AQUACEL® Foam

In-vitro Bio-Physical Performance Characteristics of AQUACEL® Foam Dressings

ConvaTec

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Introduction

Wound healing is complex with many critical factors affecting the efficacy and speed of recovery. The function of the dressing during this healing process should be holistic, including protecting the impaired tissue, effectively managing exudate and creating an optimal moist wound environment for proliferation and tissue regeneration.

In chronic wounds, a balanced approach to exudate management is crucial in aiding healing. Exudate contains important nutrient and components needed during the healing process, however excess exudate may delay the healing of wounds as it is considered to be a 'corrosive biological fluid' due to its range of harmful constituents (e.g. bacteria and enzymes)[1]. Excess exudate may cause subsequent breakdown and further deterioration of the wound bed, maceration of surrounding tissue and physical and psychological morbidity. These affects may delay or prevent wound healing and consequently increase the burden on healthcare resources. However, exudate is also vital in preventing the wound bed from drying out and supporting the healing process. Exudate is known to aid migrations of fibroblasts to the wound site, providing essential nutrients for metabolism and assisting in the separation of dead or damaged tissue (autolysis). To achieve an effective management of wound exudate, the goal is to create a balanced level of exudate and a moist environment for healing[2].

Exudate absorption and retention is not the complete requirement in wound healing, protection of the wound site from further damage is also a key factor in the healing process. Such as, shielding from both external contact and infection whilst the tissue is vulnerable.

Bacteria are often present in high numbers in wound fluid, it is important that dressings with high fluid retention levels are also able to absorb and lock away the bacteria[3,4,5]. Therefore, sequestration is a key factor in protecting the healing tissue and in helping prevent infection.

To reduce the possibility of infection further, dead space created between the dressing and wound surface must be minimised to eliminate areas where bacteria and viruses can thrive. These pockets provide the ideal location for the harmful substances contained in exudate to proliferate and subsequently slow down or even reverse the healing process.

Maceration of surrounding healthy tissue during the healing process is often overlooked as an important criterion in wound dressing. Lateral spread of exudate absorbed can damage the integrity of the surrounding peri-wound tissue and may cause infection and subsequently delay the healing process. Exudate management is very important as it can cause patients a great deal of discomfort and pain as well as prolonging healing time[2].

