An ‘in-vitro’ comparison of the physical characteristics of hydrocolloids, hydrogels, foams, and alginate/cmc fibrous dressings.

Summary

This document describes the results of a testing programme that was undertaken to compare certain elements of the performance of dressings produced by one major European manufacturer with similar products from other companies that hold a significant market share in each of the categories examined. Standard test methods were used during the study to eliminate bias and facilitate future testing by other interested parties.

The publication of test data generated from standard methods by an independent accredited test laboratory in this way provides both clinicians and manufacturers with a baseline for future comparisons, and should also reduce biased or inaccurate product claims resulting from the use of data derived from manufacturers’ ‘in-house’ test methods that could favour a particular product design.

Introduction to current study

The present study was commissioned and funded by Coloplast Ltd to provide both the company, and potential users of their products, with independent comparative test data on certain key aspects of the physical characteristics and performance of the various dressing groups derived using standard test systems. No attempt was made to identify or predict how the clinical use of these materials would impact upon the biochemical or physiological processes involved in wound healing. Publication of test data was undertaken in accordance with the terms and conditions identified on http://www.dressings.org/.

Product groups tested

Hydrocolloid dressings

The term ‘hydrocolloid’ was coined in the 1960s during the development of muco-adhesives and oral bandages, and was first referenced in a US patent authored by J.L Chen published in 1967. In the early 1970s the description was applied to a new family of gel-forming, adhesive sheet dressings typically containing carboxymethyl-cellulose (CMC) as the principal absorbent dispersed in a mixture of adhesives and tackifiers.

Recently, however, the term ‘hydrocolloid’ has been used to describe two very different products, an amorphous hydrogel dressing and a fibrous dressing made from modified carboxymethylcellulose (CMC), which are totally dissimilar in structure and appearance to the adhesive sheet dressings that were first described in this way.

Whilst it is possible to argue that most hydrogels are in fact true colloidal dispersions and that the CMC fibres form a colloidal dispersion in the presence of liquid, the same can also be said of other gel-forming fibres made from alginates, hyaluronidase, chitin or chitosan. Extending the use of the term hydrocolloid in this way to materials with totally different physical characteristics and clinical indications from the original adhesive gel-forming sheets cuts across existing and well understood, dressing classification systems.

For the purpose of this investigation, the term hydrocolloid will therefore be applied to the adhesive sheet formulation in which, typically, the gel forming agents are combined with elastomers and adhesives and applied to a carrier – commonly consisting of a sheet of polyurethane foam or film, to form an absorbent, self adhesive, waterproof dressing.

When applied to a wound the adhesive mass in such dressings absorbs liquid and forms a gel, but the speed of this process and the properties of the resultant gel are determined by the nature of the formulation.

In the intact state most hydrocolloid sheet dressings are impermeable to water vapour, but as the gelling process takes place, the dressing becomes progressively more permeable. The loss of water through the dressing in this way enhances the ability of the product to cope with exudate production.

Hydrocolloid sheets are widely used as primary dressings in the management of many different types of wounds including leg ulcers, burns, donor sites and pressure ulcers but their relatively limited fluid handling properties tend to restrict their use to the management of light to moderately exuding wounds. For more heavily exuding wounds, products made from polyurethane foam are often preferred.

Thinner versions of the standard hydrocolloid dressings are also available and these may be used as alternatives to vapour permeable film dressings in the management of superficial injuries, or as secondary dressings over products such as alginates or hydrogels.

The hydrocolloid dressings included in the present study are shown in Table 1.

Table 1: Hydrocolloid dressings tested

Manufacturer	Item	Batch/Lot No
Coloplast A/S	Comfeel Plus Ulcer Dressing	95504.01
Coloplast A/S	Comfeel Plus Transparent Dressing	95961.20
Competitor A	A bordered standard hydrocolloid	
Competitor A	An extra thin hydrocolloid	

Fluid Handling Studies

Summary of test method

The fluid handling properties of the dressings were examined using SMTL test method TM-65, which is based upon that described in **BS EN 13726-1:2002.** *Test methods for primary wound dressings. Part 1: Aspects of Absorbency, section 3.3 Fluid Handling Capacity.*

In this test five samples of each dressing of known weight are applied to Paddington cups (modified Payne cups) to which are added 20 ml of Solution A, a solution of sodium/calcium chloride containing 142 mmol/litre of sodium ions and 2.5 mmol/litre of calcium ions, concentrations which are comparable to those present in serum and wound fluid.

The cups are weighed and placed in an incubator at 37+/-2°C, together with a tray containing 1kg of freshly regenerated self-indicating silica gel for a period of 24 hours. At the end of the test the cups are removed from the incubator, allowed to equilibrate to room temperature and reweighed. From these weighings the loss in weight due to the passage of moisture vapour through the dressing is determined.

The base of each cup is then removed, and any remaining fluid allowed to drain for 15 minutes. (If there is an accumulation of test fluid between two components of the dressing, the inner component must be slit with a scalpel blade to allow free drainage of the entrapped fluid).

Each cup is then reweighed once again and the weight of fluid retained by the dressing calculated by difference.

From a clinical perspective, this standard test provides valuable information on two important mechanisms of exudate management.

- Absorbency, the ability for the dressing to absorb and retain wound fluid
- Moisture vapour loss, the evaporation of a proportion of the aqueous component of wound fluid through the outer surface of the dressing to the external environment.

The total fluid handling capacity of a dressing is defined as the sum of the values determined during the course of these tests.

In clinical practice, fluid-handling capacity determines the wear time of a dressing because it affects both exudate leakage and/or maceration of the peri-wound skin, factors that can adversely affect a patient's quality of life.

Fluid Handling Results

The results of the fluid handling tests conducted over 24, 48 and 72 hours are presented in Tables 2-4 and summarised in Figures 1 to 4 which clearly show that although the absorbent capacity of the four products examined is reached after 24 hours, the dressings continue to permit the passage of moisture vapour throughout the period of the test.

