AQUACEL® Pro Foam

A Comparison of the In-vitro Physical Performance Characteristics of Silicone Foam Dressings used in Skin Protection & Exudate Management

ConvaTec

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1.0 **Introduction**

Modern wound dressings are a useful tool in the management of chronic and acute wounds.

The primary requirements for modern wound dressings should be to effectively manage exudate, provide an optimal moist wound environment and to support the body's healing processes to ensure wound progression towards healing.

Upon removal, a dressing should cause minimal trauma to the wound bed and peri-wound areas, to not disrupt the healing process. Adhesive dressings should carefully balance the need for good adherence during the wear time of the dressing with minimal trauma and pain to the patient upon removal.

In chronic wounds, exudate management is crucial, as the exudate produced is considered to be a 'corrosive biological fluid' due to its range of harmful constituents (e.g. bacteria and enzymes)[1]. The effective management of wound exudate and the importance of locking away its harmful constituents is therefore key to protecting the healing tissue and in helping prevent further tissue breakdown.

Recently, modern foam-based wound dressings have found an alternative use in pressure ulcer prevention. In this application, dressings are used to protect vulnerable but intact skin to reduce the potential risk of skin breakdown[2].

The main requirements for a prevention dressing, such as AQUACEL® Foam Pro, include the following:

- **Skin Protection:** to reduce the shear forces exerted upon vulnerable areas of the skin and to be repositionable to allow for the skin to be routinely inspected
- **Fluid Management:** to manage the moisture and microclimate of the skin

Many foam dressings, of varying compositions and modes of action, are available for the prevention of skin breakdown. These foam dressings claim to have different physical performance characteristics; however, all are indicated in the management and protection against potential skin breakdown.

This report provides comparative *in-vitro* test data for a range of silicone foam dressings and discusses how this should be interpreted against the different requirements for the dressing: Skin Protection and Fluid Management.

2.0 **Dressings Assessed**

	Hydrofiber® Technology Wound Contact Layer	Absorption Layers	Cover Film
AQUACEL® Foam Pro ConvaTec	**Yes** – with a perforated silicone interface	Hydrofiber® Technology with a soft absorbent foam	Waterproof Viral Barrier Bacterial Barrier
ALLEVYN® Gentle Border Smith & Nephew	**No** – perforated silicone wound contact layer	Hydrocellular foam pad	Waterproof Bacterial Barrier
ALLEVYN® Life Smith & Nephew	**No** – perforated silicone wound contact layer	Hydrocellular foam pad with superabsorbent layer	Waterproof Bacterial Barrier
Mepilex® Border Mölnlycke	**No** – perforated silicone wound contact layer	Absorbent foam pad, spreading layer and superabsorbent retention layer	Waterproof Viral Barrier Bacterial Barrier
Mepilex® Border Flex Mölnlycke	**No** – perforated silicone wound contact layer	Absorbent foam pad, spreading layer and superabsorbent retention layer	Waterproof Viral Barrier Bacterial Barrier
Optifoam® Gentle Medline	**No** – foam wound contact layer	Absorbent foam pad	Waterproof Bacterial Barrier

3.0 **Methodology**

The requirements for the skin protection and fluid management indications are different and as such each requires a different method of analysis.

A combination of *in-vitro* tests allowed a good overview of the physical performance characteristics, and have been used to assess the properties listed below under each indication:

Skin Protection:

- Adhesive Peel: the force required to remove the dressing's adhesive border from a standard surface
- Co-efficient of Friction: the frictional force created by the outer layer of the dressing across a surface such as a cotton sheet

Fluid Management:

- Fluid Uptake: long term absorption capacity and on-going moisture loss by controlled evaporation
- Fluid Retention: the ability to retain absorbed liquid when exposed to a compressive force of 40mmHg as per standard compression bandaging practices
- Lateral Spread: the ability to limit the spread of fluid across the wound contact surface of the dressing

3.1 Skin Protection

> ***" A pressure ulcer is localized injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear. A number of contributing or confounding factors are also associated with pressure ulcers; the significance of these factors has yet to be elucidated." [3]***

Evidence for the use of modern wound dressings in facilitating pressure ulcer prevention is growing. As is the agreement on the key design requirements of a dressing to be effective in this area, such as:

- reduction of shear forces,
- management of the skin microclimate, and
- to be repositionable to allow for regular skin inspection.

The potential role of wound dressings in reducing direct forces and 'cushioning' is more controversial since dressings alone have a limited (or no) role in alleviating the level of static pressure when compared to the effects of regular patient re-positioning or specifically designed devices, such as pressure-relieving mattresses or pressure off-loading devices. The National Pressure Ulcer Advisory Panel (NPUAP) advises the consideration of applying a prophylactic dressing to bony prominences in areas of the body that are subjected to friction and shear[3].

