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Quality of wound dressings: a first step in establishing shared criteria and objective procedures to evaluate their performance

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Quality of wound dressings: a first step in establishing shared criteria and objective procedures to evaluate their performance

Objective: There are no well-defined criteria for assessing the efficacy and quality of wound dressings, and evaluation is often simplistic and based on the subjective opinion of the health-care professional. The aim of this study was to identify specific parameters suitable for measuring dressings' performance, and to recommend laboratory tests able to evaluate these specific criteria in an objective manner.

Method: After reviewing all tests currently used in Italy and examining the criteria for evaluating the quality of dressings, the authors selected 12 clinically significant parameters. These parameters were measured using standard and non-standard tests, and in some cases, these tests were modified and improved to simulate real-life conditions more accurately.

Results: Most of the tests used were able to discriminate well between dressings belonging to different brands, with some tests being more suitable than others for the assessment of specific dressings.

Conclusion: These results highlighted some issues in the standard testing procedures, such as the need of a suitable fluid that mimics the real exudate, and the importance of standard temperature and humidity conditions during testing. Our study paves the way for a larger project aimed at a systematic evaluation of dressing quality able to assess every wound dressing on the market.

Declaration of interest: The authors have no conflict of interest to declare.

wound dressing • test model • performance • in vitro • wound exudate

To obtain maximum performance from dressings under various clinical conditions, suitable parameters to assess the dressing quality need to be identified. To date, there are few standardised tests available for assessing the quality and performance of dressings in an objective and non-operator dependent way; moreover, there are no well-defined criteria for assessing the efficacy and quality of wound dressings. The identification of objective parameters is particularly urgent in countries (for example Italy) where the National Health Service does not reimburse wound dressings. The non-reimbursement leads to sole use of dressings that are included in the contract governing tenders, limiting the options of professionals treating patients with wounds. The criteria used for the selection of such products are often simplistic and involve a subjective judgment by the selection boards.

The main objective for wound management is to eliminate all factor that prevent healing from the wound-bed, and to develop and maintain conditions that aid healing. For over 10 years in the international literature these procedures have borne the acronym TIME. The wound dressing is one of the tools used to create tissue repair conditions in chronic wounds, and the wrong dressing can affect the healing progress and/or determine the clinical deterioration of the wound. Choosing the most suitable dressing is therefore of fundamental importance.[1]

Wound dressings are currently classified according to their trade name. In 2006 Van Rijswijk[2] and later in 2011 Cutting[3] urged review this classification by categorising dressings by their clinical objectives, and therefore, by their function helping health-care professionals choose the appropriate dressing. In an attempt to fill this void the Italian Association for Cutaneous Ulcers (AIUC) has proposed to classify dressings by function into four categories:[4]

- Dressings favouring autolysis and debridement
- Dressings favouring granulation
- Antimicrobial dressings
- Eudermic re-epithelialisation dressings.

Often the dressing choice is based on the ability to manage exudate, however, it needs to take into account other important functions in the healing process, such as debridement, bio-interaction, infection control, and protection of periwound area. This classification allows the identification of dressings beyond their primary function and includes functions which are apparent only for high-quality technology dressings.

In a comparative study, Thomas[5] showed that similar dressings submitted to the same tests performed very differently from each other; further differences in

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Table 1. Parameters evaluated and the respective categories of dressings which were examined

Parameter evaluated	Category of dressing examined
Fluid handling capacity (FHC)	Waterproof foams, hydrocolloids
Free swell absorptive capacity	Waterproof and non-waterproof foams, alginate dressings, chemically modified cellulose fibres (CMC carboxymethyl cellulose fibres and other fibres alike CMC), hydrocolloids
Moisture vapour transmission rate (MVTR)	Non-waterproof foams
Retention under pressure	Waterproof and non-waterproof foams, alginate dressings, hydrocolloids, chemically modified cellulose fibres
Volumetric strain	Waterproof and non-waterproof foams, alginate dressings, hydrocolloids, chemically modified cellulose fibres
Lateral and vertical spread	Polyurethane foams
Dispersion characteristics	Polyurethane foams, alginate dressings and chemically modified cellulose fibres
Waterproofness	Waterproof foams, hydrocolloids
Resilience	Polyurethane foams
Viscosity	Hydrogels
Hydration capacity	Hydrogels

performance were also observed when the dressings were under elastic compression.[6]

The objective of this study was to identify the functional parameters of the main categories of dressing and propose specific analysis tests that can evaluate them scientifically rather than in an operator-dependent manner.

Materials and methods

The clinically relevant parameters of wound dressings listed in Table 1 were evaluated according to the commercial classification of the dressings, functional classification of the dressings, and British standard evaluation criteria. For each category of dressing, the parameters corresponding to its primary function were identified, and the possible tests to measure those parameters were evaluated.

The dressings listed in Table 2 were tested at the University of Florence, Department of Chemistry. Tests were repeated at least three times, and results were analysed for statistical significance by the Student's t-test using GraphPad Prism (GraphPad Software, Inc., San Diego, CA, US).