Table 2: Fluid handling properties following 24 hours incubation

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Comfeel Plus Ulcer Dressing	0.23 (0.062)	3.10 (0.916)	3.32 (0.900)
Comfeel Plus Transparent Dressing	2.48 (0.129)	1.79 (0.130)	4.27 (0.217)
Competitor A Bordered	0.36 (0.126)	1.96 (0.456)	2.31 (0.469)
Competitor A Extra Thin	0.26 (0.009)	1.62 (0.048)	1.88 (0.053)

Table 3: Fluid Handling Properties following 48 hours incubation

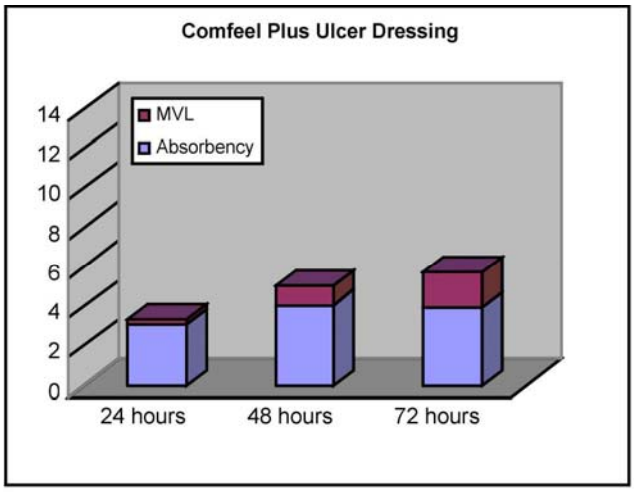
Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Comfeel Plus Ulcer Dressing	1.01 (0.260)	4.07 (0.151)	5.08 (0.311)
Comfeel Plus Transparent Dressing	5.72 (0.221)	1.83 (0.209)	7.55 (0.287)
Competitor A Bordered	1.31 (0.070)	1.92 (0.087)	3.23 (0.096)
Competitor A Extra Thin	0.79 (0.163)	2.26 (0.106)	3.05 (0.191)

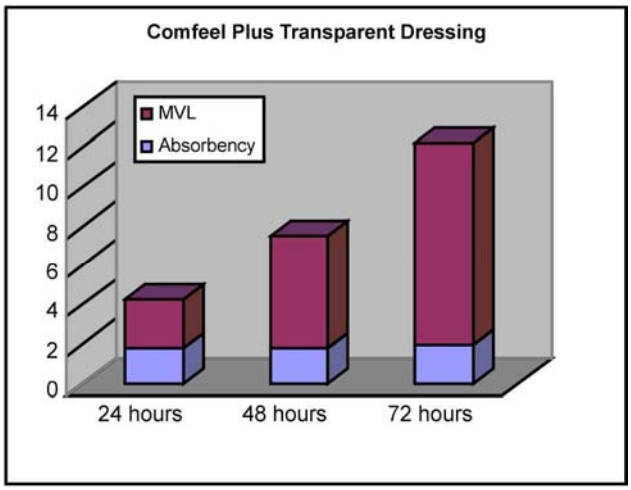
Table 4: Fluid Handling Properties following 72 hours incubation

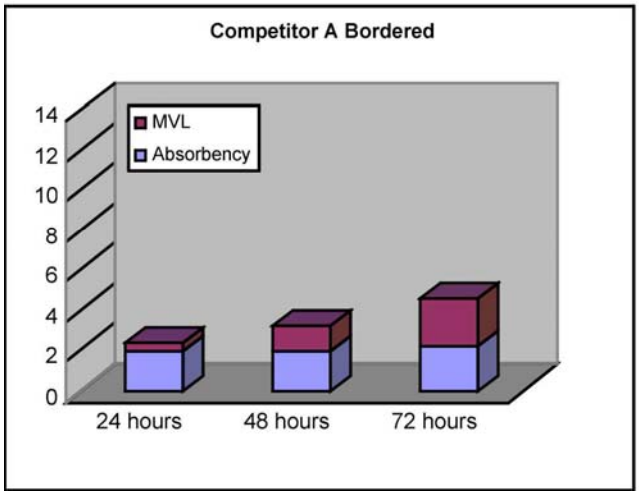
Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Comfeel Plus Ulcer Dressing	1.85 (0.330)	3.92 (0.035)	5.77 (0.330)
Comfeel Plus Transparent Dressing	10.30 (0.603)	2.00 (0.167)	12.30 (0.579)
Competitor A Bordered	2.39 (0.121)	2.21 (0.008)	4.61 (0.126)
Competitor A Extra Thin	0.89 (0.035)	2.69 (0.118)	3.57 (0.121)

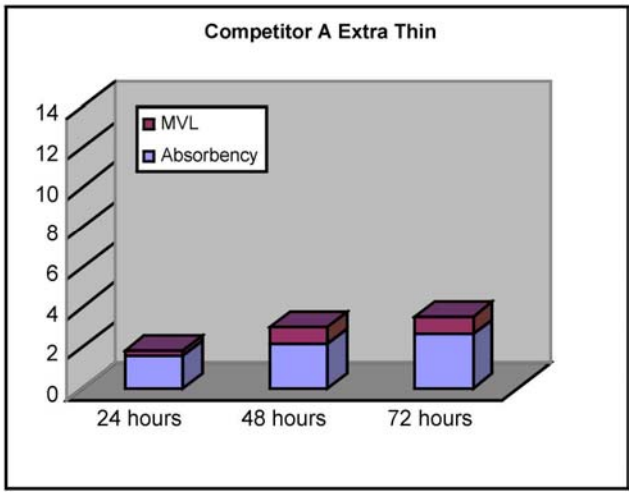
(Note: In all these tables, the results quoted represent the mean of 5 determinations and the figures in brackets denote standard deviations)

Figures 1-4


Comfeel Plus Ulcer Dressing
MVL
Absorbency
14
12
10
8
6
4
2
0
24 hours
48 hours
72 hours


Comfeel Plus Transparent Dressing
MVL
Absorbency
14
12
10
8
6
4
2
0
24 hours
48 hours
72 hours


Competitor A Bordered
MVL
Absorbency
14
12
10
8
6
4
2
0
24 hours
48 hours
72 hours


Competitor A Extra Thin
MVL
Absorbency
14
12
10
8
6
4
2
0
24 hours
48 hours
72 hours

Permeability: Moisture Vapour Transmission Rate (MVTR)

Test method

The previously described fluid-handling test measures both the absorbency of a dressing and the total weight of moisture vapour lost through the outer surface during the period of the test.

