FLUID HANDLING PROPERTIES OF ALLEVYN DRESSING

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Abstract

…… in order to achieve the optimum rate of wound healing, the moisture content of new or vulnerable tissue must be carefully controlled….

Changes in the moisture content of a wound and the surrounding skin can have a marked effect upon the healing process. Accumulation of excess fluid can cause maceration or infection. Conversely, in a wound that is allowed to become too dry, healing may be delayed or otherwise compromised.

The optimum healing environment is achieved by the application of an appropriate dressing or dressing system, which must be removed at the appropriate time to prevent maceration or adherence.

Many conventional absorbent dressings simply wick-away excess exudate until they become saturated; at this point they must be replaced. Sometimes the affinity of a highly absorbent dressing for wound fluid is such that it will temporarily reduce the moisture content of the wound surface to the point at which pain is induced.

A new absorbent dressing has recently been introduced which incorporates an 'intelligent' semipermeable polyurethane membrane the permeability of which increases in the presence of liquid, but which reverts to its previous level once the excess fluid is removed.

Results of independent laboratory studies, interpreted in the light of previously published clinical data, suggest that this new dressing may be suitable for the extended treatment of even the most heavily exuding wounds, whilst retaining the ability to reduce evaporative loss from lightly exuding lesions.

Key words:

Foam, film, absorbency, permeability, exudate, wear time

This article was produced from the results of a testing programme commissioned by Smith and Nephew Ltd and undertaken by SMTL, an independent UKAS accredited testing laboratory. The results of these tests may be viewed in full on the SMTL website.

http://www.dressings.org/TechnicalPublications/PDF/S+N-Allevyn-March-2007/

Introduction

The effective management of exudate is one of the principal requirements of a dressing,[1] and a key element of the process known as 'wound bed preparation'. [2-4]

Prior to the early 1960s, it was believed that a wound should be kept as dry as possible in order to prevent the development of infection. This was often achieved by the use of liberal quantities of surgical gauze or absorbent cotton, sometimes used in combination in the form of Gamgee tissue, first described by Dr Samson Gamgee in 1880.[5]

This philosophy was challenged by the work of Winter,[6] and Hinman *et al*.,[7] who demonstrated that superficial wounds which were kept moist healed more rapidly than those that were left exposed to the air or covered with traditional dressings.

…… wounds that were kept moist healed more rapidly than those left exposed to the air.

Under simple absorbent dressings, the outer surface of a wound may dry out and become devitalized, forming a barrier to the migration of epidermal cells from the wound margin or from epidermal elements surviving within the dermis. This dry barrier effectively forces the migrating cells to burrow deeper into the living dermis to achieve closure, further increasing the loss of healthy tissue and thereby prolonging healing time.

If all remaining epidermal elements in the dermis are destroyed by dehydration, a partial thickness wound will effectively become full-thickness, with important implications for the mechanism, and therefore the speed, of healing.

Winter showed that it was possible to prevent this from happening by the application of a plastic membrane that retained exudate within the wound and allowed the process of epithelialisation to occur at the maximum possible rate.

In later studies, Winter found that not all plastic films were capable of producing the perfect environment to promote moist wound healing. He concluded that to provide the optimum conditions, a film should be sufficiently permeable to water vapour to prevent moisture transpired through the intact peri-wound skin from becoming trapped beneath it as this could potentially lead to maceration, bacterial proliferation and possibly infection. He also showed that, for epidermal healing at least, permeability of the film to oxygen appeared to facilitate the healing process.

Films made from polyurethane were found to be particularly suitable for this purpose and during the last quarter of the 20th century, a number of self-adhesive semipermeable polyurethane films were introduced, the properties of which have been reviewed previously.[8]

Limitations of films dressings

Although in many ways film dressings represented a major advance over what had gone before, it soon became apparent that they were unable to cope with the high levels of exudate produced by some types of moderately to heavily exuding wounds.