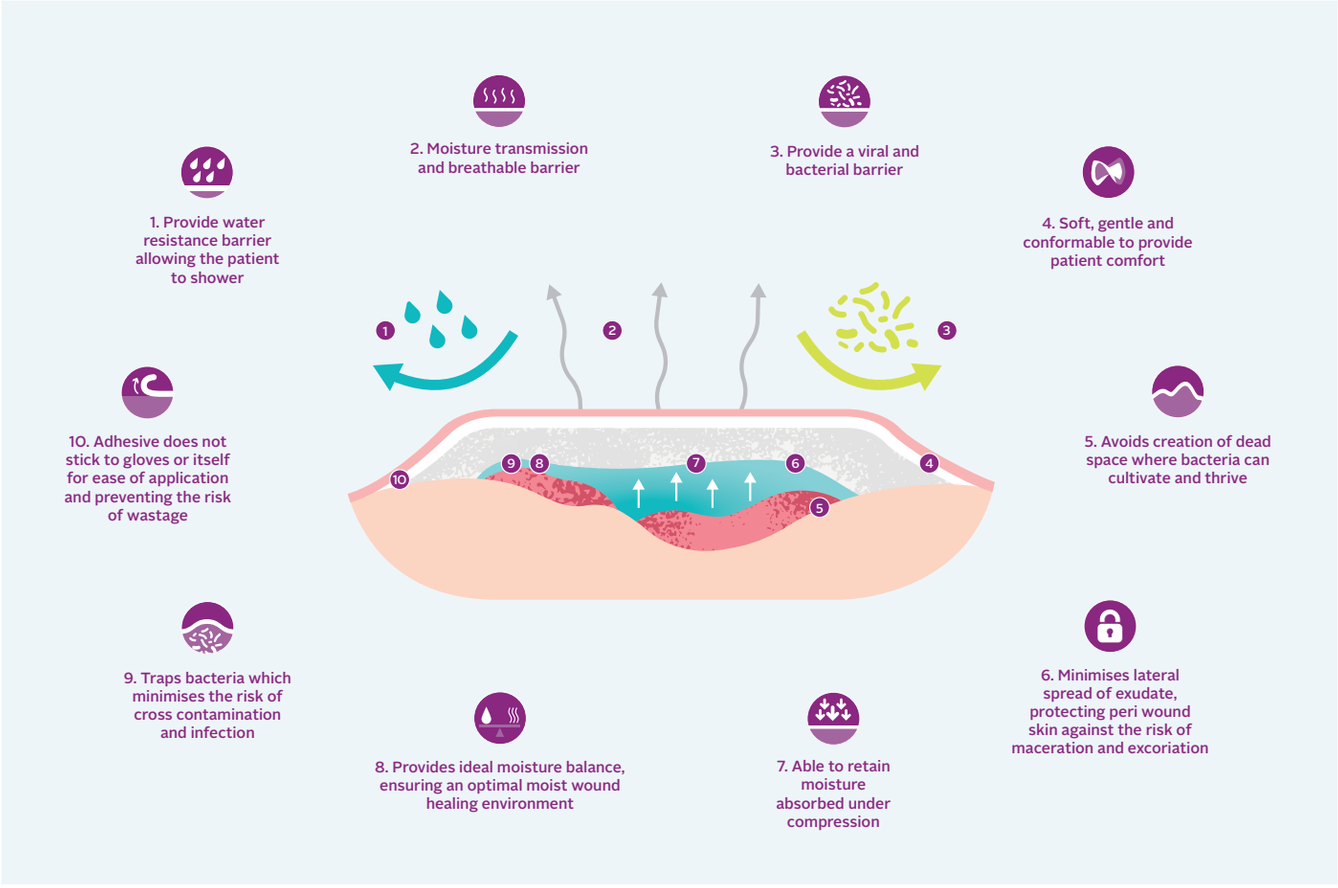

Figure 1 AQUACEL® Foam is a multifunctional dressing allowing a holistic approach to wound healing.

Patient preference has occupied a prominent place in clinical decision making in recent years. Wound dressings need to consider the patients' comfort during wear, sometimes for significant lengths of time. The dressing should have a lower coefficient of friction so that it does not catch on clothing and a resilient adhesive to ensure that it remains in place for the duration of wear.

However, 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. Therefore, upon removal, a dressing should cause minimal trauma to the wound bed and peri-wound areas, to not disrupt the healing process.

Hence, wound management is a multifactorial process and the dressing used should address a wide range of holistic challenges to provide a complete solution to aid the healing process. The *in-vitro* tests carried out during this investigation, combined with previously published data, have taken these parameters into account to assess the physical performance of the characteristics of the AQUACEL® Foam dressing from ConvaTec. For full details on methodology and raw data please refer to the appendices at the end of this document.

Results & Discussion

Exudate management has historically been linked to the absorptive capacity and fluid handling capacity (FHC) of the dressing. For the FHC test, both Solution A and Horse serum has been used as comparatives to wound exudate. Test 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, however it is considerably different, in both viscosity and composition, to wound exudate (Appendix B – T1).

To more closely mimic wound exudate viscosity and composition (e.g. protein content) the test was repeated using horse serum as the test solution. Whilst greater moisture vapour loss (MVL) through the semi-permeable film layer increases the total FHC of the dressing, it may also increase the risk of a lightly exuding wound drying out. The importance of maintaining a moist wound environment has been established since the pivotal work of Winter [6;7]. Therefore, a careful balance between higher permeability to allow greater FHC whilst providing an optimal wound healing environment is important. 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 [8].

For the FHC test with Horse serum, AQUACEL® Foam has a balanced management of vapour and fluid absorbency , therefore providing an environment that supports moist wound healing whilst managing the exudate (Appendix B – T2).

To allow for an optimal balance between higher MVL and the importance of a moist wound healing environment for wound progression, AQUACEL® Foam dressing has been designed to contain a gelling wound contact layer which can change its physical state to form a cohesive gel upon contact with wound exudate (Figure 2).

Figure 2 Cohesive Gelling of AQUACEL®

During wound healing, it is important to be able to fill the micro contours of the wound surface in order to minimise the dead spaces between the wound surface and the dressing. The less dead space there is the less possibility for the proliferation of bacteria [9; 10; 11].

An *in-vitro* laboratory test, a method was developed to assess the dressing's ability to micro-contour and to visually assess the fluid handling of the dressing.