It does not, however, provide any indication of time-related changes that may take place in the permeability of some dressings, such as hydrocolloids, which can increase dramatically as the product absorbs liquid to form a gel, reaching a steady state after a number of hours.

Time related changes in moisture vapour permeability of the dressings were determined using SMTL test method TM-8 which is also based on the methods described in **BS EN 13726-2:2002.** *Test methods for primary wound dressings. Part 2: Moisture vapour transmission rate of permeable film dressings.*

In this test, a sample of dressing is applied to a Paddington cup to which is added 20 ml of Solution A. The cup is placed in an inverted position (with the test solution in contact with the dressing in an incubator set at 37+-2.0°C upon the pan of a top loading balance. The balance is connected to an electronic data-logging device, which records changes in the weight of the cup resulting from the loss of moisture vapour through the dressing. A tray containing 1 kg of freshly dried silica gel is placed in the bottom of the incubator to maintain a low relative humidity within the chamber.

At the end of the test the recorded data is downloaded for statistical analysis. For dressings that have a lag time before the MVTR reaches a steady state, the linear part of the slope is taken for regression analysis to determine the maximum value for moisture vapour transmission.

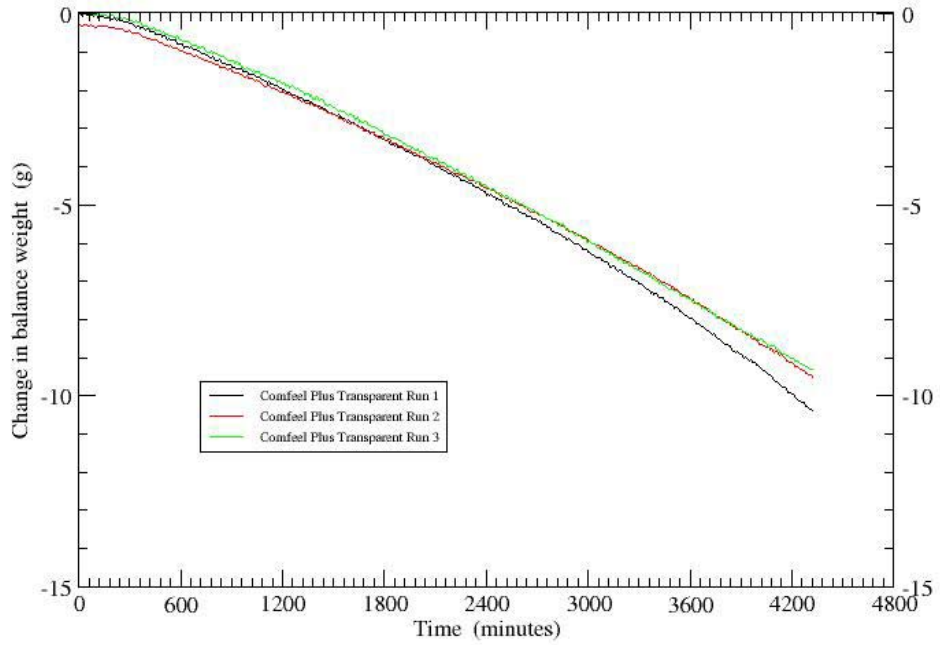
Results

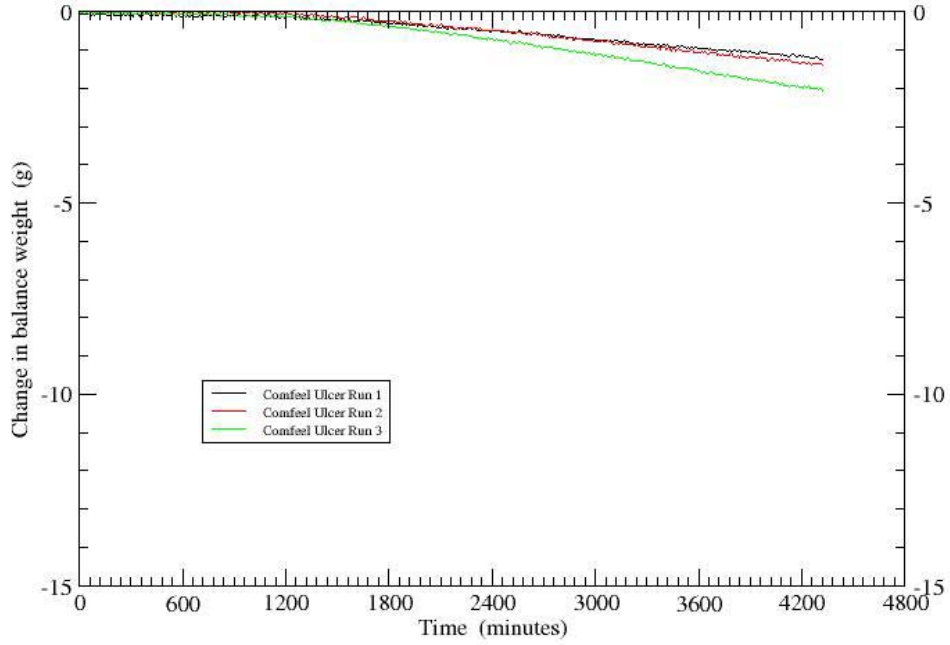
The individual results of the MVTR testing are shown in Table 5 are also expressed graphically in Figures 5 to 9.