Table 2. Dressings currently on the market included in the study

Category of dressing	Product	Manufacturer
Polyurethane foam	Biatain non-adhesive	Coloplast Ltd
	Allevyn non-adhesive	Smith & Nephew GmbH
	Farmactive schiuma PU	Farmac-Zabban Spa
	Kendall	Covidien Ltd
	Momosan bianco	Moltoplast GmbH
Alginate	Biatain Alginate	Coloplast Ltd
	Algisite M	Smith & Nephew GmbH
	Farmactive Alginato	Farmac-Zabban Spa
	Askina Sorb	B. Braun Melsungen AG
	Kaltostat	ConvaTec Inc
Chemically modified cellulose fibres	Aquacel	ConvaTec Inc
	DURAFIBER	Smith & Nephew GmbH
Hydrocolloid	Comfeel Plus	Coloplast Ltd
	NU-DERM	Systagenix Ltd
	DuoDERM CGF	ConvaTec Inc
Hydrogel	Purilon Gel	Coloplast Ltd
	DuoDERM hydrogel	ConvaTec Inc
	Askina Gel	B. Braun Melsungen AG
	NU-GEL	Systagenix Ltd

Fluid handling capacity

The fluid handling capacity (FHC) is given by the sum of the absorbency and moisture vapour transmission rate (MVTR), and is indicative of the ability of the dressings to manage exudate. The evaporation of a part of the aqueous component of exudate increases the absorbency and FHC of the dressing. Good exudate management reduces the frequency of dressings' changes thus avoiding interruption of the wound healing process and controlling the overall cost of treatment.

This parameter was assessed by standard test BS EN 13726-1.[7] FHC of polyurethane-based dressings and hydrocolloids was measured by a Plexiglas device (Paddington cup) which had the characteristics required by the standard. To contain the bulge towards the outside of the dressing and simulate real-life situation as faithfully as possible, a change was made to the standard in a way that a wire gauze of stainless steel (mesh 1.50 x 1.50mm) was inserted between the outer surface of the dressing and the upper flange of the Plexiglas device.

Unless otherwise specified, the test was performed at temperature (T) 37±1°C and relative humidity (RH) <20%, using the artificial exudate test solution A (containing 142mmol/l Na^+ and 2.5mmol/l Ca^{2+}) for 24 hours. To assess the effect of this artificial exudate on FHC, the test was repeated using deionised water, Gelofusine (B. Braun, Milano), whole UHT milk (Mukki, Italy), and horse blood PlasmaLife (Il Ceppo, Italy). To evaluate the influence of temperature and relative humidity on FHC, the test was also performed at T 23±2 °C and RH of 50±5%, maintaining test solution A at 37°C for 24 hours.

Absorptive capacity (free swell test)

This parameter was assessed by standard test BS EN 13726-1[7] with the following changes:

- The test was performed on the entire dressing to prevent a modification of the original sample from affecting performance in a noncontrollable way
- To reach saturation the test was extended to 24 hours for the evaluation of polyurethane foam and hydrocolloid dressings
- A Plexiglas tablet (40g) was positioned on top of the foam dressing to avoid distortion and possible reduction of the contact surface with test solution A

- Dripping time was prolonged from 30 seconds to 2 minutes to remove the excess liquid from the dressing.

Retention under pressure

This parameter is crucial for the quality assessment of absorbent dressings. The greater the retention ability of a dressing is, the lower the amount of potentially harmful exudate release around the edge of the wound and surrounding skin would be.

Since there is no standard test for this parameter, we suggest a variation of the method proposed by Foster[8] with the difference that the test was performed on the entire dressing, and the dressing was subject to pressure for a longer period of time (30 minutes as oppose to 1 minute).

In short, after carrying out the free swell test (30 minutes for alginates and chemically modified cellulose fibres, and 24 hours for hydrocolloids and foams), a Plexiglas tablet was placed on top of the entire dressing on absorbent paper applying a pressure of 40mmHg. After 30 minutes the weight was removed and the dressing was weighed. The retention capacity is given by the difference between the weight of the dressing after compression and the dry weight of the dressing, and is expressed as either g of fluid retained per g of dressing (for foams and hydrocolloids), or g of fluid retained over 100cm^2 of dressing (for alginates and chemically modified cellulose fibres). The per cent of fluid retention was determined by comparing the ratio of fluid held after compression to the fluid saturation.

To avoid bias, during the test the surface of the Plexiglas tablet was never lower than the surface of the dressing over which it was positioned. For this reason, in the case of polyurethane foams where the increase in size after absorption is substantial and variable, the tablet was bigger than the dried dressing (not less than 14 x 14cm). Also, the Plexiglas tablet did not touch the work plane, and therefore the weight was exerted only on the sample.

Moisture vapour transmission rate in non-waterproof dressings

This parameter was assessed by standard test BS EN 13726-2[9] The test lasted 24 hours, during which each dressing sample was kept in contact with the steam at standard temperature and relative humidity conditions (T=37 ± 1°C; RH <20%).