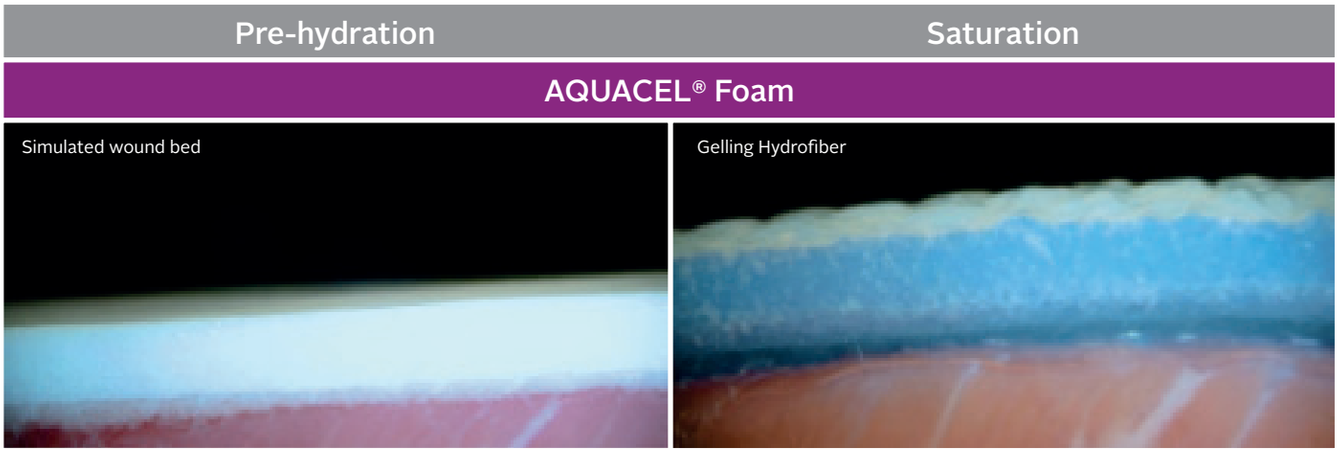

Figure 3 Pre-Hydration and Saturated images of AQUACEL® Foam and other dressings on a simulated wound bed[5].

Figure 3 demonstrates that AQUACEL® Foam dressing, through its unique gelling characteristics, can intimately contact with a simulated wound bed.

Under clinical conditions, dressings are often challenged to retain absorbed exudate under pressure i.e. due to the application of compression bandaging or by the weight of the patient. 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. Two *in-vitro* methods have been used to assess the silicone foam dressing's ability to manage fluid under the addition of 40mmHg pressure (equivalent to compression bandaging).

Appendix B – T3 shows the percentage of the absorbed fluid that is retained after being exposed to 40mmHg of compression. In this *in-vitro* test method AQUACEL® Foam dressing can be seen to retain 63% of the absorbed fluid under compression.

The ability to absorb fluid whilst under constant pressure (40mmHg) is shown in Appendix B – T4. This test was designed to replicate how a dressing may absorb fluid whilst under compression bandaging. AQUACEL® Foam absorbs a high level of exudate even when under compression.

As part of a dressing's exudate management design characteristics, lateral spread of fluid to the peri-wound skin should be controlled, as the peri-wound skin needs to be protected from wound exudate to help prevent maceration and potential for further skin breakdown.

To assess the AQUACEL® Foam dressing's ability to manage fluid over the wound site an *in-vitro* laboratory method was developed by ConvaTec™ to assess fluid movement through and across the wound contact surface of dressings.

Prevention of further damage to healthy or compromised peri-wound skin is a key component to wound healing, therefore it is important that an appropriate dressing is chosen[1,2]. The selected dressing should have the capacity to absorb exudate and to retain the exudate within its structure.

Due to the unique gelling characteristics of the Hydrofiber™ Technology within the AQUACEL® Foam dressing, absorbed exudate is locked into the dressing structure, minimising the lateral spread of fluid on the dressing surface. A minimal 9% average lateral spread was recorded (Appendix B – T5)

Dressings containing a Hydrofiber™ layer have also been found *in-vitro* to lock harmful components such as bacteria and proteolytic enzymes within its gelling structure [3,4,5]. A study by Walker et al., has shown that a Hydrofiber™ wound dressing can control fluid flow as individual fibres hydrate and swell to form a cohesive gel structure. This cohesive gel structure traps the potentially pathogenic bacteria and corrosive enzymes within the fibers of the Aquacel layer[3,4,5].