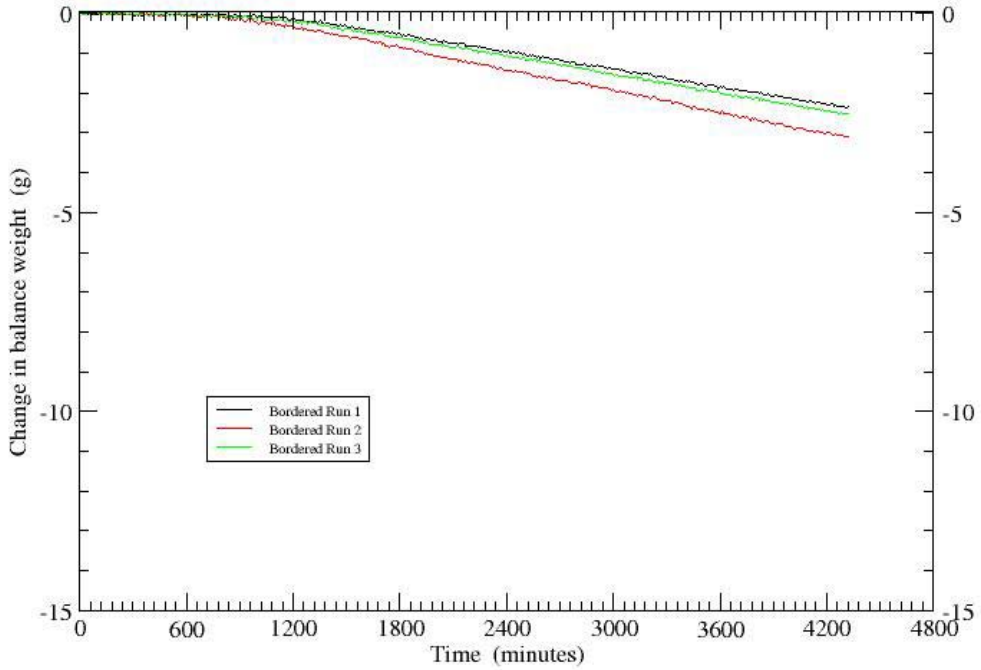
Table 5: Change in balance Weight over 72 hours

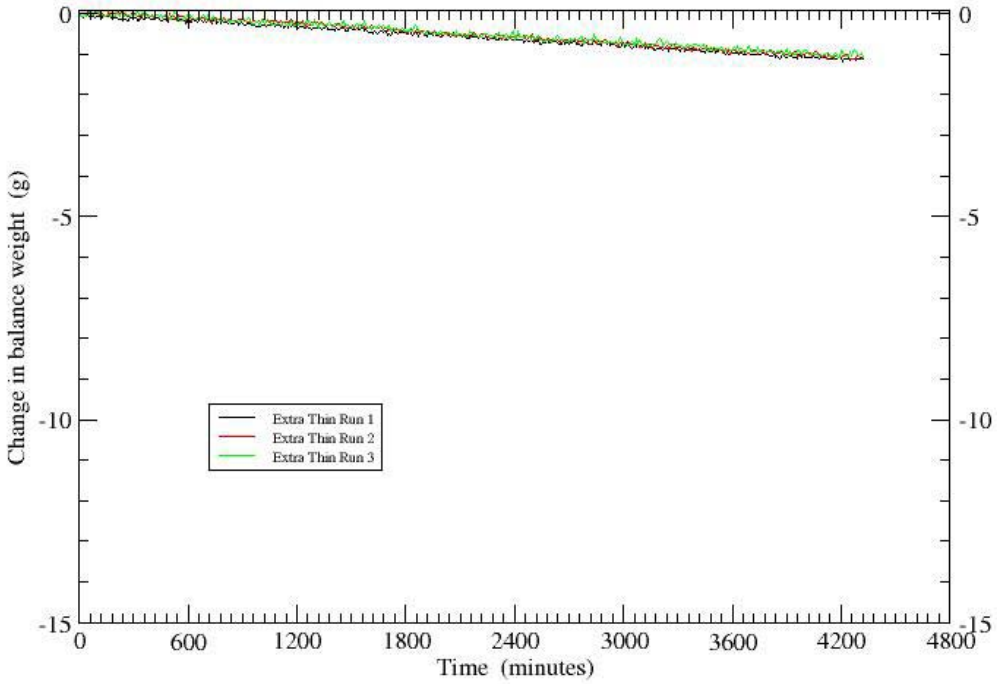
Dressing	Maximum MVTR (g/10cm^2/24Hrs)		
	Run 1	Run 2	Run 3
Comfeel Plus Ulcer Dressing	0.516	0.652	0.956
Comfeel Plus Transparent Dressing	3.704	3.321	3.429
Competitor A Bordered	1.049	1.297	1.098
Competitor A Extra Thin	0.375	0.385	0.364

Figures 5-9


Change in balance weight (g)
Time (minutes)
Comfeel Plus Transparent Run 1
Comfeel Plus Transparent Run 2
Comfeel Plus Transparent Run 3
0
-5
-10
-15
0
600
1200
1800
2400
3000
3600
4200
4800


Change in balance weight (g)
Time (minutes)
Comfeel Ulcer Run 1
Comfeel Ulcer Run 2
Comfeel Ulcer Run 3
0
-5
-10
-15
0
600
1200
1800
2400
3000
3600
4200
4800


Change in balance weight (g)
Time (minutes)
Bordered Run 1
Bordered Run 2
Bordered Run 3
0
-5
-10
-15
0
600
1200
1800
2400
3000
3600
4200
4800


Change in balance weight (g)
Time (minutes)
Extra Thin Run 1
Extra Thin Run 2
Extra Thin Run 3
0
-5
-10
-15
0
600
1200
1800
2400
3000
3600
4200
4800

Alginate/cmc fibrous dressings

Dressings made from gel-forming polysaccharides have a long history in the management of exuding wounds. Alginates derived from seaweed have been used in a fibrous form for many years as haemostats and surgical absorbents.

More recently, dressings have been produced from chemically modified carboxymethylcellulose, which are similar in appearance and gel forming properties to the alginates, and which are claimed to offer similar benefits to a healing wound.