Dressings may potentially aid in the re-distribution of pressure in other circumstances – where a specific off-loading device or support mattress may not be appropriate. For example, this may be worthwhile when the use of another medical device may introduce sustained pressure to the patient (e.g. the use of an oxygen mask).

3.1.1 Static Pressure

The primary cause of pressure ulcers is static pressure applied to both the skin and underlying tissue. When this pressure is greater than the blood pressure within the capillaries, blood flow is impeded. Maintaining interface pressures below capillary closing pressure (for example 32mmHg) is the gold standard for pressure relief[4]. Sustained and sufficient pressure to disrupt blood flow results in hypoxia, localised ischemia and tissue acidosis, leading to cellular necrosis. Pressure ulcers typically occur over bony prominences, however occasionally they can occur in soft tissue areas because of foreign objects, such as a medical device[5].

3.1.2 Shear Force

Shear force is a pressure that can be exerted onto the body of a patient which is produced when two surfaces slide across one another. In the case of a patient, some examples are; when the angle of a bed or chair is changed, or a patient sliding up or down the bed. These movements can result in pulling and stretching of the underlying tissue and vessels, and damage is often not visible on the skin surface.

3.1.2 Friction

Friction is created by movement of the patient across surfaces such as clothes or bed linen. Repeated movements can result in the superficial loss of epidermis and outer layers of the stratum corneum. This can result in abrasion type wounds, which produce large amounts of exudate. This exudate can contribute to adhesion of skin to a surface and thus introduce or worsen shear forces. Areas identified as 'at risk' which are then subjected to friction are likely to develop wounds or skin breakdown around the wound area, including the heels, buttocks, sacrum, elbows and trochanters[6].

3.2 Influence of Dressings on Pressure, Shear & Friction

Dressings can be useful as part of a protocol of care for the management of pressure ulcers by reducing shear force and friction. Ohura et al developed an *in-vitro* model to assess the impact of an external shear force and pressure on a superficial layer of skin and subcutaneous layer with an underlying bony prominence7. The model incorporated porcine skin, a Predia sensor capable of measuring shear and pressure simultaneously and a tiny strain gauge shear sensor buried in the superficial dermis, as illustrated in Figure 1. An external 1 Kg force with a cotton cloth interface was applied to the skin model. This external force was attached to a friction pull tester which pulled at a rate of 10cm / 30 seconds.

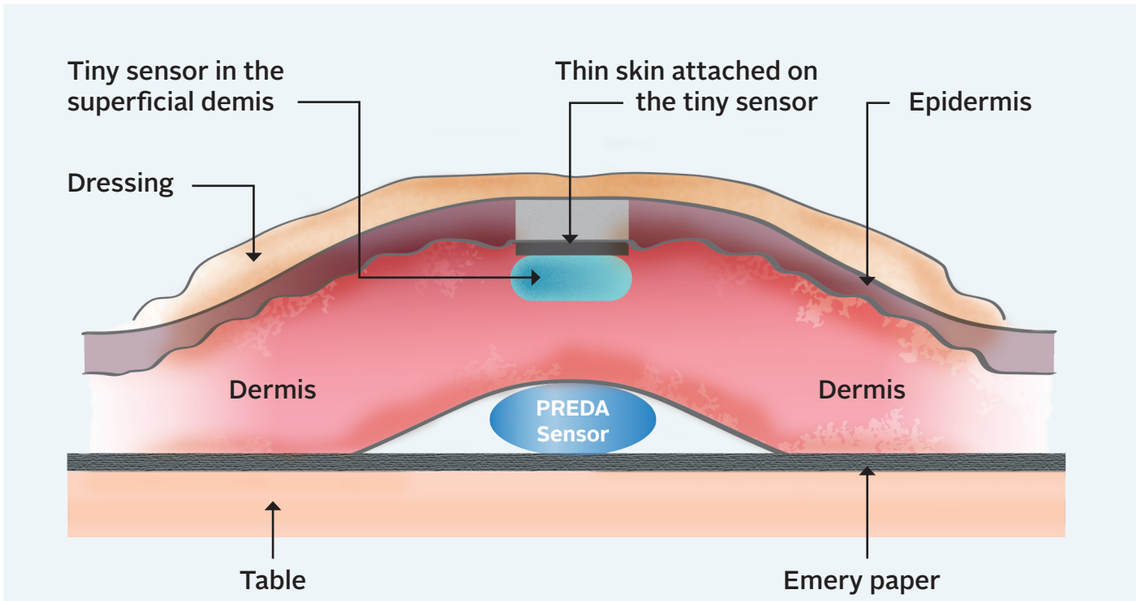

Figure 1: Illustration of Ohura et al pig skin model[7]