It is not only the exudate management capabilities of the dressing that are important but also the wear experience for the patient. The dressing should be able to stay in place for the intended wear time and have a low pain/trauma upon removal from the skin. The adhesion characteristics of the AQUACEL® Foam dressing shows a strong but gentle adhesion shown in Appendix B – T6.

Another factor to consider during patient wear is the ability for the dressing to slide against materials such as bedding and clothing. The *in-vitro* method of coefficient of friction shows the ability of the dressing to move against a cotton sheet. AQUACEL® Foam shows a very low level friction during static movement (Appendix B – T7). This is particularly important to improving the patient experience and comfort during the duration of wear.

Figure 4 summarises the results of this investigation along with data captured in previous studies on the AQUACEL® Foam dressing.

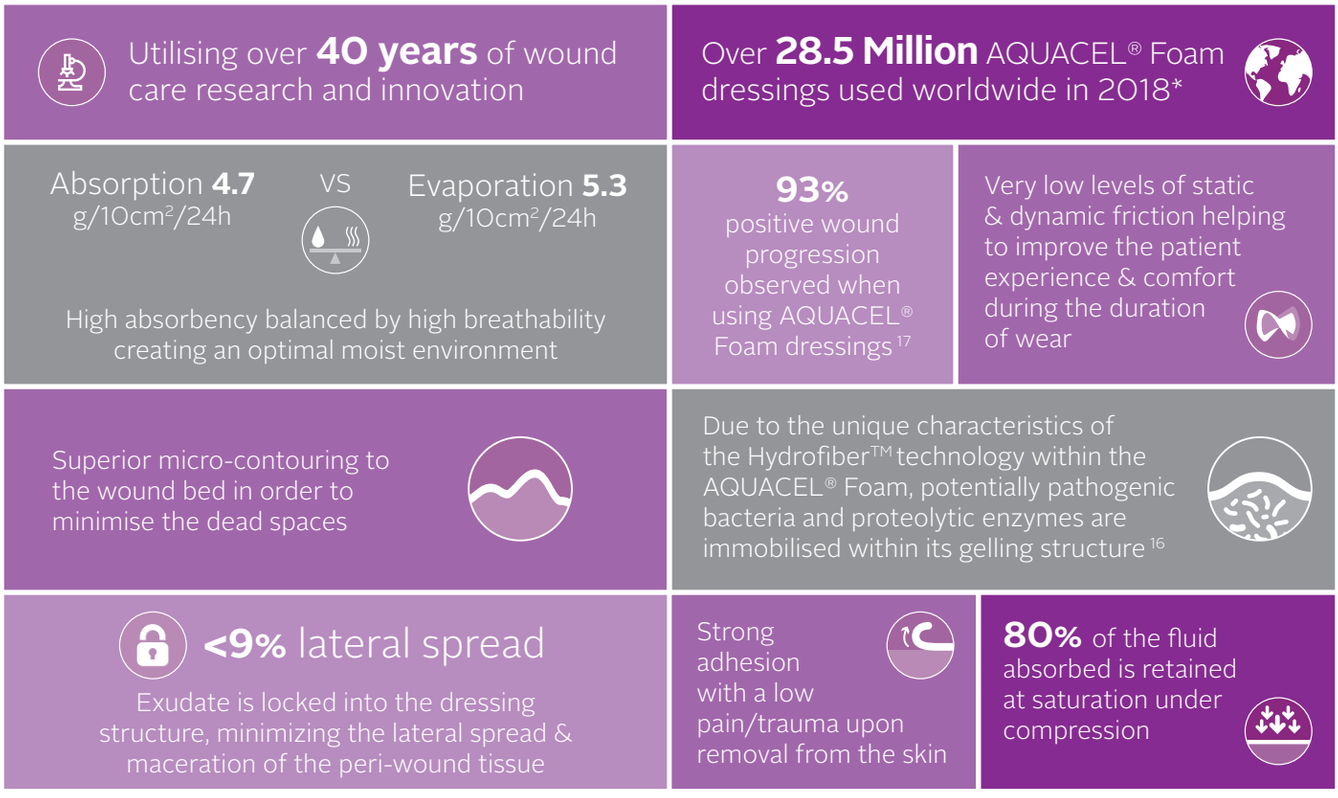

Figure 4 AQUACEL® Foam provides a multifunctional dressing allowing a holistic approach to wound healing.
** Based on internal worldwide sales figures, data held on file @ ConvaTec®*