Volumetric strain

Volumetric strain is important for the choice of the size of the dressing in relation to the surface and volume of the lesion. A decrease in surface area would expose part of the wound, and an excessive increase in surface area might cause damage by stretching the base or the rim of a non-superficial wound.

Volumetric strain corresponds to the change in volume of a dressing in contact with exudate compared with the original dry volume. Currently there is no standard test for this parameter. The method we propose here involves the measurement of:

- The thickness of the dressing at five different positions (one in the centre and four in the middle of each side at 2cm from the edge)
- The surface of the dressing, dry, and after immersion in test solution A, for a period of 30 minutes (alginates and chemically modified cellulose fibres), or 24 hours (polyurethane foams and hydrocolloids).

The volume is given by multiplying the surface by the average thickness. The test was performed simultaneously with the free swell test under the conditions previously described.

Lateral spread

The lateral spread of exudate with possible re-contamination of the area around the wound is a negative parameter of the performance of a dressing. The exudate which is absorbed and moves horizontally without being retained in the dressing damages the rim of the wound and the surrounding skin.

Since there is no standard test to evaluate lateral spread, we suggest a variation on the test proposed by Walker et al.[10] Briefly, a stainless steel cylinder open at each end was placed on the dressing previously fixed on a support grid (15 x 15 x 15cm, mesh 1 x 1cm). The steel cylinder had to rest on the dressing without exerting pressure on the surface of the dressing. The artificial exudate coloured with blue methylene (0.1%w/v) was introduced using a syringe into the centre of the cylinder in an amount able to saturate the area of application (15ml). After introducing test solution A (five minutes the time needed for the full absorption of 15ml of exudate), the cylinder was removed, a ruler was placed under the dressing and a photograph was taken. The total area of spread (A) was measured with the free programme Image tool (University of Texas Health Science Center at San Antonio [UTHSCSA]). The area of the cylinder (B) was subtracted from the total area of spread (A), and the percentage of lateral spread (D1) was calculated using the formula:

D1(%) = [(A-B)/B*100].

The percentage of lateral diffusion on the surface opposite to where the dye had been applied (D2), and the ratio D2/D1 were also calculated. Values of D2/D1>1 are indicative of a correct distribution of the exudate within the matrix of the foam. The test was performed under constant temperature and relative humidity conditions (T=23±2 °C and RH=50±5%).

In some of the dressings tested the foam produced a filtering effect, and we observed a wet not coloured area in addition to a diffused blue halo. Thus, at the end of the test and before the dressing dried, we drew the perimeter of the spread area with a marker, including the possible wet area and then easily determined the area using the software.

Given their structure, we consider the evaluation of lateral spread for the alginates as being difficult to interpret and therefore basically meaningless, since the values obtained are predictably maximum and undiscriminating.

Fig 1. Moisture vapour transmission rate (MVTR), absorbency, and fluid handling capacity (FHC) of three waterproof foams

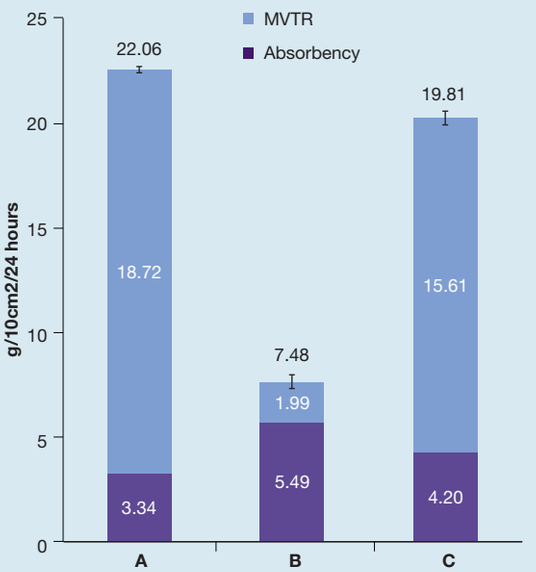
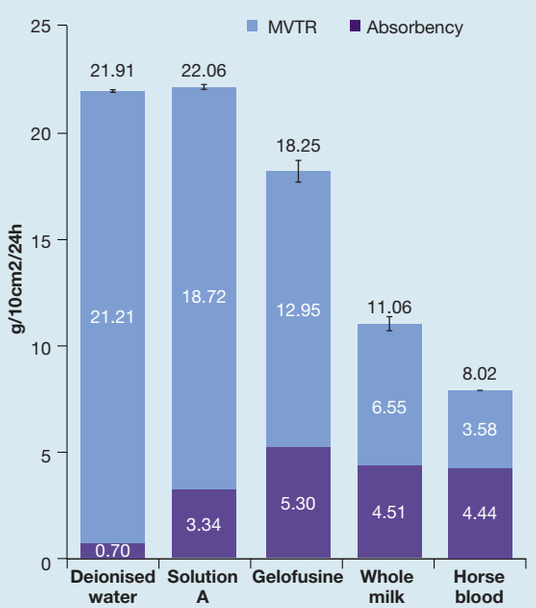


Fig 2. Moisture vapour transmission rate (MVTR), absorbency, and fluid handling capacity (FHC) of a polyurethane-based dressing in different media



Vertical spread

The property to absorb and remove the exudate internally and towards the outer surface favours, partially, the evaporation of the excess, and most of all protects the surrounding skin from damage and irritation.

