy Wound Manage*, 2003. 49(11): p. 23-51.
4. Falanga, V., *Classifications for wound bed preparation and stimulation of chronic wounds*. *Wound Repair Regeneration*, 2000. 8(5): p. 347-352.
5. Thomas, S. and S. Young, *Exudate-handling mechanisms of two foam-film dressings*. *Journal of Wound Care*, 2008. 17(7): p. 309-315.
6. Thomas, S., *Fluid handling properties of Allevyn foam dressing*. [http://www.medetec.co.uk/Documents/Fluid handling properties of Allevyn foam dressing 24-4-07.pdf](http://www.medetec.co.uk/Documents/Fluid%20handling%20properties%20of%20Allevyn%20foam%20dressing%2024-4-07.pdf), 2007.
7. Thomas, S. and P. Fram, *The development of a novel technique for predicting the exudate handling properties of modern wound dressings*. *Journal of Tissue Viability*, 2001. 11(4): p. 145-160.
8. Thomas, S. and P. Fram, *The development of a novel technique for predicting the exudate handling properties of modern wound dressings*. *World Wide Wounds*, 2001.