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Comparative evaluation of hydrocolloid dressings by means of water uptake and swelling force measurements ☆: I

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Abstract

Composite hydrocolloid dressings are used in medical practice for both skin and mucosal applications. The most important features in terms of dressing performance are adhesive interactions with either moist mucosal tissue or skin and the wear time. Both the strength and the duration of adhesion are influenced by the hydration of the patches and the consequent modification of their physical structure. The hydration process is also linked to the build up of an osmotic pressure inside the hydrocolloid phase which, under suitable conditions, leads to the development of a measurable swelling force. The swelling force development provides information on the modification of dressing structure and, in particular, how the patches disintegrate. Water uptake and swelling force measurements are used to characterise and compare different hydrocolloid dressings. Water uptake measurements were performed with a modified Enslin apparatus; it allows capillary water penetration from the adhesive surface of the patch, thus simulating in vivo conditions. Swelling force was measured by means of an apparatus previously described for measuring disintegrating force in pharmaceutical tablets. The apparatus was opportunely modified to carry out measurements on very thin samples. A correlation was found between the amont of water uptaken and the swelling force developed, which indicates that the two measurements provide complementary information on the patch performance.

Keywords: Hydrocolloid dressing; Hydration properties; Water uptake; Swelling force

1. Introduction

Unmedicated dressings are widely used in medical practice, for example, in surgical units, hospital first aid and dermatological treatments.

Composite hydrocolloid dressings, consisting of a dispersion of hydrophilic polymers (normally a mixture of gelatin, pectin and sodium carboxymethylcellulose) in a hydrophobic polymer matrix, have been proposed for the treatment of burns and ulcers (Weston-Davies, 1986; Sayag, 1988) and for wound healing (Alvarez, 1983; Falanga, 1988).

Other medical uses of such composite hydrocolloid dressings are as stomal skin barriers in

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ostomy (Hollingsbee and Timmins, 1990) and as mucoadhesive bandages for dental applications (Anders and Merkle, 1989; Ishida et al., 1992).

In occlusive dermatological therapy, hydrocolloid dressings are preferred to classic plastic films because of ease of application, conformability, resilience to water, lack of irritation due to their capability of absorbing transepidermal water loss and preventing maceration of the underlying skin (Martin and Marriott, 1989). At the same time, occlusion with hydrocolloid patches promotes the topical availability of applied corticosteroids at least to the same extent as a plastic film (Queen et al., 1988; Hollingsbee et al., 1991).

The most important features in terms of dressing performance are the hydration properties, but, depending on the type of usage, adhesive properties may also be relevant to ensure resilience.

Both these properties are believed to depend on the hydration properties of hydrocolloid dressings.

In particular, the amount of water at the tissue-patch interface controls the adhesive interaction. The more hydrophilic the patches are, the more aggressive they should be to moist mucosal tissues. At the same time, an excess of water uptake may promote disintegration and reduce wear time.

Given these premises, it is not surprising that a number of papers have dealt, on the one hand, with the relationships between hydrocolloid composition and hydration capacity (Ladenheim et al., 1991) and, on the other, with the dependence on hydration state of such physical characteristics as rheological properties (Ladenheim et al., 1990b), microscopic features and spectral profiles (Wille et al., 1991), which in turn are said to be relevant to the functionality of the patch.

Both in vitro and in vivo tests have been used for the evaluation of water uptake capacity.

Some in vitro tests determine the water vapour uptake by reweighing, at predetermined time intervals, preweighed patch samples, kept under controlled humidity conditions, over a time period lasting in the range of hours or even days (Queen et al., 1988). Moisture vapour permeability has also been measured using a method based on the use of a Paddington cup (Thomas and Loveless, 1991).

Other in vitro tests measure the liquid uptake either from a Bijou bottle (Queen et al., 1988) or from dressings sealed into bags and placed in a beaker containing test solution (Thomas and Loveless, 1992).

In vivo tests are also possible as long as there is an adequate experimental design (Queen et al., 1988; Ladenheim et al., 1990a, 1991). They should last at least as long as in vitro tests, due to the fact that the in vivo moisture uptake is even slower than in vitro water vapour uptake (Queen et al, 1988).

Although water vapour uptake tests provide very useful information on the modifications induced by water uptake in the physico-chemical characteristics of the patches, they may be cumbersome and impractical to be used either as functionally relevant tests in research and development or as routine control tests for assessing the reproducibility and stability of water uptake. On the other hand, the liquid uptake tests decribed in the literature do not allow for continuous measurements and therefore prevent evaluation of the kinetics of the water uptake process; moreover, they do not take into account the loss of hydrated materials into the hydrating fluid which can occur during measurement.