As there are no standard tests to measure vertical spread, we propose a new test in which the dressing is placed over a cavity of a circular Plexiglas device (4cm diameter, 0.3cm thick) filled with 3ml of test solution A (coloured with blue methylene, 0.1%w/v). The test was carried out with a quantity of liquid which does not saturate the surface of the dressing being analysed, and was repeated on five samples. A Plexiglas tablet (10 x 10cm; 110g) was placed on top of the dressing to reduce the tendency of certain foams to deform and to favour the adhesion to the surface of low-conformability dressings. After the start of the test (one hour, the time needed for complete absorption of 3ml exudate), the dressing was removed from the device, placed in an oven at 37°C for 24 hours to fix the colour, and cut transversely. A ruler was placed under the dressing and a photograph was taken. Using Image tool (UTHSCSA), the maximum spread path was measured in mm. We calculated vertical spread (%) as the ratio between the maximum spread path and the thickness of the dressing at the point of maximum spread.

Dispersion

The integrity of alginate dressings and chemically modified cellulose fibres is important to prevent pollution of the wound bed by dressing fragments and the resulting loss of its absorbing function. High dispersion is therefore seen as a negative factor when evaluating the quality of a dressing.

Dispersion was assessed by standard test BS EN 13726-1.[7] Briefly, a sample of dressing (5 x 5cm) was placed in a 250ml conical flask containing 50±1ml of test solution A, and kept under stirring for 60 seconds using a magnetic stirrer, at a speed that would not cause vortices. At the end of the experiment the dressing was visually evaluated for structure and loss of fibres.

Waterproofness

Waterproofness was assessed by standard test BS EN 13726-1.[11] Waterproofness resistance is defined as the ability to withstand a hydrostatic head of 500mm of water for 5 minutes. This parameter is important for foam and hydrocolloid plaques that are used as primary dressings and must guarantee the absolute protection of the injured area and surrounding skin from external contaminants.

The apparatus used consisted of a cell that allows applying hydrostatic pressure to a circular area on the outside surface of the sample (side opposite to the wound contact). The cell was filled with water and a sample of dressing of a diameter greater than 5cm was placed on the bottom ring of the cell by sliding it horizontally to avoid inclusion of air between sample and water. A filter paper with a diameter greater than the area tested was placed on the upper surface of the sample and the whole was sealed. Water was then poured to the required level above the sample surface and the hydrostatic pressure maintained for 5 minutes. The test was performed on three samples. At the end of the test, should the filter paper on any sample turn wet, then that sample will have failed the test. To avoid bias, dressings were stored at T=21±2°C and RH=60±15%, and the test was conducted under the same conditions.

Resilience

Resilience may be relevant when choosing polyurethane dressings in compression therapy and for treating pressure ulcers (PUs). Dressings of high resilience are more resistant to deformation under pressure, and favour an even distribution of pressure on the wound bed.

Resilience was assessed by a modified standard test BS EN ISO 8307:2007.[12] The whole dressing was fixed on a base and a steel ball with a diameter of 5mm and mass of 450mg was dropped onto it from a height of 50cm. The weight of the ball was chosen to avoid the ball to touch the base as this would distort the rebound height. The experiment was conducted at T=23±2 °C and RH=50±5%, and filmed by a fixed tele-camera to determine the rebound height. Resilience (R) was calculated using the formula:

R =(h/hmax) x 100

where h=height of rebound, and hmax=500mm.

Viscosity of hydrogels

Hydrogels with optimum viscosity stick quickly to the wound bed and remain in the right position even against gravity. Viscosity of a fluid may also be defined as flow resistance, and can be quantified by measuring the space covered by the sample (migration) from the point of application for a given period of time.

This parameter was evaluated by a non-standard method. To perform this test, 0.5ml of hydrogel was applied to a surface of 1cm^2 of Pyrex glass in a horizontal position, behind which a piece of graph paper was fixed. The plate was tilted at an angle of 90 degrees, left in that position for 5 minutes, and the distance between start and end point of the migration was measured using Image tool (UTHSCSA).

Hydration capacity of hydrogels

Hydration capacity is related to the supply of water, and the greater the loss in weight of the hydrogel is, the greater its ability to hydrate would be. A gel with high fluid affinity facilitates rehydration of necrotic tissue by encouraging autolytic debridement.

This parameter was assessed by standard test BS EN 13726-1.[7] Briefly, the test sample (10±0.1g) was introduced into a syringe containing 35% gelatin, and incubated at T=25 ± 2 °C for 48 hours. After removing the hydrogel from the syringe, the amount of water released by the sample was calculated as loss in weight percentage of the hydrogel.