……film dressings are unable to cope with the levels of exudate produced by many types of granulating wounds

It was not unusual for a large volume of fluid to collect beneath a film dressing which had to be aspirated off with a syringe and needle to prevent the dressing from becoming detached. The puncture wound then had to be repaired with a further piece of adhesive film. To overcome these problems, a number of leading manufacturers of surgical dressings turned their attention to other types of materials such as foams, also commonly made from polyurethane, which possessed enhanced fluid handling properties, making them more suitable for the management of heavily exuding wounds.[9]

Foam dressings

Although hydrophilic polyurethane foam dressings can absorb reasonable quantities of wound fluid, and therefore offer clinical benefits over simple films, they suffer from two principal disadvantages.

Firstly, exudate taken up by the foam is rapidly distributed throughout the body of the dressing, with the result that a moist pathway quickly forms between the wound and the external environment along which bacteria may pass in either direction.

This phenomenon, called 'strike through', provides a mechanism for bacterial contamination of the wound, and also acts as a potential source of cross infection.

Furthermore, as healing progresses and exudate production decreases, foam will rapidly dry out, potentially leading to the same problems of adherence and desiccation described by Winter in connection with conventional absorbent dressings.

This problem was resolved by combining film and foam technologies, resulting in products such as Allevyn™, consisting of foam sheets with a semipermeable film backing layer. If required, this outer membrane could also be extended past the margin of the absorbent foam pad to form a self-adhesive island dressing.

… polyurethane film forms an effective bacterial barrier which prevents the movement of micro-organisms into and out of a wound.

The film forms an effective barrier to bacteria, preventing contamination of the wound and the external environment, and reducing, but not preventing, evaporative loss from the

outer surface of the dressing.

Despite the fact that Allevyn and similar foam-film combinations are widely used for the management of a variety of exuding wounds, clinical experience suggests that, for some indications at least, their fluid handling capacity is less than optimal, necessitating more frequent dressing changes than might otherwise be considered desirable.

.... the fluid-handling capacity of a dressing is a major factor in determining wear time

Although it is theoretically possible to improve the fluid handling capacity of a foam dressing simply by increasing its thickness, this would make it uncomfortable to wear and reduce its conformability.

Once saturated with exudate, the foam would also tend to sag and separate away from the wound surface, greatly reducing its efficiency.

An alternative approach would be to replace the film with a more permeable membrane to increase the loss of moisture by evaporation. This would have the effect of enhancing the total fluid handling properties of the dressing.

Although the use of a highly permeable film offers potential advantages for the management of heavily exuding wounds, if applied to lightly exuding lesions these would rapidly dry out, when once again the benefits of moist wound healing would be lost. This problem can be resolved by the use of a film the permeability of which changes according to the degree of moisture present beneath it.

'Intelligent' film dressings

Palamand *et al.*[10], in 1992 discussed the performance and potential value of these so called 'intelligent' film dressings and suggested that the change in permeability was brought about by variations in the virtual cross-linking and orientation of the

polyurethane chains that make up the structure of the membrane.

They proposed that in the dry state the polyurethane chains have a random spaghetti-like structure that impedes the passage of moisture vapour. As the film becomes progressively more hydrated, by contact with liquid, the chains form associations with water molecules creating coil-like structures that facilitate moisture transportation. When all the available moisture is depleted, the permeability of the film returns to its previous value.

... the permeability of 'intelligent' films varies according to the degree of moisture present on the surface

A film that changes its moisture vapour permeability in this way has been incorporated into a new version of the Allevyn dressing.

This communication describes the results of a programme of laboratory testing that was undertaken to compare the fluid handling characteristics of the new Allevyn, with those of a similar product, ActivHeal,® from Advanced Medical Solutions which bears a standard film backing. The results of these investigations have been used to predict the ability of both dressings to

cope with exuding wounds *in-vivo*, using exudate rates drawn from the literature.

## Exudate: the clinical challenge

Despite the practical problems associated with the management of wound exudate, relatively little information has been published on the amount of fluid produced by different wound types.

In one study,[11] it was reported that third degree burns, donor sites, and unspecified granulating wounds generated between about 3.4 and 5.1 grams of exudate per $10cm^2$/24 hours, (Fig.1).

In a second study involving patients with leg ulcers,[12] the majority (7/10) were found to produce, on average, 5 grams of exudate per $10cm^2$/24 hours, values that were consistent with those of granulating wounds in the earlier study.