Given the constraints of the available methods, in the present paper we propose an alternative technique for carrying out hydration measurements on patches.

The method measures the capillary water (liquid) penetration into the patch from its free adhesive surface, thus simulating the in vivo conditions.

The apparatus is the one originally proposed (Van Kamp et al., 1986; Ferrari et al., 1988, 1991) for measuring water uptake of tablets and powders, which has been modified to perform long-lasting measurements on slowly absorbing materials. The water uptake of the patch is measured as the weight loss on a microbalance and recorded continuously as a function of time. This allows a kinetic as well as a quantitative evaluation of the water uptake process.

The hydration process is also linked to the

build up of an osmotic pressure inside the hydrocolloid phase which, under suitable conditions, leads to the development of a measurable swelling force. Therefore, force measurements were also performed on the examined patches, which could provide additional information on any modifications induced by water absorption, in particular, on the disintegration propensity of the patches.

The apparatus used is the one previously devised for disintegrating force measurements in pharmaceutical tablets (Caramella, 1990a,b), which has been opportunely modified to perform force measurements on the very thin patch samples. The force that develops inside the patch following hydration is measured by an extensimetric load cell and recorded as a function of time. This allows a kinetic as well as a quantitative evaluation of the force development process.

2. Materials and methods

2.1. Materials

10 different hydrophilic dressings intended for different applications, were considered in the study and are indicated by capital letters. All of them were supplied by ConvaTec Ltd, Bristol Myers Squibb Co., Deeside, U.K.

Samples A1–A5 are prototype dermatological formulations of Actiderm®; sample B (Urihesive®) is a penile adhesive for incontinence.

Samples F (Combihesive®), H1 and H2 (Stomahesive®, containing high and low surface area sodium carboxymethylcellulose, respectively) are for stomal use.

Sample G (Orahesive®) is intended for mucosal application.

2.2. Apparatus and methods

2.2.1. Water uptake measurements

The apparatus for water uptake measurements is represented schematically in Fig. 1.

It basically consists of a communicating-vessel system filled with water. One arm of the apparatus ends with a patch holder (A) on which the patch sample (B) is positioned with its adhesive surface downwards. The holder is an empty cylinder made of plexiglass, closed at the bottom by a sintered glass filter (C) of 20 mm diameter and a porosity value of 1 (pore size 100 μm). Another arm is immersed in a water-containing measuring vessel (E) and is fixed independently of it. The water container is placed on an L 429P microbalance (F) (Sartorius, Gottingen, Germany) and is covered with a lid. An additional lateral arm (D), which serves for water equilibration, is in communication with the other two arms.

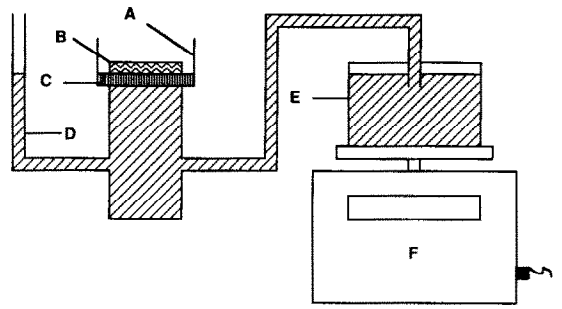

Fig. 1. Design of the apparatus for water uptake measurements. (A) Patch holder; (B) patch sample; (C) sintered glass filter; (D) lateral arm; (E) water container; (F) microbalance.

Moreover, as one of the problems in the case of measurements over extended periods is to prevent water loss due to evaporation, all the free water surfaces of the apparatus are covered with a film of liquid paraffin. The water level is adjusted so that the water in the measuring vessel is at the same level as in the upper part of the lateral arm and in the patch holder.

The amount of water taken up by the patch placed on the sintered glass filter is measured as the weight loss on the balance. The balance is connected to an IBM AT personal computer (IBM Italia, Milan, Italy) in order to record water uptake data during the experiment and to perform subsequent off-line analysis.

The patches are cut in order to obtain discs of a diameter almost identical to that of the glass filter, so that they almost completely cover the water-impregnated surface and minimise water loss due to evaporation; water uptake measurements typically last 7 h.

Since water loss due to evaporation cannot be completely eliminated, before each determination

a blank measurement is carried out under the same experimental conditions as for the patch sample, by placing a non-absorbing plastic disc of the same diameter as the patch on the glass filter. The weight loss due to evaporation is linear with time and is subtracted from the experimental data by the computer. The regression line (mean of four replicates) had a slope of 0.232 mg/min and an intercept of 0.833 mg ($R = 0.99$, $P < 0.01$).