Results

Fluid handling capacity

At standard T and RH (T=37±1 °C, RH<20%) the test was able to measure differences in FHC between three waterproof foams; Foam A, 22.06g/10cm^2/24 hours; Foam B, 7.48 g/10 cm^2/24 hours; and Foam C, 19.81g/10cm^2/24 hours; p<0.01 (Fig 1). The test also enabled the evaluation of FHC of hydrocolloids, calculated as showed in Table 3.

Table 3. MVTR, absorbency, and FHC of three hydrocolloids

Hydrocolloid	MVTR g/10cm^2/24 hours (SD)	Absorbency g/10cm^2/24 hours (SD)	FHC g/10cm^2/24 hours (SD)
A	0.18 (0.02)	3.06 (0.39)	3.24 (0.41)
B	0.33 (0.01)	4.51 (0.16)	4.83 (0.17)
C	0.12 (0.02)	2.29 (0.05)	2.41 (0.04)

FHC–fluid handling capacity; MVTR–moisture vapour transmission rate; SD–standard deviation
Significant differences were observed between A–B, B–C (p<0.01) and A–C (p<0.05)

Table 4. Absorptive capacity and retention under pressure in various types of dressings

Dressing type sample		Absorptive capacity	Fluid retention capacity	% Fluid retention (SD)
Alginates (g/100 cm^2)				
A		18.83 (0.41)	6.72 (0.03)	38.88 (0.86)
B		22.17 (0.83)	6.99 (0.53)	31.36 (2.37)
C		22.36 (0.74)	6.70 (0.43)	30.01 (2.61)
D		22.86 (1.02)	5.86 (0.11)	25.70 (0.94)
E		16.91 (0.05)	4.83 (0.35)	28.56 (2.07)
Significant differences were observed between: absorptive capacity: A–B, A–C, A–D, A–E, B–E, C–E, D–E (p<0.01); fluid retention capacity: A–D, A–E, B–E, C–E, D–E (p<0.01), and B–D, C–D (p<0.05); % fluid retention: A–B, A–C, A–D, A–E (p<0.01) and B–D (p<0.05)				
Waterproof foams (g/g)				
A		7.93 (0.56)	4.46 (0.36)	56.30 (3.44)
B		4.18 (0.26)	1.78 (0.17)	42.59 (4.65)
C		8.61 (1.18)	3.04 (0.81)	34.89 (4.45)
Significant differences were observed between: absorptive capacity: A–B and B–C (p<0.01); fluid retention capacity: A–B (p<0.01) and A–C (p<0.05); % fluid retention: A–B (p<0.05) and A–C (p<0.01)				
Non-waterproof foams (g/g)				
A		11.12 (0.05)	3.48 (0.27)	31.27 (2.60)
B		3.55 (0.46)	1.03 (0.08)	29.33 (6.11)
Significant differences were observed between: absorptive capacity: A–B (p<0.01); fluid retention capacity: A–B (p<0.01)				
Chemically modified cellulose fibres g/100 cm^2				
A		24.83 (0.91)	14.31 (0.57)	57.66 (3.30)
B		21.43 (2.33)	11.56 (1.30)	54.02 (3.04)
Fluid retention capacity: A–B (p<0.05)				
Hydrocolloids (g/g)				
A	After 30 minutes	0.18 (0.03)	0.12 (0.01)	69.50 (6.81)
	After 24 hours	2.38 (0.24)	1.95 (0.08)	82.06 (8.94)
B	After 30 minutes*	0.40 (0.01)	-	-
	After 24 hours	1.39 (0.03)	0.56 (0.02)	39.96 (1.78)
C	After 30 minutes	0.14 (0.00)	0.09 (0.01)	62.14 (6.40)
	After 24 hours	1.87 (0.02)	1.63 (0.03)	87.12 (0.74)
Significant differences were observed between: absorptive capacity: A–B and B-C (30 minutes and 24 hours, p<0.01), and A-C (p<0.05, only after 24 hours); fluid retention capacity: A-B, A–C, B–C (after 24 hours, p<0.01), and A-C (after 30 minutes, p<0.05); % fluid retention: A–B and B–C (after 24 hours, p<0.01)				

*Fluid retention capacity and % fluid retention could not be calculated for hydrocolloid B due to its strong adhesion to the absorbent paper; SD–standard deviation

