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

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Abstract

Hydrocolloid dressings are composite systems made of a hydrophobic matrix and a hydrophilic phase, which renders them capable of absorbing water. In a previous paper, water uptake and swelling force measurements, carried out in separate experiments were used to characterise and compare different hydrocolloid dressings. In particular, swelling force measurements provide information on the modifications induced by water absorption, which influence the in vivo performance of patches. In the present work, simultaneous measurements of water uptake and swelling force were carried out on some hydrocolloid dressings in order to achieve a better understanding of the relationship between the two phenomena. A computer-aided apparatus, which is a combination of the two apparatus formerly described for separate water uptake and swelling force measurements, was set up. A parameter referred to as the 'force equivalent', which represents the capability of the patch of transforming water uptake into swelling force, was used for characterising the various patches. This parameter is suitable to differentiate between patches characterised by similar composition but different hydration and swelling propensity. The patches examined in the present work could be divided into two groups, depending on their greater or lesser capability of transforming water uptake into swelling force. The time course of the derivative of the swelling force vs water uptake curve allowed a further differentiation between and within groups. It is envisaged that both the force equivalent value and the rate of attainment of force equivalent are related to adhesion performance.

Keywords: Hydrocolloid dressing; Hydration properties; Simultaneous water uptake-swelling force measurements

1. Introduction

Hydrocolloid dressings are composite systems made of a hydrophobic matrix (whose composition is pretty much the same: rubber and tackifiers) and a hydrophilic phase (consisting of one or a mixture of hydrocolloids, pectin, gelatin and sodium carboxymethylcellulose). Other additives may also be present, depending on the intended applications: dermatological (for skin disorders, treatment of burns and ulcers, wound care), stomal (skin barriers in ostomy) and mucosal (i.e.,

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dental application) (Hollingsbee and Timmins, 1990).

Due to the presence of a hydrophilic phase, hydrocolloid dressings possess the capability of absorbing water and becoming hydrated upon contact with an aqueous medium (Queen et al., 1988; Ladenheim et al., 1991; Thomas and Loveless, 1991, 1992; Edwardson et al., 1993).

The hydration process results in a swelling phenomenon, which leads to the building up of an osmotic pressure inside the patch; this in turn is measurable as a force (Ferrari et al., 1994). It is suggested that swelling force measurements provide information on the modifications induced by water absorption, in particular on the disintegration propensity of the patches. These modifications influence the in vivo performance of patches.

In a previous work (Ferrari et al., 1994) measurements of water uptake and swelling force development during hydration were carried out on two types of hydrocolloid dressings, which, on the basis of their hydration propensity, were classified as 'slow absorber' and 'fast absorber' patches. Whereas for the slow absorber patches, mainly intended for dermatological use, a significant correlation was found between water uptake and force development rates, in the case of fast absorber patches no more than a rank-order correlation could be found between the kinetics of the two processes.

This could be explained by the fact that the two measurements were carried out in separate experiments and therefore under different experimental conditions. In fact, force measurement should be considered as a monodimensional experiment, since a patch is penetrated by water unidirectionally and is prevented from expanding in the radial direction, whereas water uptake measurement should be regarded as a three-dimensional experiment as the patch is free to expand in all directions.

Given these considerations, the next logical step was to measure water uptake and swelling force in the same experiment (simultaneous measurements).

In the present work, in order to achieve a better understanding of the relationship between the two processes, simultaneous measurements of water uptake and swelling force were carried out on some hydrocolloid dressings belonging to the category of fast absorber patches.

A computer-aided apparatus was set up for this purpose (Caramella, 1990).

Water uptake and swelling force vs time curves, simultaneously collected, were fitted according to the same mathematical model (Weibull function). This enabled us to calculate kinetic parameters, in particular the rates of water penetration and force development. These parameters were compared with those previously obtained (Ronchi et al., 1992; Ferrari et al., 1994) on the same patches in separate experiments.

Swelling force vs water uptake curves were also fitted according to the Weibull distribution function. The derivative of the curves was then calculated at each point of the curve and plotted vs time. A parameter, named force equivalent, which represents the maximum value of this derivative, was used for characterising the various dressings. The time course of the derivative was used to differentiate further between patches having similar force equivalent values.