Water uptake profiles were fitted according to a linear or a saturation (Weibull) model depending on the type of patches. Fitting was accomplished by means of a computer programme supported by an IBM personal computer (Siphar® Simed, Creteil, France).

In the case of a linear model, the water uptake rate is described by the line slope. When the Weibull equation is used, the most significant parameter is the time parameter (t_d), which represents the time needed to take up 63.2% of the maximum water amount. The derivative of the fitted curve is calculated at this particular time. This is an instantaneous water penetration rate (WPR) and is used for characterising the kinetics of the water uptake process.

2.2.2. Force measurements

A schematic drawing of the apparatus for swelling force measurements is given in Fig. 2.

It basically consists of a sample holder (C) (a cylindrical plexiglass cage with wide lateral openings) and a load cell (B). The holder has a threaded upper section and can be screwed up to a metallic support (A). A steel punch is fastened to the lower face of the load cell which in turn is bolted to the metallic frame. The metallic support is fixed horizontally to a vertical slide bar, by an arm, to allow vertical displacement.

The holder ends with a perforated plate (F) a few hundred microns thick with 2 mm diameter large holes in it. The plate is covered with a filter paper and is sealed to the lower end of the holder. The patch (E) is placed with its adhesive face turned downwards on the perforated plate. The patch is cut into discs of 15 mm diameter, the same diameter as the perforated plate, thus preventing radial expansion of the patch when it contacts water. A plastic disc (D) is placed between the patch and the measuring head of the load cell in order to ensure even contact and complete force transmission. This is accomplished by screwing up the holder to the load cell until a preload of about 100 g is attained; this value has been found to be the best compromise between the attainment of an even contact and the necessity of avoiding an excessive load on the patch, which could impair force development.

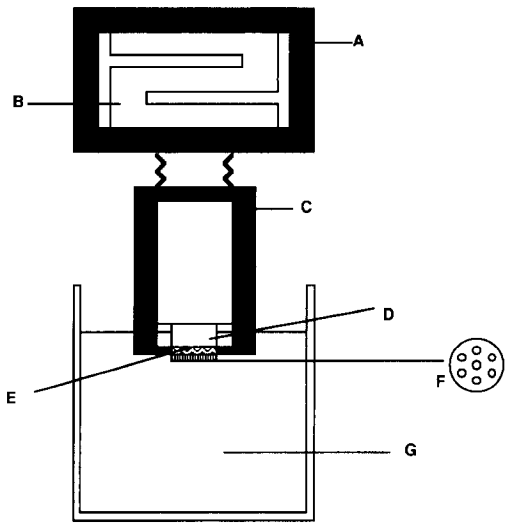

Fig. 2. Design of the apparatus for force measurements. (A) Metallic support; (B) load cell; (C) patch holder; (D) plastic disc; (E) patch sample; (F) perforated plate; (G) = water.

When the holder is lowered and submerged in water (G), water penetrates into the patch through the holes in the perforated plate. The force that builds up inside the patch is measured by the load cell. The load cell signal is amplified and transmitted to the computer's memory.

Typically, force experiments last 2–4 h and the entire force vs time curves are recorded and stored for subsequent off-line analysis. Force development profiles were fitted according to the Weibull function. In this case, the time parameter (t_d) represents the time needed to develop 63.2% of maximum force. The derivative of the fitted curve is calculated at this particular time. This represents an instantaneous force development rate (FDR) and is used for characterising the kinetics of the process.

3. Results and discussion

In Fig. 3 the water uptake profiles of all the patches examined are given. Water uptake is expressed as mg/cm^2 of area exposed to water supply.

Each profile is the mean of three replicates (C.V. < 5%). In Fig. 3a the so-called slow-absorber patches have been grouped. They take up relatively little water (typically far less then 100% of their initial weight by the end of a 7 h experiment) and belong to the category of dermatological patches.

In Fig. 3b the so-called fast-absorber patches have been grouped. They take up a much greater amount of water (up to 500% of the initial patch weight in the case of patch G) and belong to the category of mucosal or stomal patches.