Conclusion

The findings from these evaluations and previous clinical data show the importance of dressing design and choice in order to provide:

- Effective exudate management, in terms of fluid handling capacity, fluid retention and low lateral fluid spread across the dressing surface;
- Balanced adhesion characteristics, in terms of adhesiveness and wear time, with atraumatic removal, to assist in providing an extended wear-time and
- The provision of an intimately-contacting wound interface to provide an optimal moist wound healing environment all the way across the surface of the healing wound.

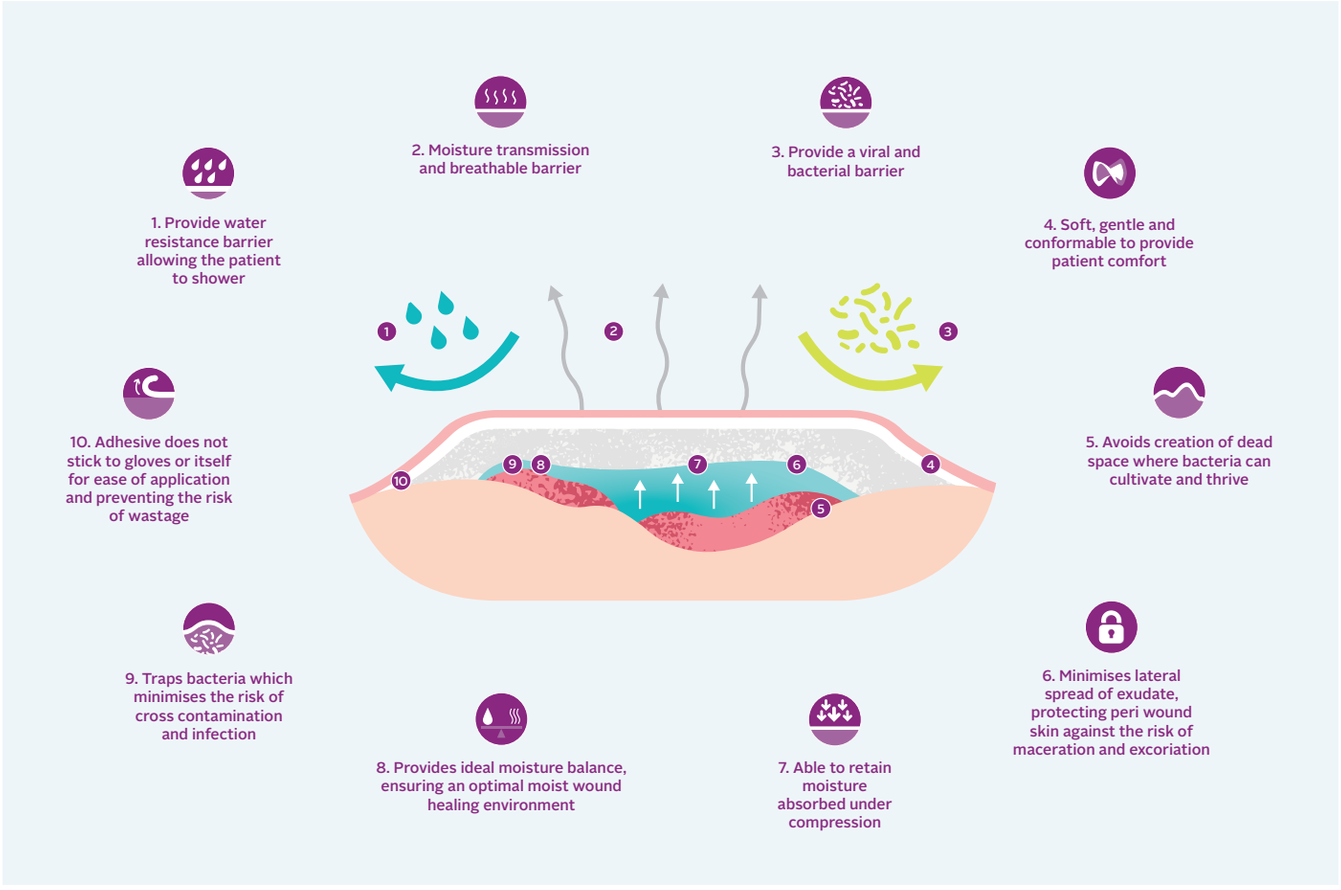

Figure 5 AQUACEL® Foam provides a multifunctional dressing allowing a holistic approach to wound healing.