2. Materials and methods

2.1. Materials

Six commercial patches of similar composition but intended for different applications were considered in the study, as set out below.

Sample D (Hollister®, Hollister Ltd, Ballina, Ireland) is for dermatological use; sample E (Biotrol®, Clinimed Ltd, Bucks, UK) is an ostomy product; samples F (Combihesive®), H1 and H2 (Stomahesive®, containing high and low surface area sodium carboxymethylcellulose, respectively) are for stomal use; and sample G (Orahesive®) is for mucosal application. These four samples were supplied by ConvaTec Ltd, Bristol Myers Squibb Co., Deeside, UK.

2.2. Methods

The apparatus employed for simultaneous measurements of water uptake and force devel-

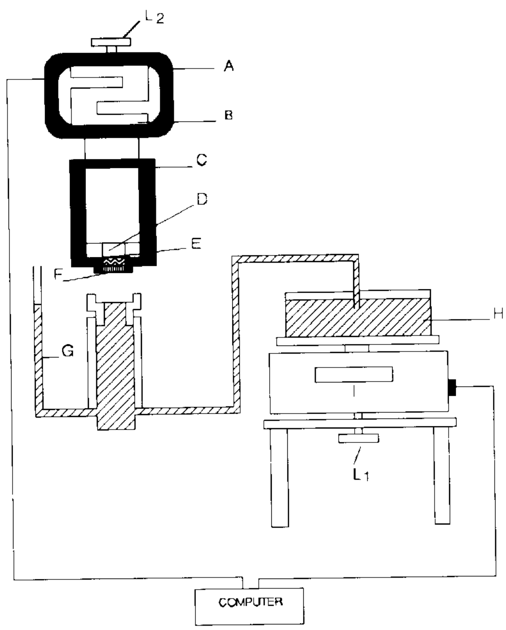

Fig. 1. Design of the apparatus for simultaneous measurements of water uptake and force development: A, metallic support; B, load cell; C, patch holder; D, plastic disc; E, patch sample; F, perforated plate; G, lateral arm; H, water container; I, microbalance; L1, L2, micrometric devices.

opment is represented schematically in Fig. 1 (Caramella, 1990).

The apparatus is comprised of a combination of the two apparatus formerly described for separate water uptake and swelling force measurements: a modified Enslin apparatus and a load cell device, respectively.

At the beginning of the experiment the patch sample (E) is placed in the patch holder (C) with the adhesive face in contact with the perforated plate (F). A plastic disc (D) is placed between the patch and the measuring head of the load cell (B), in order to ensure even contact and complete force transmission.

Some modifications were required in order to assemble the modified Enslin apparatus (shaded area in Fig. 1) to the load cell. In particular, a micrometric device (L2) allows the lowering of the patch holder to fit the upper part of the central arm of the Enslin apparatus.

During this operation the water level is kept just below the perforated plate. Then the water level is raised gently by means of another micrometric device (L1) placed under the microbalance (I).

As soon as the water contacts the patch sample, data collection of both water uptake (measured as weight loss of the container (H) placed on the microbalance) and force development (measured by the load cell) is triggered off by the computer.

Experiments were performed in three replicates for each dressing examined.

Water uptake and swelling force vs time curves were fitted by means of a software package (Siphar®, Simed, Créteil, France) to an exponential model (Weibull equation) using a non-linear regression procedure. The derivatives of the curves at the centre of the Weibull distribution (corresponding to 63.2% of the maximum value) were calculated. These parameters represent an instantaneous water penetration rate (WPR) and an instantaneous force development rate (FDR), respectively. Both rates were normalised per unit surface area exposed to water supply (2.01 cm^2) and are expressed as mg/cm^2 per min and N/cm^2 per min, respectively.

The derivative of swelling force vs water uptake curve (fitted according to the Weibull function) was also calculated at each point and plotted vs time. The maximum value of such a derivative was named force equivalent (Caramella, 1990) and expressed as $N/mg/cm^2$.