Table 5. Changes in area and volume of various types of dressings

Dressing type sample	Time of immersion	Change in area % (SD)	Change in volume % (SD)
Alginates	30 minutes		
A		–9.33 (0.00)	–12.91 (7.81)
B		–8.08 (0.52)	–35.46 (3.73)
C		–8.77 (0.46)	–26.56 (21.24)
D		–4.62 (0.57)	–19.93 (2.35)
E		–16.99 (1.09)	–39.48 (15.82)
Significant differences were observed between: % change in area: A–D, A–E, B–D, B–E, C–D, D–E ($p<0.01$) and A–B ($p<0.05$)			
Waterproof foams	24 hours		
A		+92.80 (2.68)	+183.99 (8.21)
B		+15.95 (1.03)	+26.91 (2.33)
C		+10.24 (1.90)	+35.75 (1.31)
Significant differences were observed between: =% change in area: A–B, A–C ($p<0.01$) and B–C ($p<0.05$). % change in volume: A–B, A–C, B–C ($p<0.01$)			
Non-waterproof foams	24 hours		
A		+1.00 (0.00)	+14.26 (1.73)
B		+67.71 (2.21)	+89.63 (5.82)
Significant differences were observed between: % change in area and % change in volume: A–B ($p<0.01$)			
Chemically modified cellulose fibres	30 minutes		
A		–30.10 (2.12)	+0.75 (0.14)
B		–27.59 (2.50)	+6.28 (2.59)
Significant differences were observed between: % change in volume: A-B ($p<0.05$)			
Hydrocolloids	24 hours		
A		+9.14 (0.47)	+162.42 (5.58)
B*		–-	–
C		+8.28 (0.60)	+93.84 (0.24)
Significant differences were observed between: % change in volume: A–B ($p<0.01$)			

*Data not available because the adhesive border of hydrocolloid B rolls up after getting wet, and prevents a correct measure of the dressing size; SD–standard deviation

Fig 3. Dressing that remains intact (a), and dressing that breaks up (b) in dispersion medium

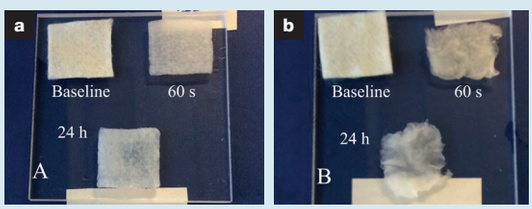
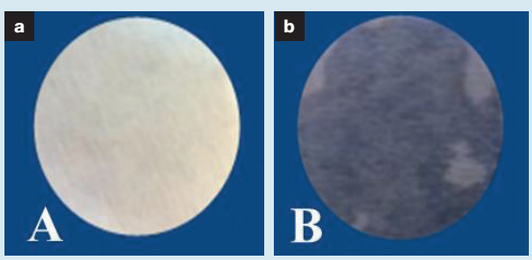


Fig 4. Example of polyurethane dressing which passed (a), and not passed (b) the waterproofness test



The FHC of a polyurethane-based dressing varied considerably with T and RH conditions under which the test was performed. For example, a FHC of 10.01 (SD 0.18) g/10cm^2/24 hours was recorded at T=23±2°C and RH=50±5%, and FHC of 22.06 (SD 0.13) g/10 cm^2/24 hours was recorded at T=37±1°C and RH<20%.

We also observed that under stable T and RH conditions (T=37±1°C, RH<20%), the FHC values depended on the artificial exudate used (Fig 2).

Absorptive capacity (free swell test) and retention under pressure

As shown in Table 4, the free swell test was able to identify differences between dressings in the same category, and statistical significant differences were found between samples for alginates, waterproof and non-waterproof foams. As for the hydrocolloid samples, the absorptive capacity after 24 hours was higher than that observed after 30 minutes of immersion in artificial exudate. As both retention capacity and the % of fluid retention increased over time, it is appropriate to conduct the test after 24 hours of free swell to achieve saturation.

Moisture vapour transmission rate in non-waterproof dressings

MVTR provided useful information for non-waterproof polyurethane foams, resulting in significant differences ($p<0.01$) between sample A (0.56 [SD 0.05] g/100cm^2) and sample B (0.28 [SD 0.04] g/100cm^2).

Volumetric strain

This test could identify differences in volumetric strain between polyurethane foams (waterproof and non-waterproof) and hydrocolloid dressings. However, the test was not suitable for calculating the volumetric strain of chemically modified cellulose fibres and alginates as the irregularity of the surface prevents exact measurement of their thickness (Table 5). With this test we could also determine the variation in the surface of polyurethane foams, hydrocolloids, alginates and chemically modified cellulose fibres. In particular we observed a reduction in surface area after immersing alginates in exudate, while both measurements, % change in area and volume, increased for polyurethane foams and hydrocolloids. Chemically modified cellulose fibres showed a decrease in surface area and increase in volume as the thickness of the dressing increases significantly after immersion.

Lateral and vertical spread

Lateral spread is associated with poor dressing performance, and vertical spread is associated with

Table 6. Vertical and lateral spread of three polyurethane foams

Lateral spread	D1, % (SD)	D2, % (SD)	D2/D1
A	568.7 (79.7)	672.5 (91.6)	1.17 (0.21)
B	337.5 (33.0)	390.6 (59.8)	1.13 (0.19)
C	1028.6 (52.1)	388.2 (72.0)	0.40 (0.08)
Vertical spread	**% (SD)**	**-**	**-**
A	45.00 (2.4)	-	-
B	59.22 (1.0)	-	-
C	15.68 (1.2)	-	-

Lateral spread. D1: significant differences were observed between A–B, A–C, B–C ($p<0.01$). D2/D1: A–C, C–B ($p<0.01$).
Vertical spread; A–B, A–C, B–C ($p<0.01$)
D1–percentage of lateral diffusion on the surface where dye has been applied; D2–percentage of lateral diffusion on the surface opposite to where the dye has been applied; SD–standard deviation

improved performance. As shown in Table 6, this test was able to identify differences in lateral and vertical spread between polyurethane foams.