.... full-thickness wounds can produce over 5 grams of exudate per $10cm^2$/24 hours.

Three remaining patients (at least two of whom were suspected of having an underlying malignancy) produced almost double this amount of fluid.

Figure 1: Exudate production by different wound types
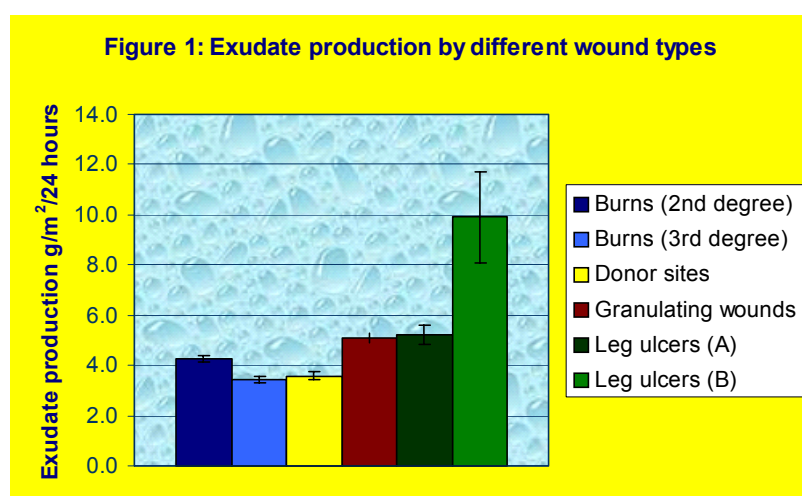
By comparing these clinical values with the fluid handling capacity of the dressings determined in the laboratory, it is possible to estimate their likely wear time when applied to wounds exuding at different rates.

Experimental

Fluid handling properties of dressings

The dressings were tested by the Surgical Materials Testing Laboratory (SMTL), an independent test facility that has been accredited by the United Kingdom Accreditation Service (UKAS).

The test reports relating to this project have been published in full on the SMTL web site with the full agreement of the client.

The fluid handling capacity of dressings such as Allevyn may be determined using a technique described in a European Standard BS EN 13726-1:2002.

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 (Fig. 2).

The appropriate volume of a sodium/calcium chloride solution containing 142 mmol/litre of sodium ions and 2.5 mmol/litre of calcium ions, values typical of those found in serum and wound fluid, is then added to the cup.

The cup is securely sealed, weighed and placed, with the liquid in contact with the foam, in an incubator capable of maintaining an environment of 37(±2°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 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.

> .... the fluid-handling capacity of a dressing is the sum of its absorbency and moisture vapour permeability.

For the purpose of the current investigation, the test was performed on five samples of new Allevyn and an equivalent number of a reference product, ActivHeal, which contains a standard film dressing as part of its structure.

Each dressing was tested three times in total using incubation periods of 24, 48 and 72 hours.

In a slightly modified version of this test, five additional samples of each dressing in Paddington Cups were placed in the incubator in the inverted position, with the foam on the top so that it was not in contact with the liquid.

The cups were left for 48 hours before being removed and weighed as previously described (Fig. 3).

Moisture vapour permeability

The effect of liquid upon the permeability of the dressings over time 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 balance readings were logged

electronically for 24 hours, downloaded and used to construct a series of graphs which recorded time-related changes in the weight of the cup caused by the loss of fluid through the dressing.

Initially, this test was 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 (Fig.4)
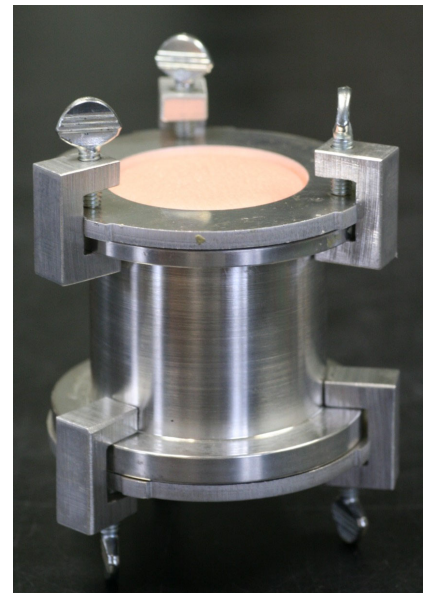

Figure 2: Paddington Cup with dressing sample in place

A further test was then carried out in which additional cups were placed on the balance in turn with the fluid not in contact with the dressing.