The dressings function by absorbing exudate to form a moist gel on the wound surface that is thought to facilitate healing. They are, therefore, best suited for application to exuding wounds as a primary dressing beneath a more absorbent secondary layer. If a wound is too dry to transform an alginate fibre into a hydrogel-like material, then the wound surface remains dry and the undissolved fibres do not provide a moist healing environment

Gel formation involves an ionic exchange process in the case of alginate dressings as insoluble calcium alginate is partially converted into the soluble sodium form as it takes up sodium ions from wound fluid. The process of gel formation with CMC fibre dressings is more of a physical process due to the uptake of water by the fibres although the presence of sodium and calcium ions still exerts an effect upon gel formation.

The dressings included in the present study were as shown in Table 6..

Table 6: Fibrous dressings tested

Manufacturer	Item	Batch/Lot No
Coloplast A/S	SeaSorb Soft Dressing	75083.02
Competitor A	Carboxymethylcellulose Dressing	
Competitor B	Alginate Dressing	

Absorbency of alginate/cmc forming fibrous dressings

Test method

The absorbency of the dressings was determined using SMTL test method TM-101 based **BS EN 13726-2:2001.** *Test methods for primary wound dressings. Part 1: Aspects of Absorbency, Section 3.2, Free swell absorptive capacity.*

In this test, a 400ml solution of Solution A is brought to 37°C in a water bath. A sample of dressing measuring 5 x 5 cm of known weight is placed in a Petri dish and a volume of test solution equal to 40 times the weight of the test sample added to that sample using a pipette. The Petri dish and its contents are incubated at 37+/-2.0\°C for 30 +/- 1 minutes. Using forceps, the sample is removed from the Petri dish, suspended for 30 seconds and reweighed. This test is repeated until 10 samples have been tested. From these results, the mean weight of solution retained per 100cm^2 is calculated.

Results

The results of the absorbency testing are summarised in Table 7 and Figure 10. These predict how much fluid each dressing may be expected to retain in clinical practice when applied to an exuding wound.

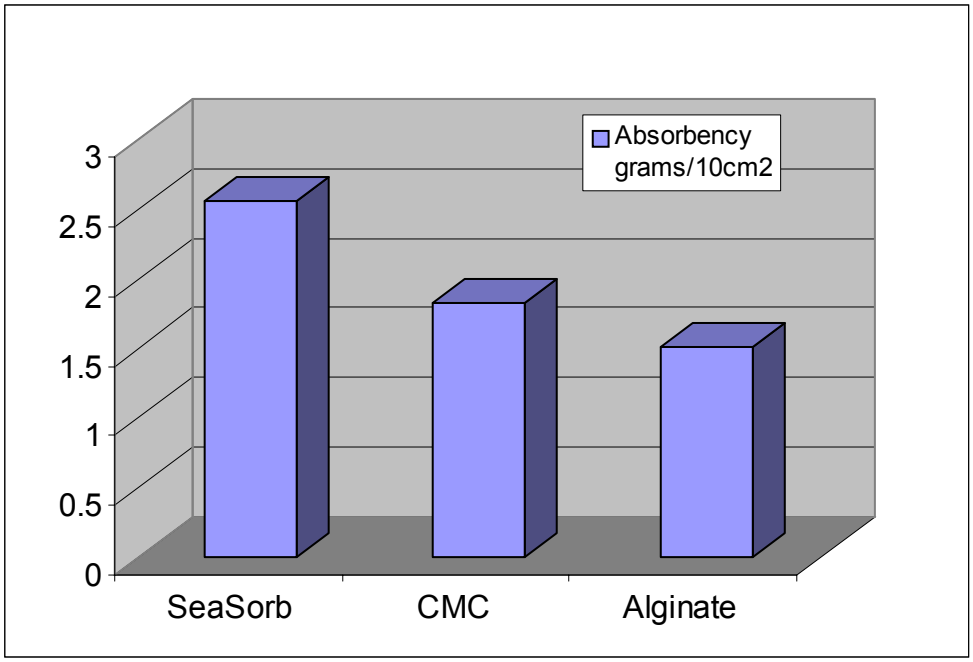
In this table the absorbency results have been expressed as g/10cm^2/24 hours to facilitate comparisons with the results of the hydrocolloid and foam products.

Table 7: Absorbency of alginate/cmc fibrous dressings

Dressing	Absorbency grams/10cm^2
SeaSorb Soft Dressing	2.57 (0.20)
Carboxymethylcellulose Dressing	1.83(0.13)
Alginate Dressing	1.51 (0.10)

Each result is the mean of 10 determinations and figures in brackets are Standard Deviations.

Figure 10: Absorbency of alginate/cmc fibrous dressings



Dispersion Characteristics/Wet Integrity

Test method

The dispersion characteristics/wet integrity of the dressing samples were examined using SMTL test method TM-112.which is based upon the recommendations contained within **BS EN 13726-2:2001.** *Test methods for primary wound dressings. Part 1: Aspects of Absorbency, Section 3.6, Dispersion characteristics,*

In this test a 5 x 5 cm sample of the dressing under test is placed into a 250 ml conical flask, to which is added 50 +/- 1ml of Solution A. The flask is gently swirled for 60 seconds without causing a vortex, and the integrity of the dressing is visually established. The dressing can then be categorised in accordance with the descriptions laid down in the standard.

Results

The results of the dispersion characteristics test are summarised in Table 8.

Table 8 Dispersion characteristics

Dressing	Dispersion/Non-dispersion
Seasorb Soft Dressing	No Dispersion
Carboxymethylcellulose Dressing	No Dispersion
Alginate Dressing	Dispersion

The results of the wet integrity/dispersion test indicate how the physical characteristics of a dressing will change when it interacts with wound fluid. Specifically it will determine whether it will form an amorphous gel or retain its original structure, factors which will have implications for the method of removal. Hence, a product with no dispersion will retain its original structure during removal and therefore be easier to remove.