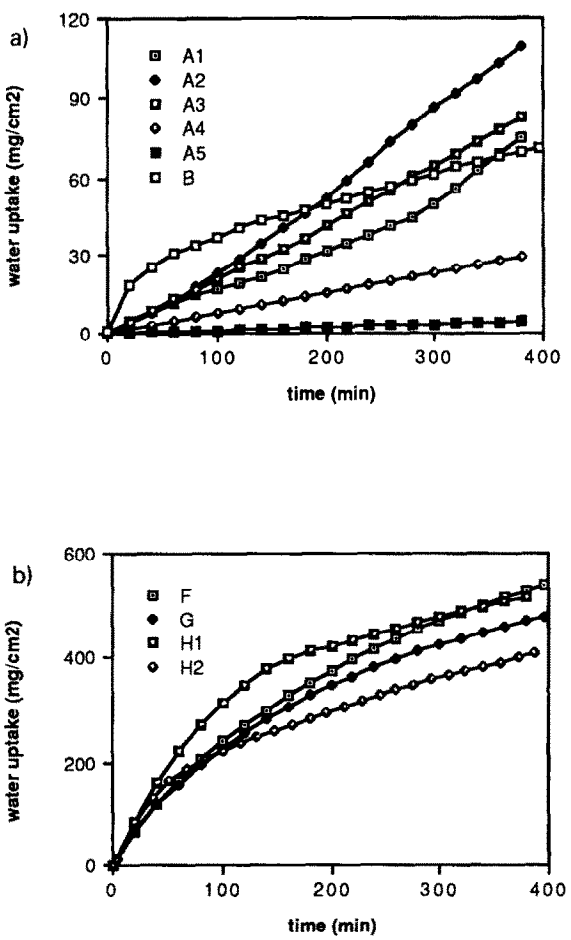

Fig. 3. Mean water uptake profiles: (a) slow-absorber patches; (b) fast-absorber patches.

The two sets of profiles (Fig. 3a and b) also differ as far as the type of kinetics is concerned. For most dermatological patches (except for type B) (Fig. 3a), the water uptake is linear with time and saturation is not reached by the end of the experiment.

For mucosal or stomal patches (Fig. 3b), the water uptake profiles, after a steeper initial phase, tend to level off and the hydration process is usually almost completed by the end of the experiment. In these cases, water uptake curves are fitted to the Weibull function.

The force development profiles of slow-absorber and fast-absorber patches are depicted in Fig. 4a and b, respectively. The forces developed are expressed as N/cm^2 of area exposed to the water supply. Each profile is the mean of three replicates (C.V. < 5%).

For all the patches examined, independently of the category, the force development curves show a saturation pattern. This is because the force development process tends to be completed by the time the patch sample is completely invaded by water.

This process, given the particular experimental conditions of the test, does not take more than 2–4 h.

In Table 1 the parameters obtained from the best fitting of the mean water uptake and force development curves are listed (C.V. of estimated parameters was always less than 7%). In particular, the maximum water uptake (Q_{max}), maximum force developed (F_{max}), instantaneous water penetration rate (WPR) and instantaneous force dvelopment rate (FDR) are given. The maximum water uptake at the end of the experiment (Q_{max}) is given only for those patches for which the water uptake process approached saturation. To take into account the fact that the patches are characterised by slightly differing thicknesses, the values are normalised per unit weight. The highest water uptake is demonstrated by the mucosal patch (G), followed by stomal (H1, H2) and dermatological (B) patches.

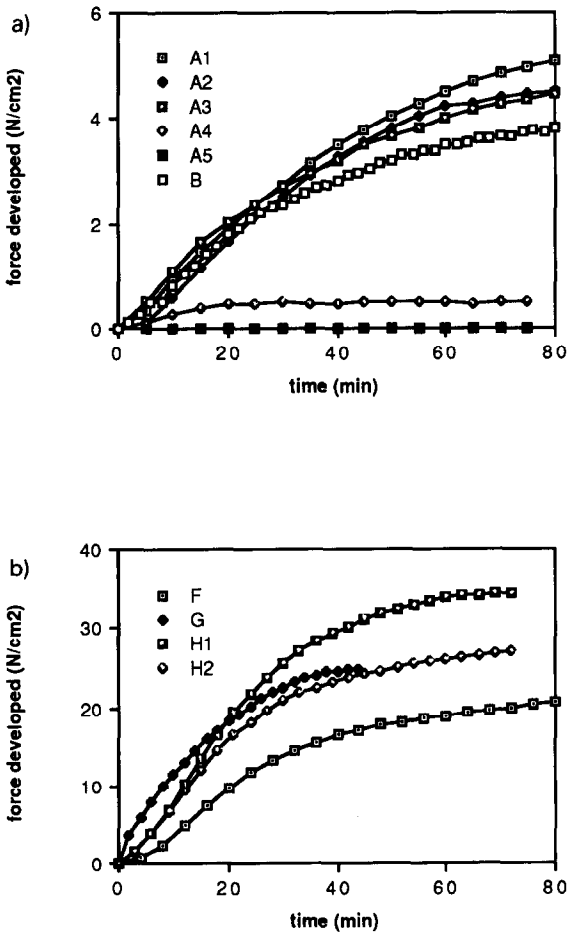

Fig. 4. Mean force development profiles: (a) slow-absorber patches; (b) fast-absorber patches.