The change in weight of each cup was recorded as before, then after about six hours, without stopping the logging process, the cup was inverted so that the dressing came into contact with the test fluid.

Logging was continued for a further 18 hours at which time the balance readings were downloaded and used to construct the graphs shown in Figure 5.

Results

Fluid handling capacity

When the two dressings were placed in direct contact with liquid, their ability to absorb fluid was found to be broadly comparable. ActivHeal retained in the order of 3.5 grams of test solution, Allevyn retained around 4 grams (Fig. 3).

However, under the conditions of test, the permeability of Allevyn was such that the total fluid handling capacity of the dressing was approximately four times that of ActivHeal.

When the dressings were not placed directly in contact with liquid, but only exposed to moisture vapour, the permeability of both films was reduced as anticipated (Fig. 4).

Somewhat unexpectedly, however, both dressings still increased slightly in weight, suggesting that the foam itself had an affinity for moisture vapour.

This effect was more pronounced with ActivHeal than Allevyn.

The most notable feature of the results, however, was the change in the moisture vapour permeability of the Allevyn dressing in the presence of moisture.

This increased from less than 2 grams in a 48 hour period when the dressing was not in contact with fluid, to approximately 25 grams when the dressing was fully hydrated.

In Figures 3 and 4, the dense blocks of colour represent the weight of fluid absorbed by the dressing; the light blocks represent the loss of moisture by evaporation through the film

The apparent decrease in the amount of fluid absorbed by Allevyn at 72 hours in Figure 3 is due to the fact that, by this time, all the liquid in the Paddington cup had evaporated, including that originally absorbed by the foam.
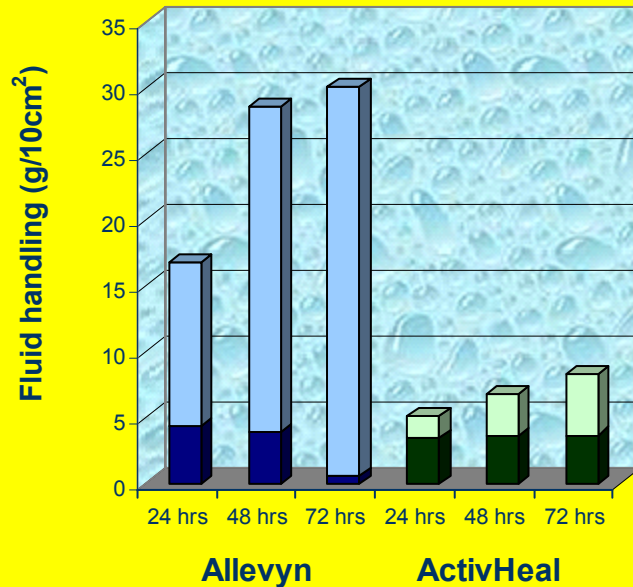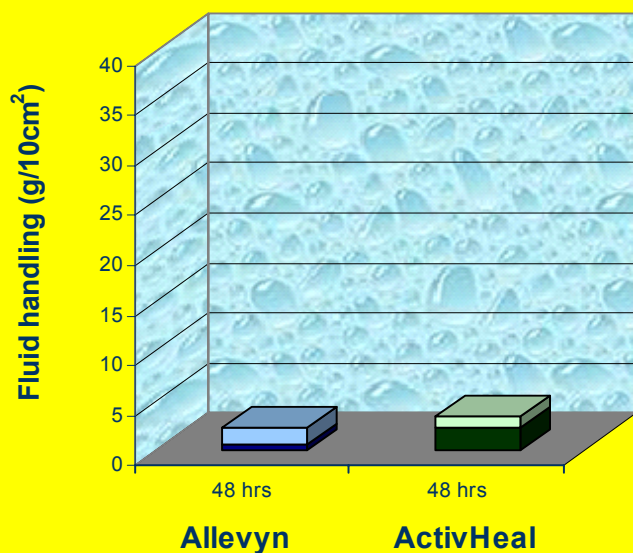

Figure 3: Fluid Handling Capacity (Wet)

Figure 4: Fluid Handling Capacity (Dry)

Moisture vapour permeability

The difference in the permeability of the two dressing in contact with liquid was confirmed in the second study, in which the weight of water lost from the Paddington Cup was monitored continuously for 24 hours (Fig. 4).