Five dressings were evaluated in this model; ALLEVYN® ADHESIVE (Smith and Nephew), TIELLE® (Systagenix), Tegaderm™ (3M Healthcare), Development Opsite® (product under development Smith and Nephew) DuoDERM® CGF (ConvaTec Ltd). The static pressure of the control (no dressing) was not altered by any of the dressings analysed and remained within a range of 6.1-7.2mmHg. During weight movement, the pressure of the control was raised to 16.36 mmHg, all dressings tested were shown to produce a 26-46% reduction compared to the control pressure in the subcutaneous layer.

The mean control (no dressing) for shear force in the subcutaneous layer was 0.47N. The shear forces were reduced by 31-45% compared to the control, with no significant difference between dressings. The shear force within the superficial layer was 1.35N. For all dressings the shear force in the subcutaneous layer was reduced compared to the shear force within the superficial layer. DuoDERM® CGF, was shown to have the lowest shear force in the superficial layer compared to the other dressings tested.

Nakagami et al compared interface pressures and shear forces over the heel in a pressure ulcer preventative dressing and a thin film dressing in a clinical setting[8]. 30 hospitalised elderly patients participated. The results of their study showed that a dressing with a low friction external surface can significantly reduce shear force; however, it did not significantly reduce interface pressures.

Call et al performed a series of in vitro studies comparing the modes of action of dressings and their effect on shear and friction forces[9]. They reported that the dressing construction 'dramatically influences' the shear force and the point load deflection.

In-vitro testing was performed at ConvaTec, Deeside, UK to determine the co-efficient of friction of some commonly used wound dressings. This test method is based on the standard test method for static and kinetic co-efficient of friction of plastic film and sheeting (ASTM D 1894-01). This test determines the co-efficient of friction of dressings when attached to a moving sled when sliding over a stationary plane. Figure 2 demonstrates that all the dressings tested have a similar and low coefficient of friction.

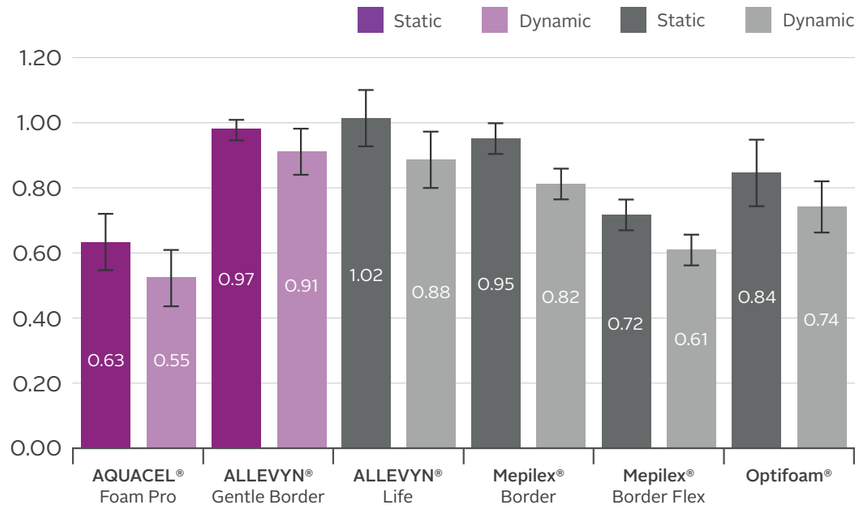

Figure 2: Co-efficient of Friction[10]

AQUACEL® Foam Pro is designed to help reduce the risk of skin breakdown by providing a low coefficient of friction. This means that the dressing can move easily across surfaces such as bedding without rucking, resulting in reduced shear forces

3.3 Managing Microclimate

Poor management of the skin microclimate is deemed a contributing factor in the role of Pressure Ulcer formation[11].

Perspiration, faeces and urine are all common sources of excess moisture, with the corrosive nature of urinary and faecal incontinence potentially leading to chemical damage and skin breakdown. If skin is exposed to excess moisture it may become macerated, denuded or broken[12] (Figure 3, Figure 4).