Dispersion

Only one of the alginate dressings examined lost its integrity under the test conditions (Fig 3). No dispersion but jellification was observed for chemically modified cellulose fibres.

Waterproofness

Since all samples examined were waterproof, the test was repeated on water-permeable dressings to evaluate the ability of the test to discriminate between the two categories of dressings.

As shown in Fig 4a, the filter paper placed on the water-permeable dressing turned completely wet at the end of the test, in contrast to the dry filter paper on waterproof dressing (Fig 4b), thus demonstrating the validity of the test.

Resilience

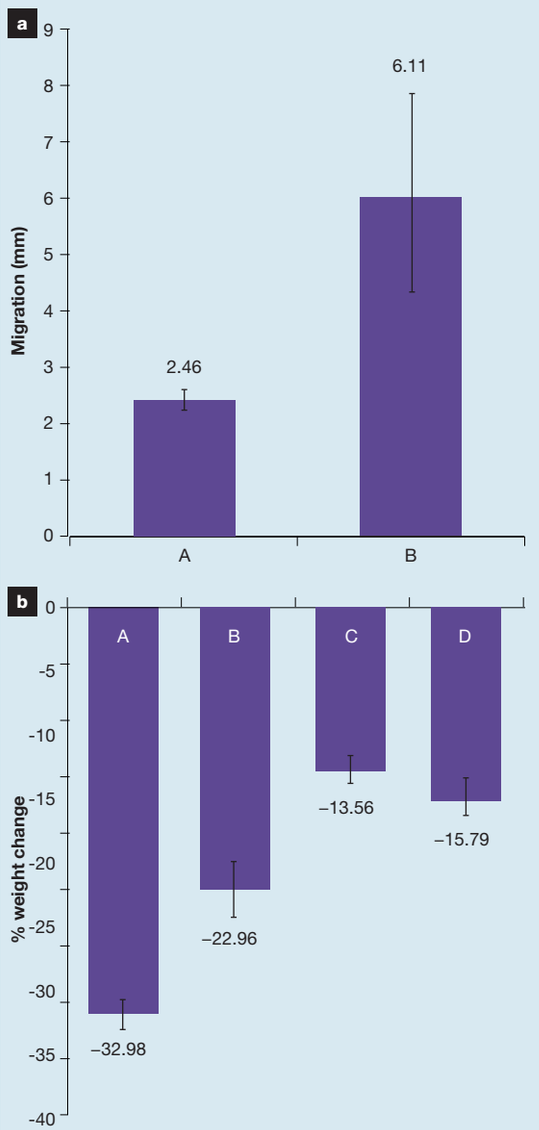
The test was able to identify differences in resilience between polyurethane foam dressings of different brands. Sample A had a resilience of 11.48 (SD 0.50)%, sample B of 29.55 (0.50)%, sample C of 5.25 (0.30)%, and sample D of 25.90 (0.20)%. Statistical significant differences ($p<0.01$) were observed for all comparisons between samples.

Viscosity and hydration capacity of hydrogels

Both viscosity (migration) and hydration capacity tests were able to discriminate between hydrogels belonging to different brands (Fig 5), and statistical significant differences were found between samples for both tests. To test viscosity, each sample was measured five times due to the high variability of sample B.

The hydration capacity test performed on a hypertonic hydrogel produced opposite result, with an increase in hydrogel weight of 14.5%. This result may be due to the osmotic effect of the hydrogel, and further investigation is needed to confirm the applicability of the test to hypertonic hydrogels.

Fig 5. Migration (a) and loss in weight (b) of different hydrogels



Discussion

This study identified laboratory tests able to assess parameters and functional characteristics of the main commercial categories of wound dressings in an objective and non-operator-dependent way. The systematic testing will provide the necessary data to help choose the most suitable dressing for a specific problem.

To identify testing procedures we focused on literature concerning standard and non-standard quality control

Table 7. Overview of parameters and tests for the assessment of specific dressings