Under the conditions of test, the permeability of Allevyn was found to be 12.6 grams/10cm^2/24 hours, and Activheal to be 1.8 grams/10cm^2/24 hours.

After a short period of equilibration, both curves were found to be essentially linear, indicating that the passage of moisture through the film on both dressings took place at a consistent rate.

The final test was designed to investigate how quickly the moisture vapour permeability of the Allevyn film in particular would change in response to the presence of liquid.

Initially both products were tested without the dressing in contact with liquid but when the Paddington Cup was inverted, bringing the dressing and therefore the film into contact with liquid, a very rapid and dramatic change in the slope of the Allevyn graph at the 6 hour mark became immediately apparent (Fig. 5).

This clearly demonstrates that the change in the permeability of the film occurs very quickly once the dressing has absorbed liquid.

A small change in the permeability of the Activheal product was also detected at six hours upon inversion of the Paddington cup, but this difference was considered unlikely to be of clinical significance.

Figure 4: Moisture vapour permeability (MVP) of dressings in contact with liquid
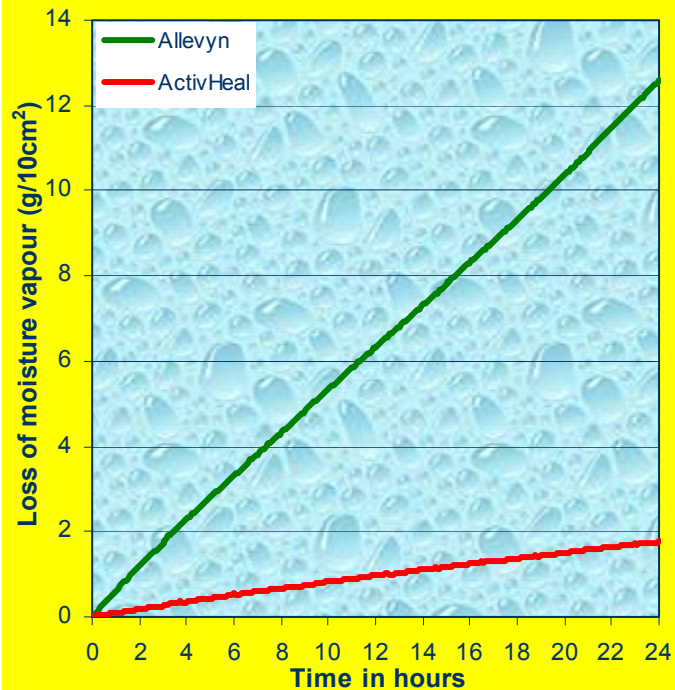
Figure 5: Change in MVP following inversion of cup after six hours
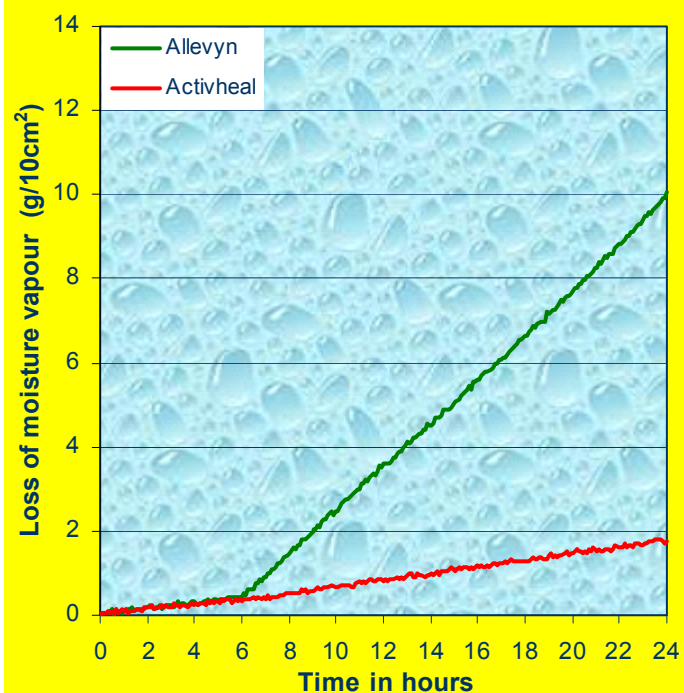
Clinical relevance of results