3. Results and discussion

Fig. 2 demonstrates the relationship between the values of water penetration rate (WPR) obtained in separate and simultaneous experiments.

In Fig. 3 the same relationship obtained for force development rates (FDR) is given.

A significant correlation is obtained both between water penetration rates and force development rates. We can assume that simultaneous measurements provide information, on water uptake and force development processes, which are consistent with those obtained in separate measurements.

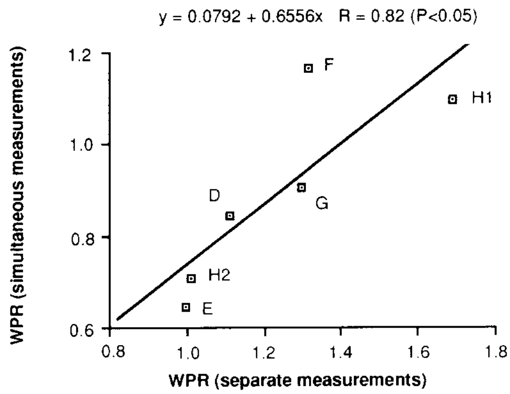

Fig. 2. Relationship between water penetration rates (WPR) obtained in separate and simultaneous water uptake and swelling force measurements (mean values, $n = 3$, C.V. $< 5\%$).

The correlation coefficient is greater for FDRs than for WPRs; this can be explained by the fact that the experimental conditions in which swelling force measurements are effected are quite similar in separate and simultaneous experiments, whereas those of water uptake measurements are quite different in the two cases.

Fig. 4a–c illustrates an example (patch type F) of profiles obtained from simultaneous water-force measurements. The water uptake vs time curve (Fig. 4a) does not reach saturation and, after an initial steeper portion, shows a slowly increasing linear pattern: this behaviour can be explained by a partial dissolution of hydrocolloids

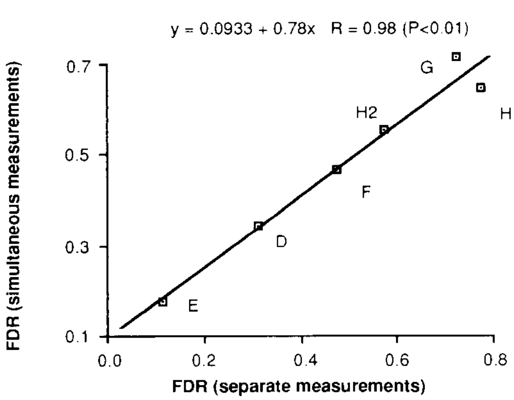

Fig. 3. Relationship between force development rates (WPR) obtained in separate and simultaneous water uptake and swelling force measurements (mean values, $n = 3$, C.V. $< 5\%$).