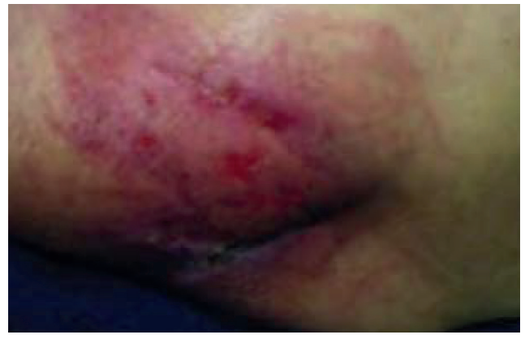

Figure 3: Maceration with friction or shearing injury

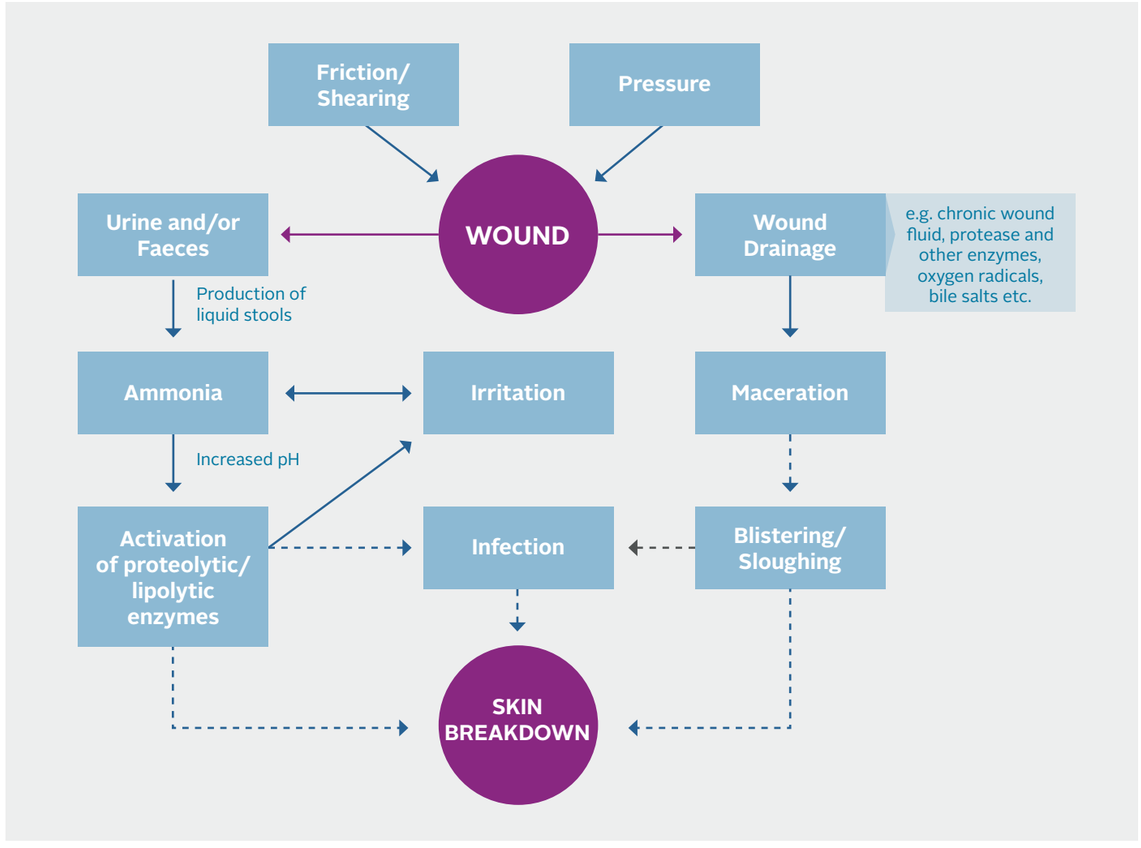

Figure 4: Schematic of a WET skin environment and how it can lead to potential skin breakdown complications[12]

In the case of sacral pressure ulcers, the importance of protecting the skin from urinary and faecal incontinence is well documented. Although moisture on the skin does not directly cause pressure ulcers, it can potentially macerate the skin, making it more susceptible to damage from friction or shearing.[11,12]

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Just as the skin acts as a barrier, a product that provides a barrier to liquids offers a form of protection to help maintain healthy skin and to protect skin at risk from the damaging effects of incontinence, moisture and friction.

To maintain the skins normal softness and pliability a level of 10-20% water is needed, lack of water in the upper layers of the skin results in dry or chapped skin (Figure 5). If the stratum corneum is removed the barrier is lost, whichenhances the absorption capacity of the skin and increases water vapour loss.[2] (Figure 6).