From the laboratory data, it is possible to make some broad predictions concerning the likely fluid handling properties of both dressings in the clinical situation. Graphs have been constructed from published data, which represent the quantity of exudate that various types of wounds will produce over a seven day period. Overlaid on these graphs are estimates (shown in green) of the fluid handling capacity of each product calculated from the laboratory results.

The upper boundary of the green area represents the maximum amount of fluid that the dressing might be expected to handle, determined from the absorbency and permeability test data.

The lower boundary of the green area is derived from the moisture vapour permeability of the dressings in the absence of wound fluid. This provides an indication of the ability of the dressings to retain low levels of moisture within the wound in order to maintain a moist wound healing environment.

In the case of Allevyn (Fig. 6), the projected volume of exudate produced by all the wound types fell between the upper and lower boundaries of the green area, suggesting that the dressing should be able to cope with even the most heavily exuding wounds for an extended period because of the high permeability of the polyurethane film backing.

In contrast, the results obtained with Activheal (Fig. 7) appear to suggest that for many wounds the fluid handling capacity of the dressing will be exceeded after about 24-48 hours.

... the fluid handling properties of new Allevyn are such that the dressing should be able to cope with even the most heavily exuding wounds

In the absence of liquid, both products appear capable of forming an effective barrier to moisture vapour and are thus able to facilitate moist wound healing.

Figure 6: Predicted ability of Allevyn to cope with exudate from different wound types
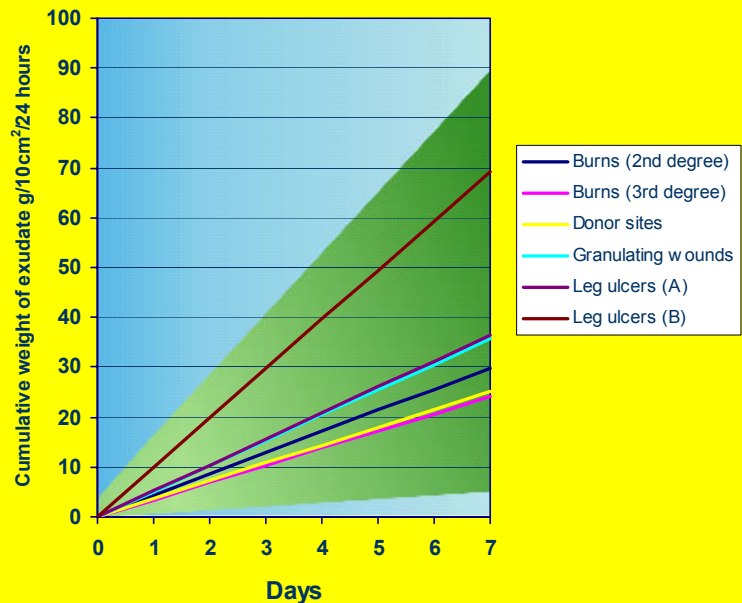
Figure 7: Predicted ability of ActivHeal to cope with exudate from different wound types
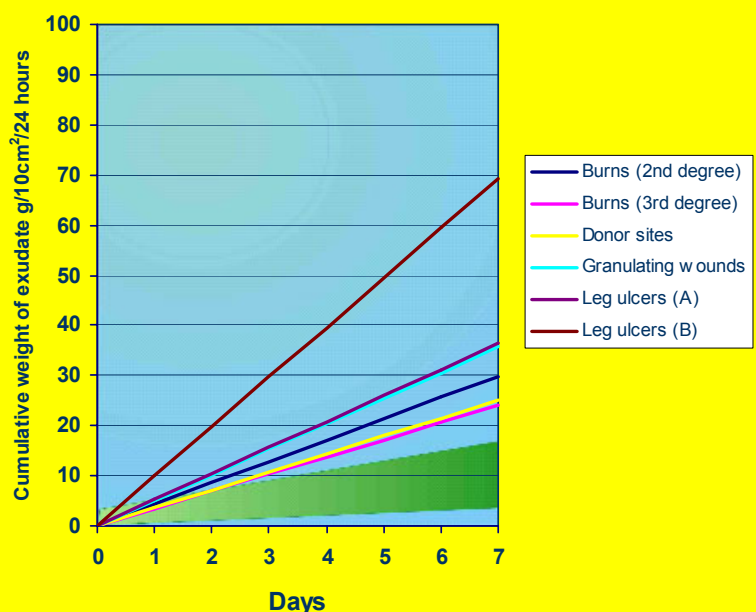
Discussion