Hydrogel dressings

Hydrogel dressings in various forms have been used in wound management for over 20 years. They are available in several forms, based upon a variety of different polymers. Some polymers are cross-linked to impart a degree of structural stability to the final product, which often takes the form of a thin sheet used for application to relatively shallow surface wounds. The absence of structural cross-links result in the formation of gels that have no defined structure, and these are more suitable for introduction into cavity wounds or sinuses. Originally conceived as alternatives to absorbent dressings in the treatment of chronic wounds such as leg ulcers, most amorphous hydrogels are now used to facilitate wound cleansing and promote autolytic debridement although some products are used for more specialized indications. The high moisture content maintains a desirable moist interface which facilitates cell migration and prevents dressing adherence.

The hydrogel dressings included in the present study are shown in Table 9.

Table 9: Hydrogel products tested

Manufacturer	Item	Batch/Lot No
Coloplast A/S	Purilon Gel	95749.71
Competitor C	Amorphous Gel	

Fluid affinity

The fluid affinity of a hydrogel dressing determines the way in which a product might be expected to influence the moisture content of a wound and the standard test investigates its ability to donate moisture to, or absorb liquid fluid from standard substrates.

A product that is capable of donating fluid will facilitate the rehydration of dry necrotic tissue or slough to promote autolytic debridement. A product that has a marked affinity for liquid will absorb excess wound exudate and liquefied tissue debris once autolytic debridement has taken place. A product that combines good absorption and moisture donating properties should therefore be suitable for the treatment of a wider range of wound types.

Test for fluid affinity

The fluid affinities of amorphous hydrogels were determined using the SMTL test method TM-238 based upon **BS EN 13726-1:2002** *Test methods for primary wound dressings. Part 1 Aspects of absorbency, Section 3.4,Fluid affinity of amorphous hydrogel wound dressings.*

In this method 10 +/- 0.1gram samples of the test material are placed onto the surface of a series of 10 +/- 0.1gram plugs of gelatine (20 and 35%) or agar (2 and 8%) contained within the barrel of 50/60ml syringes from which the closed (nozzle) ends have been removed to form smooth-sided cylinders. Once the test materials are in place, the open ends of the cylinders are sealed with an impermeable cover. For the purpose of this test both the gelatine and agar are made up with Solution A.

Following incubation of the sealed syringes for 48 hours +/-30minutes at 25 +/-2ºC the test material is gently removed from the plugs, which are then re-weighed. From these results the percentage change in weight of each hydrogel sample is calculated.

The standard only requires that the gel be tested upon 2% agar and 35% gelatine, but the additional substrates were included at the request of the client. A dressing that absorbs a large volume of fluid from 2% agar but does not donate significant amounts of fluid to 35% gelatine may be categorised as a 'Type 3a' hydrogel in accordance with Table 10 below. Conversely, a dressing that donates fluid well but is less able to absorb liquid could be categorised as a 'Type 1c' hydrogel.

Table 10: Classification of hydrogels by fluid affinity

Agar (absorption)		Gelatine (donation)	
Type	**% Increase in hydrogel weight**	**Type**	**% Decrease in hydrogel weight**
1	0-10	a	0-5
2	>10-20	b	>5-10
3	>20-30	c	>10-15
4	>30-40	d	>15-20
5	>40-50	e	>20-25

Results

The results of fluid affinity testing of the hydrogels included in this study are presented in Table 11 and Table 12 from which the gels are classified according to the system described previously. Based upon the test method BS EN 13726 and the definitions contained therein, Purilon Gel is classified as a Type 3c hydrogel and the competitor product is a Type 2b hydrogel.

Table 11: Fluid uptake by hydrogel dressings

Hydrogel	Agar concentration	Mean % increase in hydrogel weight
Purilon Gel	2%	21.90 (0.503)
	8%	3.66 (0.511)
Competitor C	2%	15.67 (0.884)
	8%	1.90 (0.100)

Table 12: Fluid donation by hydrogel dressings

Hydrogel	Gelatine concentration	Mean % decrease in hydrogel weight
Purilon Gel	20%	4.15 (0.727)
	35%	11.87 (0.390)
Competitor C	20%	0.07 (0.311)
	35%	7.00 (0.702)

(Data in brackets denotes standard deviations, only four samples were tested for 20% gelatine.)

Hydrogel Migration

Test Method

The migration of amorphous hydrogels were determined using the SMTL test method TM-384

The apparatus consists of a hinged stainless plate upon which is securely mounted an angle meter. Using a clamp stand, boss and clamp, the plate is held horizontally under the crosshead of a constant rate of traverse machine (Instron tensiometer), with one end able to swivel vertically at the hinge. The movable end of the plate is connected to the clamp in the movable crosshead, which allows the plate to move at a constant rate.

One ml of the hydrogel under examination is applied to a square box 10 mm x 10mm drawn on the plate, the hydrogel being applied to cover the area of the box in a uniform layer.

Using the attached angle meter, the plate is levelled and the Instron switched on with a constant rate of traverse of 50mm/min to allow the free end of the swivelling plate to move down under its own weight. A timer is started at the same time as the Instron is set in motion.

As the plate is allowed to move, the angle that the hydrogel starts to migrate is noted, and the plate is allowed to continue to move at the same speed until it reaches an angle of 90 degrees (ie. vertically straight down). The hydrogel is then observed as it migrates down the plate and the time is noted that it takes to reach a line drawn across the plate at a distance of 10mm from the lower edge of the box.

Should the hydrogel reach the line marked at 10mm from the starting point before the angle of the plate reaches 90 degrees, then the time and angle at which it reaches the line is recorded.

This information provides an indication of the viscosity/ cohesive properties of the gel, which, in clinical practice, will determine its ability to stay in place once applied to a wound.

Results

The results of the hydrogel adhesion/migration testing are presented in
Table 13. None of the test samples reached the 10 mm mark before the plate reached the 90-degree position.