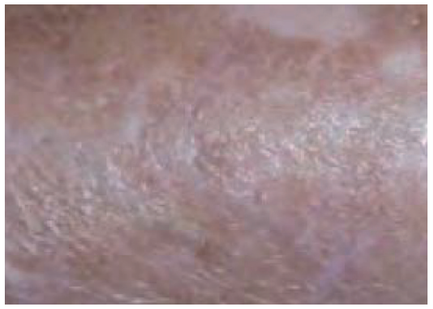

Figure 5: Dry skin

Studies have shown that water vapour loss of forearm skin increases 100-fold, to approximately that of a water layer alone. When skin loses moisture, it becomes dry, flaky and less pliable. Ulcers are more likely to develop where a patient has dry skin.[14,15]

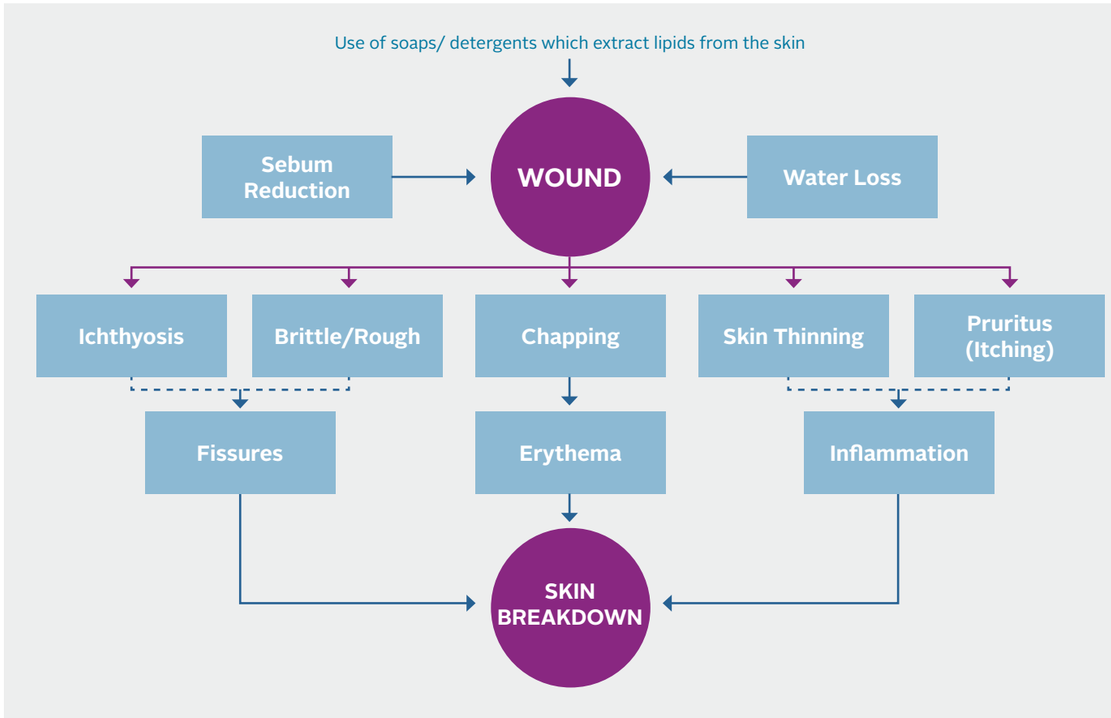

Figure 12: Schematic of a DRY skin environment and how aspects can lead to potential skin breakdown[12]

Dressings can also be useful in providing protection from microbial contamination, such as bacteria and viruses, at the areas of skin most at risk of breakdown.

AQUACEL® Foam Pro is designed to help manage the skin microclimate through controlled Moisture Vapour Loss (MVL), which may help to reduce Trans Epidermal Water Loss (TEWL) and prevent dry skin when used as part of a protocol of care[13]

3.4 Dressing repositioning

With the advancement of adhesive technologies, dressings can now be re-positioned allowing regular skin inspection without the increased cost of dressing changes.

(Note: Only during preventative care, dressing corner can be lifted for inspection of skin and resealed. Dressing must be changed if skin is broken.)

Ongoing assessment of the skin is necessary to detect early signs of pressure damage. The NPUAP and EPUAP Quick Reference Guide recommends 'Inspect skin regularly for signs of redness in individuals identified as being at risk of pressure ulceration. The frequency of inspection may need to be increased in response to any deterioration in overall condition'.[3]

AQUACEL® Foam Pro is designed to be repositionable allowing skin inspection on intact skin[13]

Some dressings may adhere too strongly to the wound surface upon removal, which can disrupt the fragile epithelial tissue. This can be painful for the patient. Dressings containing Hydrofiber® as a wound contact interface have demonstrated low potential for cells to adhere to the dressing.[16] Soft silicone dressings are also designed to minimise trauma on removal and do not leave an adhesive residue on the skin.[17]

Pain and trauma, both during wear time and upon dressing removal, are of primary importance both to the care-giver and the patient, it is also important that an applied adhesive dressing has sufficient adhesive strength to remain in place throughout its intended wear time.