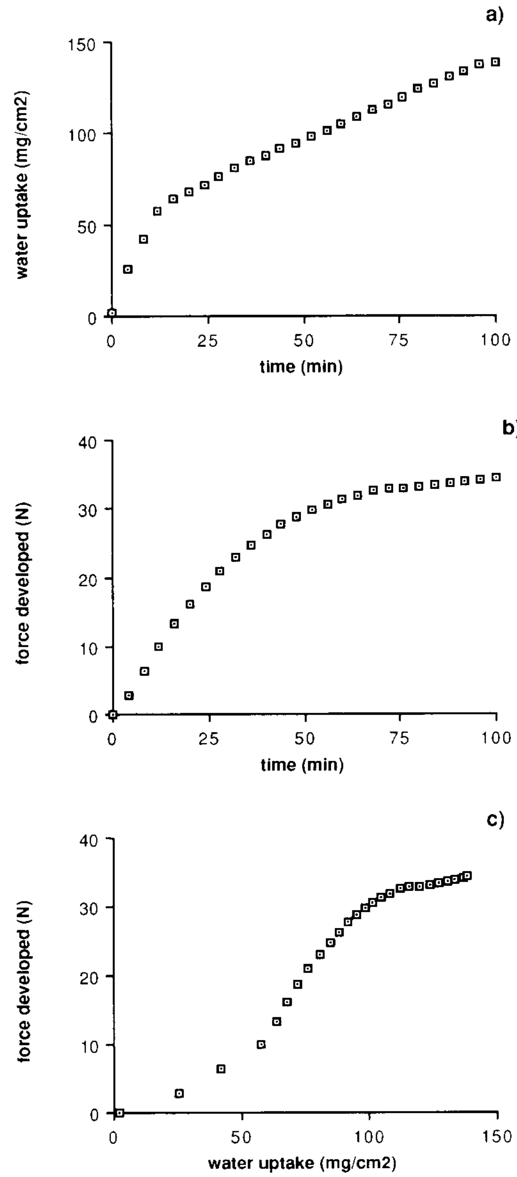

Fig. 4. Typical profiles obtained from simultaneous water uptake and swelling force measurements: (a) water uptake vs time; (b) force developed vs time; (c) force developed vs water uptake (mean curves, $n = 3$, C.V. $< 3\%$).

by the end of the experiment. On the other hand, the force developed vs time curve (Fig. 4b) shows a saturation pattern.

The force developed vs water uptake curve (Fig. 4c) is characterised by a sigmoidal shape. This means that, at the beginning of the experiment, water is taken up by the patch without producing force and the slope of the curve is very low. Subsequently, the force increases faster with increasing water uptake, which corresponds to an increase in slope and to an almost linear relationship between water uptake and force development. At the end of the experiment, when the phenomenon of force development is almost finished, a certain amount of water is still taken up; this corresponds to a reduction of the slope value.

Similar results were obtained for all the patches examined.

In Table 1 the mean WPR and FDR values obtained for all the patches examined are listed together with mean force equivalent values. No correlation was found ($R = 0.37$, $n = 6$) between the WPR and FDR values. In a previous work (Ferrari et al., 1994) the lack of such a correlation was attributed to the fact that water uptake and force development were performed under different experimental conditions.

The lack of correlation between the kinetics of the processes, which is confirmed by simultaneous measurements, provides evidence of the fact that, during water uptake, part of the developing force is lost because of the disintegration/dissolution of the sample. This is in line with visual inspection of the patches that showed, at the end of the simultaneous water uptake-swelling force experiment, loss of integrity of the hydrated components. However, the amount of force lost due to dissolution also depends on the composition of the hydrophobic phase of the patches. This further justifies the lack of correlation between water penetration and swelling force rate.

Table 1
Parameters obtained from simultaneous measurements of water uptake and force development (mean ± SE, $n = 3$)

Patch	WPR (mg/cm^2 per min)	FDR (N/cm^2 per min)	Force equivalent (N/mg per cm^2)
D	0.83	0.33	0.55 [a]
	(0.025)	(0.010)	(0.028)
E	0.69	0.16	0.47 [a]
	(0.021)	(0.006)	(0.039)
F	1.15	0.45	0.56 [a]
	(0.035)	(0.014)	(0.044)
G	0.89	0.70	0.92 [b]
	(0.024)	(0.022)	(0.026)
H1	1.08	0.63	0.93 [b]
	(0.030)	(0.018)	(0.031)
H2	0.63	0.54	0.99 [b]
	(0.019)	(0.020)	(0.029)

$P < 0.05$, Kruskall-Wallis test a vs b.

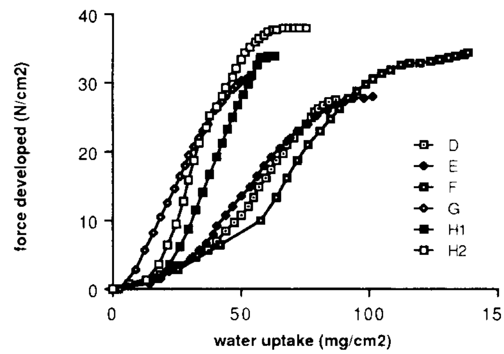

Fig. 5. Mean swelling force vs water uptake curves of all the patches examined ($n = 3$, C.V. < 3%).