The maximum force values (F_{max}) were also normalised per unit weight. They show the same rank order as that observed for maximum water uptake. A significant linear correlation is found between the maximum water uptake and the maximum force developed (Table 2), which indicates that the two types of measurements provide similar information on the patch performance.

The water avidity of mucosal or stomal patches is in line with their propensity to swell and disintegrate upon water absorption. This behaviour is confirmed by the capability of rapidly developing a high swelling force and is especially evident in the case of H1 and H2 types. Disintegration propensity may lead to a decrease in wear time and impair patch resilience.

Table 1
Parameters obtained from the best fitting of the mean water uptake and force development curves

Patch	Q_{max} (mg/mg)	F_{max} (N/mg)	WPR (mg/cm^2 per min)	FDR (N/cm^2 per min)
A1	[a]	0.064 [c]	0.17 [b]	0.08 [c]
A2	[a]	0.045 [c]	0.28 [b]	0.08 [c]
A3	[a]	0.045 [c]	0.21 [b]	0.06 [c]
A4	[a]	0.006 [c]	0.08 [b]	0.02 [c]
A5	[a]	0.001 [c]	0.01 [b]	0.001 [c]
B	0.64 [c]	0.031 [c]	0.16 [c]	0.06 [c]
F	2.54 [c]	0.089 [c]	1.30 [c]	0.46 [c]
G	5.12 [c]	0.232 [c]	1.28 [c]	0.71 [c]
H1	2.37 [c]	0.139 [c]	1.67 [c]	0.76 [c]
H2	1.90 [c]	0.110 [c]	0.98 [c]	0.56 [c]

[a] Not calculated because the patches do not reach saturation. Fitting according to linear [b] or Weibull [c] model.

The rate of water penetration (WPR) is more pronounced for the mucosal and stomal patches than for the dermatological ones. Similarly to water uptake, the rate of force development (FDR) is more pronounced for the mucosal and stomal patches than for dermatological ones.

However, a significant linear correlation is found between water penetration rate and force development rate only when the slow-absorber patches are considered, whereas no significant correlation is obtained for the fast-absorber patches (Table 2). This means that a high rate of water penetration does not necessarily correspond to a high rate of force development. In fact, even though the qualitative composition of

Table 2
Linear regression analysis between the parameters obtained from the best fitting of the mean water uptake and force development curves

Parameters	Regression equation	R	n
F_{max} vs Q_{max}	$y = 0.012 + 0.043x$	0.95 [a]	5
FDR vs WDR (slow-absorber patches)	$y = 0.0024 + 0.3114x$	0.94 [a]	6
FDR vs WDR (fast-absorber patches)	$y = 0.2451 + 0.2887x$	0.59 [b]	4

[a] Statistically significant ($P < 0.01$).
[b] Not significant.

the patches, as far as the hydrocolloid phase is concerned, is similar, slight changes in the amount of hydrocolloids as well as in the hydrophobic matrix may render the patch more or less capable of transmitting and exerting a force.

4. Conclusions

Patches having similar composition but intended for different applications are characterised by different hydration properties.

The dermatological patches absorb relatively little water according to linear kinetics and over a long time.

The patches for stomal or mucosal application, besides taking up more water and more rapidly, show hydration kinetics which tends to reach saturation by the end of the experiment.

Patches are also characterised by different swelling force development. In particular, the affinity of stomal patches for water, accompanied by much higher rates of force development, is in line with their propensity to lose integrity and eventually disintegrate with excessive water uptake.

While water uptake and force development tests provide useful information as the amount of water taken up and the amount of force developed, they do not always allow an understanding of the kinetics of the two processes. This can be explained by two facts: the different composition of the patches and the different experimental conditions in which the two measurements are carried out. In fact, whereas the water uptake test is a three-dimensional experiment, since the patch is free to expand in all directions, the force development test might be considered a mono-dimensional experiment, because the patch is penetrated by water unidirectionally and is prevented from expanding in the radial direction.

Considering these factors, it was worthwhile to combine both measurement techniques into one apparatus in order to enable us to carry out the two measurements simultaneously. Investigations are continuing on this aspect.

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