The balance between low pain and trauma upon dressing removal and dressing adhesion during wear has been enhanced through the introduction of silicone adhesive technologies.

The silicone adhesion strength was measured using the polycarbonate peel test. A sample strip is placed on a standard plate of polycarbonate before being removed using a mechanical testing machine which measures the force required to remove the strip of silicone from the plate. The lower the force, the easier the silicone adhesive should be to remove.

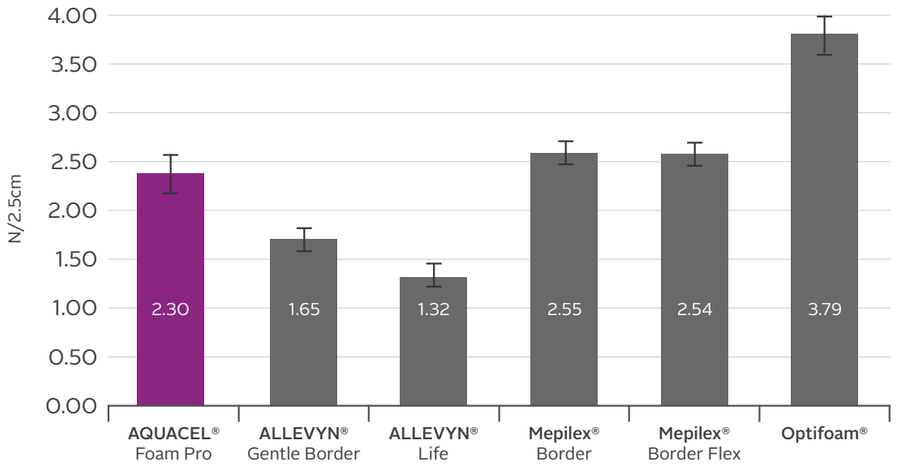

Figure 7: Silicone Peel Strength from Polycarbonate (10)

Figure 7 shows that in this *in-vitro* test, AQUACEL® Foam Pro has better adhesion that both ALLEVYN® Gentle Border and ALLEVYN® LIFE.

The silicone contact surface in AQUACEL® Foam Pro provides secure, skin friendly adhesion[13]

3.5 Fluid Management

The management of fluid at the dressing interface is multi-faceted, often with conflicting requirements, therefore no single performance parameter should be used in isolation and a multifaceted approach to analysis should be taken.[18]

The Fluid Handling test provides an *in-vitro* indication of the maximum volume of fluid a dressing may be able to manage. Under controlled environmental conditions, a known surface area of dressing is held in contact with a known excess of Solution A (simulated exudate) or horse serum.

The reduction in weight of the fluid after 24 hours is termed the Fluid Handling Capacity (FHC); the weight gained by the dressing is termed Absorbency (Abs), and the difference between the two figures is calculated to be the amount of moisture evaporated through the back of the dressing and is referred to as the Moisture Vapour Loss (MVL).

Solution A is considered to have an ionic composition comparable to human serum or wound exudate, and is the laboratory standard test solution for testing wound dressings, horse serum is used as it represents the consistency of wound fluid more closely than Solution A.

Although a high FHC is often used to claim superiority, the ratio of absorbency to MVL is more significant. A high Abs value means that there will be a significant increase in the weight and volume of the dressing. If this weight becomes too great, the dressing may feel heavy and bulky therefore uncomfortable, the dressing is also more likely to leak by the action of gravity and become detached from the skin/ wound area.

Exudate management has historically been linked to the FHC of the dressing. Thomas et al found mean exudate weight from 10 patients ranged between 0.19 to 0.83g/cm2/24h.[19] All dressings tested demonstrated a maximum FHC in excess of 0.83g/cm2/24h (Figure 8). It is however misleading to consider the exudate management potential of a dressing without also considering other factors such as the rate of moisture production and exudate consistency.[20]