The AQUACEL® Foam dressing has been designed to meet these important requirements, with an effective fluid transition being assured between the Hydrofiber™ wound contact layer and the foam layer within the dressing. Additionally, the silicone adhesive has been positioned at the border of the dressing for effective skin adhesion, without disruption to the Hydrofiber™ – wound interface.

The importance of good exudate management and the ability of a dressing to provide an optimal wound healing environment are key requirements for wound progression. The *in-vitro* laboratory studies performed demonstrate that the AQUACEL® Foam dressing addresses all the key factors that affect the rate of healing and wound progression. As shown in Figure 5 above, this dressing provides a multifunctional approach to wound healing.

Appendix A - Methodology

Fluid Handling Capacity

This *in-vitro* laboratory method is carried out in accordance with BS EN 13726-1:200214 and includes some minor adjustments to consider the superabsorbent nature of multi-layered wound dressings.

This method was performed using two test solutions – Test Solution A (sodium/calcium chloride BP) and Horse Serum.

Test Solution A

The test dressing is cut (55mm diameter) and placed onto two stacked Payne/Paddington cups, which are weighed (W1).

A volume of 60m l of test solution (sodium/calcium chloride BP [Solution A]) is added, each dressing is massaged gently to allow entrapped air within the dressing to be released prior to fixing the solid plate in place, the whole cup is then re-weighed (W2).

This method modification is performed as it was observed that some dressings were not able to completely hydrate when restricted within the test apparatus.

A minimum of five samples per dressing were evaluated and each cup was placed in a controlled environment incubator (37°C±2°C and ≤20%RH) for 24 hours, after which the cup is removed and equilibrated to room temperature before re-weighing (W3).

The solid plate is then removed from the cup excess fluid is drained and the cup re-weighed (W4).

Horse Serum

The test dressing is cut (55mm diameter) and placed onto two stacked Payne/Paddington cups, which are weighed (W1).

A volume of 30ml of test solution (horse serum [Biowest, Cat# S0910-500]) is added, and the whole cup is then re-weighed (W2). Horse serum is used as a test solution to more closely mimic the viscosity and composition of wound exudate.

Each dressing is massaged gently to allow entrapped air within the dressing to be released prior to fixing the solid plate in place. This method modification is performed as it was observed that some dressings were not able to completely hydrate when restricted within the test apparatus.

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The solid plate is then removed from the cup excess fluid is drained and the cup - re-weighed (W4).

CALCULATIONS

The weight of moisture vapour lost through the dressing is calculated from the following formula:

Moisture Vapour Loss = W2 - W3

The weight of fluid absorbed by the dressing is calculated from the following formula:

Fluid absorbed by the dressing = W4 - W1

The fluid handling capacity (FHC) of the dressing is calculated from the following formula:

FHC of dressing = (W2 - W3) + (W4 - W1)

Micro-contouring to a Simulated Wound Surface

The visual assessment of fluid handling is a specialised test method, developed by ConvaTec® to demonstrate the movement of fluid through a dressing sample. A purpose build test rig is used to visually capture how the wound contact surfaces of a dressing interact with a simulated wound upon hydration.

1.5 x 1.5 x 6cm piece of pork belly is cut to fill the recess in the intimate contact rig and flattened flush to the sample platform. Solution A, dyed with blue food dye (10ml in 1L), is placed into a 50ml syringe and attached to a syringe pump. This is set at a rate of 35ml/h and fluid replenished when necessary. The syringe attached to tubing with a Terumo Agani Needle, 194, regular bevel, which is inserted into the pork belly, approximately 1mm below the top surface of the pork, and secured in place.

A 2cm wide strip of padded dressing (across longest side of dressing) is cut, retaining 3 adhesive borders. The dressing sample is placed onto the sample platform (over the pork belly strip) with the cut edge against the clear screen, wound contact side down. The adhesive border is stuck to the surrounding plastic, to secure in place and should be aligned with the edge of the pork.