It is important to recognize that a laboratory-based study such as described, can do no more than provide a broad indication of the ability of a dressing to cope with wound exudate *in vivo* as numerous factors, some of which are discussed briefly below, will undoubtedly impact upon the product's clinical performance.

Some of these factors will tend to overestimate the fluid handling capacity, whilst others will have the opposite effect. In the present study, results were obtained using a circular piece of dressing approximately 3.5cm in diameter with an effective area of $10cm^2$. In clinical practice, however, a small wound with an area of $10cm^2$ would normally be dressed with an island dressing or absorbent pad with an area of perhaps $100cm^2$.

If wound fluid were to be distributed uniformly throughout this pad, the intact dressing could actually absorb 5-10 times the weight of fluid predicted experimentally. Similarly the area of film available for evaporation would also be 5-10 times greater, which would further increase the fluid handling properties of the dressing.

This suggests that the laboratory results quoted here will tend to significantly underestimate the fluid handling ability of a standard 10x10cm dressing when applied to a relatively small wound. If, however, the same size pad were to be applied to a larger wound, perhaps 8-9 cm in diameter, the fluid handling capacity of the intact dressing would approximate more closely to predicted values.

In the case of extensive leg ulcers or pressure ulcers, the area of dressing not directly in contact with the wound is likely to be substantially less in percentage terms. This means that the laboratory test data will be less likely to underestimate the fluid handling properties of a large dressing applied to an extensive wound.

The laboratory results also take no account of the effects of gravity. In the case of a dressing applied to a large leg ulcer, for example, fluid will always tend to move towards the lowest point of the dressing with the result that the upper part may not be fully utilized.

Another potential source of error is the fact that the laboratory data was generated with a simple aqueous solution whereas wound fluid consists of a complex mixture containing proteins, and cellular debris. As the aqueous component evaporates, the concentration of these solutes will increase, with the result that they may be deposited on the surface of the film, thereby partially occluding it and potentially reducing its permeability over time.

The rate at which water vapour passes across a film dressing is proportional to the difference in partial pressures (simplistically the amount of moisture vapour in the air) on both sides of the membrane. In the laboratory test, the relative humidity inside the Paddington Cup is 100%, but within the test chamber it is maintained below 20% thus producing a concentration gradient that will facilitate the passage of moisture through the membrane.

In clinical practice although the humidity beneath a dressing will be very high, the humidity outside will vary. In most instances, however, it will be considerably higher than 20%, - perhaps 50-65%. This means that clinically, the passage of moisture vapour through the dressing will be substantially reduced compared with experimental values.

The temperature outside the dressing is also likely to be lower than 37ºC and this will further influence the passage of moisture vapour across the film.

Despite these limitations the results of this investigation clearly demonstrate that the replacement of the standard polyurethane membrane by an intelligent film has greatly increased the fluid handling properties of the Allevyn dressing which should allow the interval between dressing changes to be extended in the management of heavily exuding wounds.

It should be recognized, however, that there may be other good reasons for changing a dressing that are not related to its fluid handling capacity. Furthermore, only clinical experience with the new formulation will positively confirm that the dressing remains suitable for the treatment of superficial or lightly exuding lesions.

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