Parameter	Test	Recommended changes and/or notes	Waterproof foams	Non-waterproof foams	Alginates	Chemically modified cellulose fibres	Hydrocolloids	Hydrogels
Fluid handling capacity (FHC) and Moisture vapour transmission (MVTR)	BS EN 13726 section 3.3	- Temperature of 23 ± 2 °C - RH = 50±5% - Use a more viscous and corpuscolated artificial exudate - Use of a wire gauze of stainless steel to contain the bulge towards the outside of the dressing	X	-	-	-	X	-
Free swell absorptive capacity	BS EN 13726 section 3.2	- Test performed on the entire dressing - Test time: 24 hour for foams and hydrocolloids - Dripping time: lengthened from 30–120 seconds - Position of a Plexiglas tablet on the top of the foam.	X	X	X	X	X	-
MVTR	BS EN 13726 section 3.3	- Measure absorbency and MVTR at the same time - Test time 24 hours	X	-	-	-	X	-
	BS EN 13726-2	- Dressing in contact with the water vapour	-	X	-	-	-	-
Retention under pressure	Non-standard Foster et al.[8]	- Test performed on the entire dressing - Test time 30 minutes - Position of a Plexiglas tablet (not less than 14x14cm) on top of the foam	X	X	X	X	X	-
Volumetric strain and change in area	Non-standard	- For the alginates and chemically modified cellulose fibres the test is valid only for determining change in area	X	X	X	X	X	-
Lateral spread	Non-standard Walker et al.[10]	- Placement of the dressing on a support grid - Test time 5 minutes - Use of a blue methylene solution as artificial exudate - Evaluation of the lateral spread on the surface of application of and the opposite surface	X	X	-	-	-	-
Vertical spread	Non-standard	- Position of a Plexiglas tablet on the top of the foam to prevent deformation of the foam - Fix the colour before cutting the foam transversely to avoid smudging the dye	X	X	-	-	-	-
Dispersion characteristics	BS EN 13726 section 3.6	- Test time: 1 hour	-	-	X	-	-	-
Waterproofness	BS EN 13726-3	- No changes needed	X	-	-	-	X	-
Resilience	EN ISO 8307/2007	- Weight of the ball: 450mg - Size of the ball: 5mm	X	X	-	-	-	-
Viscosity	Non-standard	- No changes needed	-	-	-	-	-	X
Hydration capacity	BS EN 13726 section 3.4	- No changes needed	-	-	-	-	-	X

RH–relative humidity; X–applicable; - not applicable or not useful

tests for wound dressings. We then highlighted potential issues, identified possible solutions to be shared with the scientific community, and proposed new tests for assessing some parameters for which we found no references in the literature. The changes made to some standard tests varied from one test to another to simulate real-life conditions as closely as possible. This was one of the innovative aspects of this study.

While comparing the standard tests with real-life conditions, we became aware of limitations such as the use of only portions of the dressing sample, the testing time, the temperature and humidity conditions set, and

the use of solutions with different chemical-physical characteristics from those of the exudate.

The use of portions of the dressings, when compared with the entire dressing, may change the performance results and compromise the validity of the test. In some cases the time set for the standard test was too short and the tests were extended to replicate as far as possible real-life application times (minimum 24 hours). Our results show, as previously observed by Thomas,[13] that temperature and humidity conditions during testing strongly influence the test results. For this reason, as far as possible, we used environmental values closer to those of real-life (T=23±2°C and RH = 50±5%).

Our results highlight also how important is the selection of a suitable fluid to mimic the real exudate in terms of viscosity and particle size. Different artificial exudates such as blood substitutes, whole milk, and horse blood, behaved significantly different with regard to the absorption capacity of dressings (Fig 2). One of the main goals of future studies is therefore to develop a suitable artificial exudate, which is readily available, and which has constant chemical and physical characteristics.

One dressing parameter we believe to be very important is the absorption under pressure, simulating bandaged conditions. For this parameter, there are no standard tests specific for wound dressings, but there are several examples of potential tests in the literature. Walker et al. [10] and Bishop et al.[14] propose a test that refers to the evaluation of the retention capacity of water reported in pharmacopoeia for surgical dressings.[15] Severin and Kristensen[16] propose a variation of this test by inserting a porous filter between the exudate and the dressing, which allows the fluid to be released from the side of the dressing in contact with the wound bed. However, the test is carried out on only a portion of the dressing and the exudate is not maintained at 37°C.

Thomas[6] proposes an interesting device that simulates clinical conditions more accurately. It is a system able to adjust the flow of exudate, control its temperature, evaluate the absorption both under and not under pressure, and evaluate MVTR. A similar system which could be positioned both horizontally and vertically (to evaluate the performance of the dressing applied, for example, to the lower limbs), will allow measuring in a single experiment the absorption characteristics, breathability, and lateral and vertical diffusion of a dressing. This would reduce the number of experiments and the time and cost of analysis. We aim to develop such a device and test it on various types of dressings.

Another important dressing parameter which needs to be evaluated is conformability, for which a standard test BS EN 13726-1: 2002[17] already exists. However, a test that measures the adaptability of the dressing to an uneven surface such as that of a wound bed is needed. This test would provide a more realistic reflection of the dressing real-life use and we see its development as future goal.

Other parameters for which we identified the need to develop suitable tests are the osmotic capacity of saline dressings and hypertonic hydrogels, the hydrocolloid's hydration capacity, and the degree of drying of a traumatic dressing. To evaluate these parameters we currently apply tests that need to be validated or improved. Table 7 shows an overview of the parameters and corresponding tests.

Conclusion

Most of the tests used were able to discriminate well between dressings belonging to different brands, with some tests being more suitable than others for the assessment of specific dressings. This study paves the way for a larger project aimed at a systematic evaluation of dressing quality able to assess every wound dressing on the market. JWC

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