Table 13: Adhesion/Migration of hydrogel dressings

Hydrogel Dressing	Run Number	10mm Migration time and inclination angle
Purilon Gel	1	20 min 40 s at 90º
	2	13 min 39 s at 90º
	3	8 min 0 s at 90º
	4	6 min 42 s at 90º
	5	6 min 44 s at 90º
Competitor C	1	4 min 15 s at 90º
	2	5 min 14 s at 90º
	3	4 min 24 s at 90º
	4	5 min 53 s at 90º
	5	4 min 44 s at 90º

The results show that both gels migrated slowly down the plate in the vertical plane, but the Purilon Gel due to its higher viscosity took a little longer to move 10 mm.

Foam dressings

Foam dressings are commonly produced from polyurethane and may be used alone or in combination with an integral backing layer to form a bacterial barrier.

Foam dressings are capable of absorbing significant volumes of exudate and therefore are sometimes regarded as the products of choice for moderate to heavily exuding wounds. As with hydrocolloid dressings, the fluid handling capacity of foam dressing is a function of its absorbency and moisture vapour permeability but unlike hydrocolloids there is usually no extended lag phase during which the product increases its permeability as the hydrocolloid adhesive layer becomes saturated with fluid. The foam products included in the study are shown in Table 14.

Table 14: Foam dressings included in study

Manufacturer	Item	Batch/ Lot No
Coloplast A/S	Biatain Non-Adhesive Dressing	95749.34, 95749.65
Coloplast A/S	Biatain Adhesive Dressing	95749.66
Competitor C	Adhesive foam dressing	
Competitor C	Non-adhesive foam dressing	
Competitor D	Adhesive bordered dressing	
Competitor D	Adhesive dressing	

Fluid Handling Properties

Test method

The fluid handling properties of the dressings were examined using the Paddington Cup technique previously described for the hydrocolloid dressings according to **BS EN 13726-1:2002** Part 1.

Fluid handling results

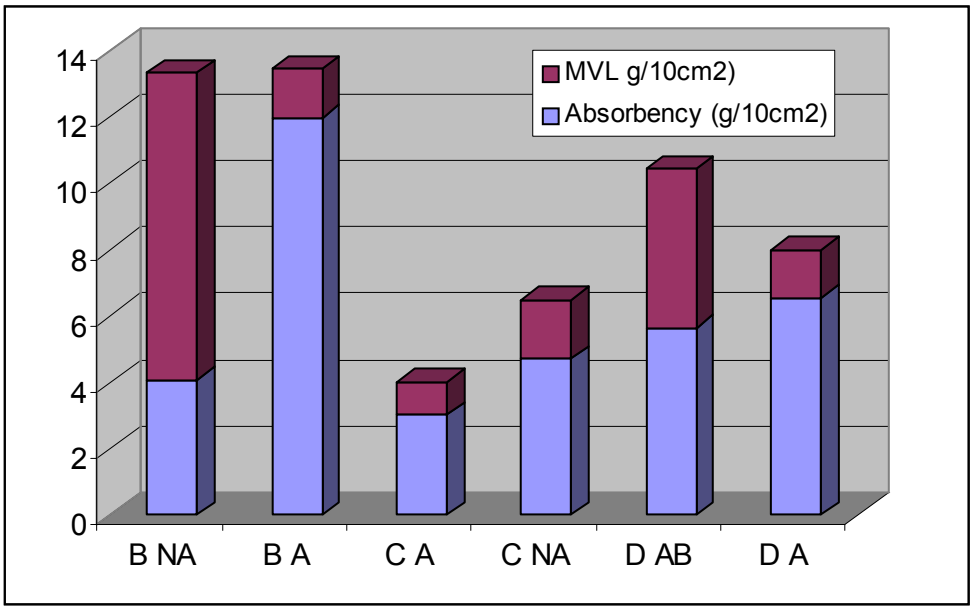
The results of the fluid handling tests are shown in Table 15 and summarised in Figure 11.

Table 15: Fluid handling properties of foam dressings

Dressing	Code	Moisture Vapour Loss g/10cm^2)	Absorbency (g/10cm^2)	Fluid Handling Capacity (g/10cm^2)
Biatain Non-Adhesive	B NA	9.27 (1.233)	4.06 (0.429)	13.33 (1.328)
Biatain Adhesive	B A	1.48 (0.146)	11.97 (0.162)	13.44 (0.274)
Competitor C Adhesive foam dressing	C A	0.98 (0.051)	3.03 (0.406)	4.01 (0.404)
Competitor C Non-adhesive foam dressing	C NA	1.80 (0.059)	4.70 (0.276)	6.51 (0.304)
Competitor D Adhesive bordered dressing	D AB	4.82 (0.241)	5.63 (0.223)	10.45 (0.371)
Competitor D Adhesive dressing	DA	1.44 (0.075)	6.56 (0.165)	7.99 (0.170)

The results are the mean of 5 determinations and figures in brackets denote standard deviations
As with the hydrocolloid dressings, in clinical practice absorption is important in terms of preventing leakage and maceration. The fluid handling capacity, the sum of absorbency and moisture vapour loss, influences not only prevention of maceration and leakage but also dressing change frequency and can therefore impact upon the total cost of care.

Figure 11: Fluid Handling Properties of Foam Dressings



Moisture Vapour Transmission Rate (MVTR)

Method

The moisture vapour permeability of the dressings was determined as previously described for the hydrocolloid dressings.

Results

Results from MVTR tests on foam dressings are presented in Table 16.

Table 16: Change in Balance Weight over 24 hours

Dressing	Maximum MVTR (g/10cm^2/24 hrs)		
	Run 1	Run 2	Run 3
Biatain Non-Adhesive	8.074	9.253	8.283
Biatain Adhesive	2.025	2.352	2.208
Competitor C Non-adhesive foam dressing	1.898	1.895	1.752
Competitor C Adhesive foam dressing	0.922	0.985	0.918
Competitor D Adhesive bordered dressing	4.174	6.101	4.571
Competitor D Adhesive dressing	1.706	1.657	1.656

Thickness and weight per unit area

Determination of weight per unit area

The length, width and weight of ten intact samples is determined and the individual and mean weight per unit area of the samples is calculated.