A camera is attached to the optical section of a microscope. Images are captured at a rate of 1 image per second. The syringe pump is started along with the first photo and run until the sample is visibly saturated.

Fluid Absorbency & Retention

Free Swell Absorbency / Retention Under Compression

The absorbency aspect of this in-vitro test method was carried out in accordance with BS EN 13726-1:2002[14].

Each test sample is cut to 5cm x 5cm and the area [A1] recorded.

The test sample is then weighed [W1] and placed into an absorption container. The volume of hydrating fluid is calculated as 40x the weight of the sample. The pre-determined volume of warmed hydrating fluid (37°C(±1°C) sodium/calcium chloride BP [Solution A]) is added to the container.

The sample is gently massaged to allow for any trapped air bubbles to be expelled. The samples are incubated for 30 minutes (±1 minute) at 37°C(±2°C).

The sample is removed from the solution and allowed to drain for 30 seconds.

The sample is weighed again [W2].

CALCULATIONS

$$\textit{Weight of fluid absorbed per g of sample} = \frac{W2 - W1}{W1}\ g/g$$

$$\textit{Fluid uptake per unit area} = \frac{W2 - W1}{A1}\ g/cm^2$$

For fluid retention, the hydrated sample is placed onto a perforated metal sheet and a compression load (e.g. a weight equivalent to 40 mmHg as commonly applied with a high compression bandage therapy) is applied to the sample for 1 minute.

Any unbound liquid is allowed to drain, the sample is then re-weighed [W3], and this value gives the fluid retention.

CALCULATIONS

$$\textit{Weight of fluid retained per g of sample} = \frac{W3 - W1}{W1}\ g/g$$

$$\textit{Fluid retention per unit area} = \frac{W3 - W1}{A1}\ g/cm^2$$

Absorbency Under Compression

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The sample is removed from the solution and allowed to drain for 30 seconds.

The sample is weighed again [W2].

CALCULATIONS

$$\textit{Weight of fluid absorbed per g of sample} = \frac{W2 - W1}{W1}\ g/g$$

$$\textit{Weight of fluid retained per g of sample} = \frac{W3 - W1}{W1}\ g/g$$

$$\textit{Fluid absorbed per unit area} = \frac{W2 - W1}{A1}\ g/cm^2$$

$$\textit{Fluid retention per unit area} = \frac{W3 - W1}{A1}\ g/cm^2$$

Lateral Movement of Fluid

This method has been developed by ConvaTec® to assess the lateral spread of fluid in fibrous dressings where ISO 9073-6:2000[15] cannot be used.

The dressing is placed wound contact side up on a suitable flat surface. A plastic vial (Ø29.2mm, 65mm length, vial area = 669.7mm^2) is placed on the centre of the dressing and held in place with a 500g weight.

20ml of horse serum [Biowest, Cat# S0910-500] is dispensed into the vial. Once the full content of the syringe has been expelled, a stop watch is started and absorption is timed for 60 seconds. When 60 seconds has elapsed, non-absorbed fluid from the surface of the dressing is removed with the syringe. The plastic vial is then removed. A ruler is placed parallel to the dressing and a photograph taken with a digital camera. Once all photographs have been taken, the area of lateral fluid spread is measured using image analysis software. Lateral spread is expressed as a % of the original vial area.

CALCULATIONS

$$\%\ Lateral\ Spread = \frac{[(lateral\ spread\ area) \times 100] - 100}{Vial\ Area}$$

Adhesion Characteristics

In brief, a cut strip method is carried out based on a standard Pharmacopoeia method (BP 1993, Volume II, Appendix XX, H, Adhesiveness).

A 25mm x 125mm sample is cut lengthwise where there is no interference with the release liner separation. The release liner is removed and the sample is placed adhesive side down, lengthwise on the frosted side of a strip of polycarbonate (allows the adhesive characteristics of soft skin adhesives to be measured).

Pressure is applied to the attached portion of the strip by means of a roller that applies 20N (2kgf) per cm width of the sample, making two passages along the length of the strip at a speed of 60cm per minute. The sample is then allowed to stand for 30 minutes before testing.

The force required (when applied at an angle of 180° at a constant rate of travel of 10mm per second) to detach the strip from the polycarbonate plate is measured, such that the force required represents 15 to 85% of the full-scale deflection.