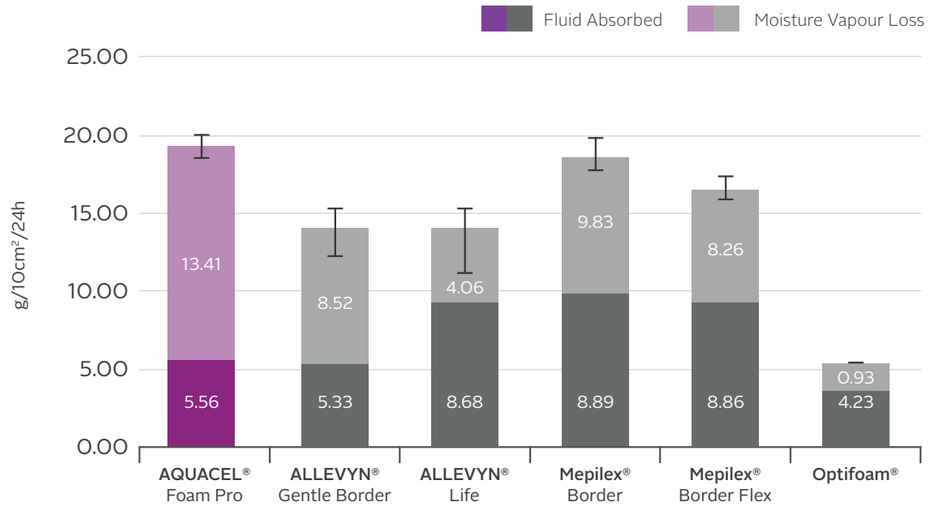

Figure 8: Fluid Handling Capacity with Test Solution A (10)

Whilst greater MVL through the semi-permeable film layer increases the total FHC of the dressing, it may also increase the risk of dehydrating an area of skin which has little or no moisture. The importance of maintaining a moist wound environment has been established since the seminal work of Winter, and AQUACEL® Foam Pro has been designed to ensure that the correct level of moisture at the wound bed is maintained.[20,21]

Wound dressings should be able to 'respond' to the wound environment, influencing the cellular environment of a healing wound through the maintenance of moisture balance. To allow for an optimal balance between higher MVL and moist wound healing for wound progression, AQUACEL® Foam Pro dressings have been designed to contain a gelling Hydrofiber® layer which changes its physical state to form a cohesive gel upon contact with wound exudate.[22] (Figure 9)

Studies have shown that the peri-wound skin area of ischaemic diabetic patients is often compromised and it is therefore important that an appropriate dressing is chosen.[23] The selected dressing should have the capacity to not only absorb moisture but also to retain the moisture within its structure. Dressings containing a Hydrofiber® layer have been found, *in-vitro*, to lock harmful components such as bacteria and proteolytic enzymes within its gelling structure.[24]

Under clinical conditions, dressings are often challenged to retain absorbed exudate under pressure for example due to the application of compression bandaging or by the weight of a patient.[10] Whilst many foam dressings can absorb large amounts of fluid within their porous structure, they are unable to retain the absorbed fluid even when low pressures are applied.

An *in-vitro* method has been used to assess the ability of silicone foam dressings to manage fluid (Solution A) following the addition of 40mmHg pressure (equivalent to compression bandaging).

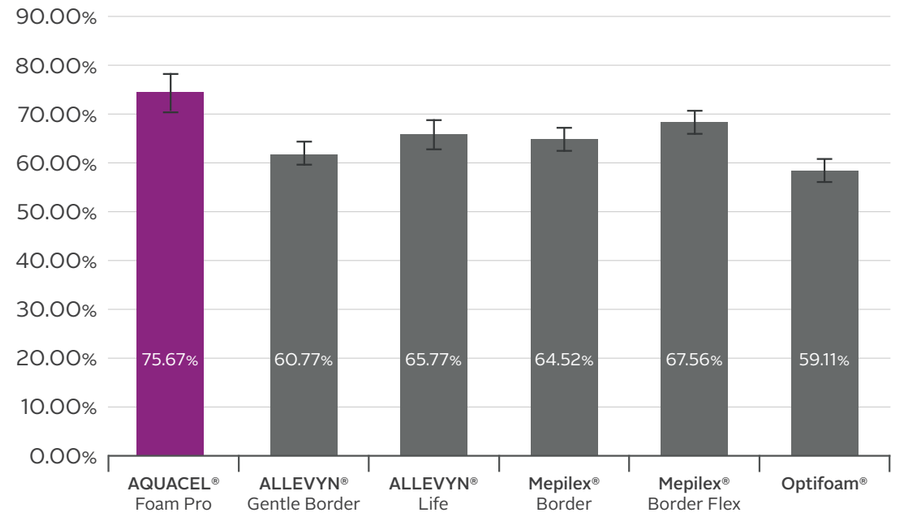

Figure 10: Percentage of fluid retained [10]

Figure 10 demonstrates the dressing's ability to retain fluid after being allowed to absorb fluid unconstrained. AQUACEL® Foam demonstrates that it has the highest retention percentage compared to all other foams analysed. Low retention capacity may lead to dressing leakage and higher risk of maceration at-risk areas or peri-wound skin.