In Fig. 5 mean swelling force vs water uptake curves of all the patches examined are depicted. The curves can be divided into two groups, depending on the capability of the sample of transforming water uptake into swelling force: the patches of the first group (D, E, F) develop swelling force less efficiently than those of the second group (G, H1, H2).

These differences are reflected by the different force equivalent values (Table 1). Statistical analysis of variance (Kruskall-Wallis non-parametric test) proved that, whereas no significant difference exists between patches belonging to the same group, a significant difference is observed between samples belonging to the first group (D, E, F) and those belonging to the second (G, H1, H2).

The high force equivalent observed for patches G, H1 and H2 is in line with their functionality and intended use. In fact, it is expected that patches for mucosal or stomal application (G, H1, H2) will be more aggressive to skin or mucosa than those intended for dermatological use. However, samples E and F, despite the fact that they are intended for stomal use, present force equivalent values similar to that of the dermatological type D.

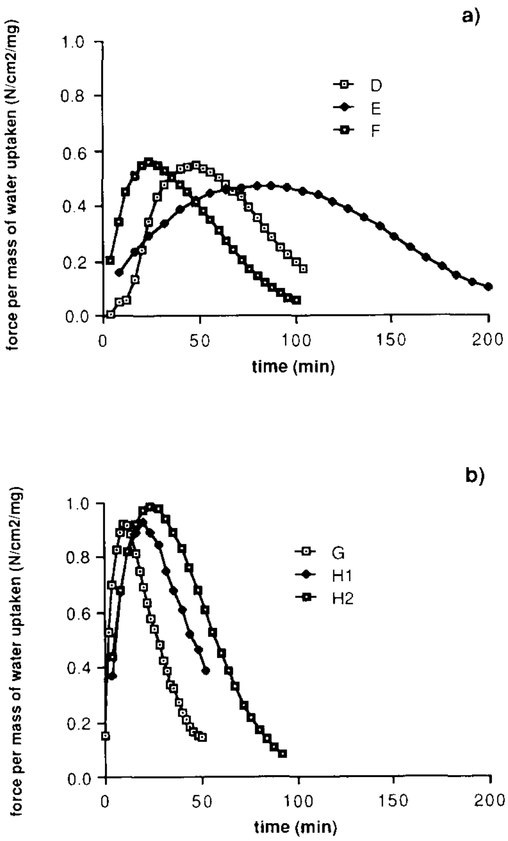

Fig. 6. Time course of the first derivative of swelling force vs water uptake curves (mean values, $n = 3$, C.V. $< 5\%$).

The time courses of the derivative of force-water curves of patches (shown in Fig. 6a and b) allow further differentiation between and within the two groups.

It is observed that the maximum value (corresponding to force equivalent) occurs more rapidly for the patches of the second group than for those of the first. Since the rate of the phenomenon is also relevant to the adhesion properties, this result is indicative of greater adhesive performance for the second group.

Moreover, the time courses of the derivative of force vs water curves allow differentiation within each group. In particular, within the first group (Fig. 6a) sample F reaches the maximum value much more rapidly than sample E. It is expected, therefore, that sample F will be more aggressive to the skin than sample E, which would suggest a different choice between the two samples depending on the therapeutic needs.

Patch type D behaves very similarly to sample F, thus suggesting that it has a considerable ability to adhere rapidly to the skin.

Within the second group (Fig. 6b) the mucosal patch (G) reaches the maximum value more rapidly than the two stomal patches (H1, H2). This behaviour is particularly favourable, taking into account that patch G is intended for dental application, i.e., for an application site which is particularly subjected to multiple stresses. In this case, the fast attainment of optimal efficiency can prevent the removal of the dressing.

4. Conclusions

The force equivalent parameter is suitable to differentiate between patches characterised by similar composition but different hydration and swelling propensity. The patches examined in the present work could be divided into two groups, depending on their greater or lesser capability of transforming water uptake into swelling force.

The time course of the derivative of the swelling force vs water uptake curve allowed a further differentiation between and within groups.

It is envisaged that both the force equivalent value and the rate of attainment of force equivalent, are related to adhesion performance. This will be confirmed by adhesion tests.

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