Friction Characteristics

The method is based on ASTM D 1894-01 Standard Test Method for Static and Kinetic Coefficients of Friction of Plastic Film and Sheeting.

This method covers determination of the coefficients of starting and sliding friction of plastic film and sheeting when sliding over itself or other substances at specified test conditions using a moving sled and a stationary plane.

The required program on the Universal Testing Machine (UTM) is opened, the cross-head speed of the UTM is set to 150 mm/minute and the test path is set to 130mm. Onto the stationary plane two strips of ~25mm wide double sided tape are placed 75mm apart and ~12cm wide cotton sheet placed on top taking care that it is free from creases.

The silicone release liner is removed and sample is placed onto the square metal sled. A shape is cut out that ensures that the screw attachment can be attached to both threaded holes in the side of the plate.

The dressing is secured to the back of the sled either with the adhesive on the dressing, ensuring that the dressing is not stretched. The specimen covered sled is attached to the screw attachment of the beaded chain and the other end passed through the pulley and attached to the load cell pin of the UTM.

With some slack on the beaded chain, the sled is placed on the sheet covered stationary plane, ensuring no tension on the chain.

The program is started and the Maximum and Average force is measured.

Each sample should be tested in two directions at 90° from each other. This is done by removing the screw from one side of the threaded hole and attaching the screw at 90° from its original position. The other end of the thread is hooked to the load cell pin and the testing repeated.

CALCULATIONS

$$\textit{Static Coefficient of Friction} = \frac{\textit{Maximum Force (g)}}{\textit{Weight of Sled (g)}}$$

$$\textit{Dynamic Coefficient of Friction} = \frac{\textit{Average Force (g)}}{\textit{Weight of Sled (g)}}$$

Visual Assessment of Fluid Handling

The visual assessment of fluid handling is an innovative test method, developed in the laboratory to demonstrate the movement of fluid through a dressing sample. A purpose build test rig is used visually indicate of how the wound contact surfaces of a dressing interact with a simulated wound upon hydration.

1.5 x 1.5 x 6cm piece of pork belly is cut to fill the recess in the intimate contact rig and flattened flush to the sample platform. Solution A, dyed with blue food dye (10ml in 1L), is placed into a 50ml syringe and attached to a syringe pump. This is set at a rate of 35ml/h and fluid replenished when necessary. The syringe attached to tubing with a Terumo Agani Needle, 194, regular beuel, which is inserted into the pork belly, approximately 1mm below the top surface of the pork, and secured in place.

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Appendix B – Raw Data

EXUDATE MANAGEMENT				
T1	Total Fluid Handling Capacity of Test Solution A [17]. Figures quoted are the mean ± 1 standard deviation.	Moisture Vapour Transmission Rate (g/10cm2/24hrs)	Absorbency (g/10cm2/24hrs)	Fluid Handling Capacity (g/10cm2/24hrs)
		14.73 ± 0.98	5.74 ± 0.15	20.47 ± 1.03
T2	Total Fluid Handling Capacity of Horse Serum [16]. Figures quoted are the mean ± 1 standard deviation.	Moisture Vapour Transmission Rate (g/10cm2/24hrs)	Absorbency (g/10cm2/24hrs)	Fluid Handling Capacity (g/10cm2/24hrs)
		5.30 ± 0.25	4.66 ± 0.21	9.95 ± 0.27
T3	Free Swell Absorbency & Retention Under Compression [16]. Figures quoted are the mean ± 1 standard deviation	Absorbency (g/cm2)	Retention (g/cm2)	% Fluid Retained
		0.45 ± 0.03	0.36 ± 0.02	79.9% ± 3.1
T4	Fluid Absorbency Under Compression [16]. Figures quoted are the mean ± 1 standard deviation	Absorbency (g/cm2)		
		0.29 ± 0.01		
T5	Percentage Lateral Spread [16]. Figures quoted are the mean ± 1 standard deviation.	% Lateral Spread		
		8.99 ± 5.98		

ADHESION AND FRICTION			
T6	Polycarbonate Peel [16]. Figures quoted are the mean ± 1 standard deviation.	Average Force to Remove from Polycarbonate N/2.5cm	
		3.96 ± 0.10	
T7	Coefficient of Friction against cotton [16]. Figures quoted are the mean ± 1 standard deviation	Static	Dynamic
		0.70 ± 0.04	0.66 ± 0.04

Appendix C – References

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