As part of the fluid management design characteristics of a dressing, lateral spread of fluid to the peri-wound skin should be controlled. The peri-wound skin requires protection from bodily fluids to help prevent maceration and further skin breakdown. An in vitro laboratory method was developed to assess fluid movement through and across the dressings. A proportion of a dressing sample was exposed to excess fluid (horse serum) for 1 minute, the area beyond the original designated proportion was then measured and the percentage increase in hydrated area was calculated to be the 'lateral spread' of fluid.

Due to the unique gelling characteristics of AQUACEL® Foam Pro dressings, absorbed fluid is locked into the dressing structure, minimizing the lateral spread of fluid on the dressing surface. AQUACEL® Foam Pro dressings demonstrated the least percentage of lateral fluid spread when compared to the other foam dressings tested (Figure 11)[10,25]

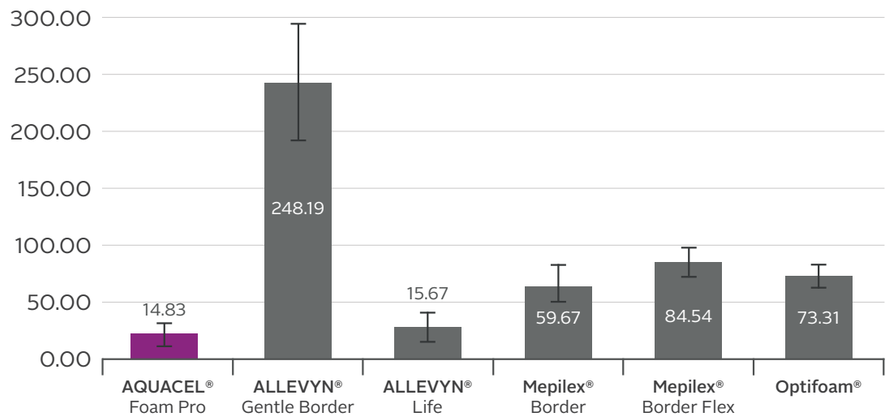

Figure 11: Percentage Lateral Spread across the dressing surface[10]

Vertical wicking locks exudate within the Hydrofiber® layer of the AQUACEL® Foam Pro dressing, which may reduce the risk of maceration of peri-wound skin[10,25]

4.0 Conclusion

4.1 Skin Protection

When used as part of a protocol of care AQUACEL® Foam Pro has been designed to provide a healthy skin microclimate and reduce both friction and shear forces on the skin.

The incident rates, economics, and impact on the quality of life to the patient, are well documented and understood. The primary cause of pressure ulcer formation is static pressure, and as such, the care-givers primary concern is to remove pressure from at-risk areas to help prevent pressure ulcer formation. However, several other factors still have a role to play in pressure ulcer formation.

The role of shear forces and excess moisture as secondary contributing factors is also well documented. Whilst these factors alone do not directly cause pressure ulcers they do soften and damage the skin making it more susceptible to further damage.

Dressing technologies have further developed in this area by introducing adhesives that are designed for low trauma upon removal and can be re-positioned. These new technologies allow the caregiver a further product choice to reduce skin damage caused by friction and excess moisture, with the confidence that the at-risk area can be inspected without causing further skin damage or incurring the cost of a dressing change upon each inspection.

AQUACEL® Foam Pro dressing is designed to protect against skin breakdown caused by excess moisture, friction or shear force and may be used as part of a comprehensive protocol of care to protect at-risk areas and help prevent skin damage

4.2 Fluid Management

The importance of effective fluid management and ability of a dressing to provide the optimal healing environment are key requirements for wound progression. The *in-vitro* laboratory studies performed demonstrate that the foam dressings tested have different physical characteristics, these differences in physical characteristics may be indicative to their clinical performance.

AQUACEL® Foam Pro dressings have been designed to effectively manage fluid, provide an optimal moist wound environment to support the body's healing process to ensure timely wound progression towards healing, and cause minimal trauma to the wound bed and peri-wound area upon dressing removal. The adhesive has been designed to carefully balance the need for good adherence during the wear-time with minimal trauma and minimal pain upon removal.

AQUACEL® Foam Pro dressing is designed to provide effective fluid management to provide an optimal healing environment and to support the prevention of tissue damage which can be caused by excess fluid in contact with at-risk areas of skin.[10,13,25]

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