Results

The results of the determination of the weight per unit area are presented in Table 17.

Table 17: Weight per unit area

Dressing	Weight per unit area (g/m^2)
Biatain Non-Adhesive	677.06 (18.993)
Biatain Adhesive	705.82 (14.800)
Competitor C Adhesive foam dressing	549.30 (12.310)
Competitor C Non-adhesive foam dressing	765.52 (35.780)
Competitor D Adhesive bordered dressing	637.39 (16.82)
Competitor D Adhesive dressing	815.15 (11.553)

Each result is the mean of 10 determinations; figures in brackets denote standard deviations.

Determination of thickness

The thickness of the dressing was determined using SMTL test method TM-267.

In this test, the thickness of the dressing at 5 different locations is determined using a Wallace thickness gauge. A total of three dressings are examined and the mean thickness is reported.

Results

The results of the thickness testing are summarised in Table 18

Table 18: Thickness of dressings

Dressing	Mean thickness (mm)		
	sample 1	sample 2	sample 3
Biatain Non-Adhesive	4.3	4.3	4.3
Biatain Adhesive	3.6	3.5	3.3
Competitor C Non-adhesive foam dressing	6.1	6.4	6.2
Competitor C Adhesive foam dressing	4.0	4.1	4.0
Competitor D Adhesive bordered dressing	3.9	4.0	3.7
Competitor D Adhesive dressing	6.1	6.0	5.7

Each results represents the mean of 5 determinations

The results of these tests indicate that the total fluid handling capacity of the dressings is not directly related to the weight or thickness of the foam in the different dressings.

Discussion

The tests undertaken during the course of the current investigation have, in the main, been designed to address key issues relating to the ability of the various dressings to control the moisture content or state of hydration of a wound.

The Paddington Cup test, performed on both the hydrocolloid dressings and the foam products, provides useful data on the ability of the various dressings to absorb liquid and allow evaporation through the outer surface, although the relative importance of these two parameters varies from product to product.

When interpreting the fluid handling results previously quoted for the various products, it is important to remember that once a dressing has become saturated with fluid over perhaps a 24 hour period, its ability to take up additional exudate will be seriously impaired although the transmission of moisture vapour will continue at a relatively constant rate over several days which may prolong the effective life of the dressing.

Information on the volume of exudate produced by chronic wounds is limited, but one published study has suggested that venous leg ulcers typically produce up to about 0.5 ml/cm^2/24 hours[1] although values double this were recorded in some patients. A dressing sample applied to a Paddington Cup has an area of 10cm^2, which means that it would be required to absorb or otherwise cope with between 5-10 ml of fluid in the treatment of a heavily exuding wound.

The results of the present study confirm that, in general terms, the foam dressings have a substantially higher fluid handling capacity than the hydrocolloids, which makes them better suited for the treatment of exuding wounds such as leg ulcers and pressure ulcers. Somewhat surprisingly, the test results suggest that the fluid handling properties of the foam products examined were not directly proportional to the thickness of the dressing.

Although not a major factor in determining clinical acceptability, the thickness of a dressing can, in some circumstances, influence the conformability and therefore the clinical acceptability of the products concerned but it is also possible that thicker foam may provide enhanced padding or protection for some indications. The ability of a dressing to retain absorbed fluid under compression is also important, but this parameter was not requested during the current investigation because it is not part of the test method.

The results from the dynamic moisture vapour transmission test indicate that some hydrocolloids initially have limited permeability, which may make them better suited for application to lightly exuding wounds or dry necrotic tissue. In such situations the relatively impermeable nature of these products in the intact state prevents the additional loss of moisture from tissue that is already partially dehydrated and therefore helps to retain moisture and facilitate autolytic debridement

The fluid handling test on the alginate/cmc fibrous dressings also showed significant differences between the various products, ranging from 0.15 to 0.25 ml/cm^2/24 hours. These values are substantially lower than the volumes of exudate determined clinically, which indicates that these materials should not be regarded as dressings in their own right, but as wound contact layers that must be used with more absorbent secondary dressings.

The fluid affinity tests performed on the hydrogel dressings clearly identify differences in the way the dressings absorb fluid from agar, representing a moist wound, and donate fluid to a gelatine gel representing a dry wound or area of necrotic tissue.

The clinical significance of these observations has not been confirmed *in vivo* but in the absence of these data it is not unreasonable to assume these differences must have some clinical relevance. The finding that it is possible for a dressing to both effectively absorb and donate fluid according to the condition of the test substrate is of interest, and suggests that it might enable the material in question to be used upon a wider range of wound types than is normally the case with hydrogel dressings although this remains to be confirmed clinically.

The migration test was designed to examine the ability of a dressing to stay in place for a reasonable length of time. When applied to a patient with a leg ulcer, for example, it is useful if the dressing can resist the effects of gravity whilst the secondary dressing or retention system is being prepared or applied.

Conclusions

The results of this laboratory study clearly demonstrate that within each of the categories examined, although the dressings are similar in appearance, differences exist in the performance of the various products, which in some instances may have important clinical implications. Considerable variation exists in the ability of both the foams and hydrocolloids to absorb test solution or transmit moisture vapour, which may have important implications for the ability of the different products to cope with exudate production *in vivo*. As previously suggested, the introduction of a classification or grading system for these materials based upon their ability to cope with fluid production would provide potential users with useful information to facilitate the selection process. Such a classification system should also take account of the conformability and ease of use of the products concerned.

References

1. Thomas, S., et al., The effect of dressings on the production of exudate from venous leg ulcers. Wounds, 1996. 8(5): p. 145-149.

Date of report

Laboratory testing completed January 2004

Expanded report completed May 2005

Report authors

Dr Stephen Thomas Director,
Dr Gavin Hughes Technical Manager,
Paul Fram Laboratory Scientist,
Alex Hallett Laboratory Scientist

Surgical Materials Testing Laboratory,
Princess of Wales Hospital,
Bridgend,
S. Wales.
CF 31 1RQ