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Design and fabrication of an instrument to evaluate characteristics of fluid handling capacity of wound care dressings

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A novel instrument has been developed to determine the fluid handling capacity of different types of wound dressings, irrespective of their structure and composition. The instrument is developed with custom built wound bed/plate with specially designed path to control the amount and flow rate of wound exudates, simulating the actual wound alike conditions. The instrument has provision to apply compression / pressure over wound dressing while testing to similar realtime compression / pressure applied on wound dressing. The study was carried out using different types of commercially available wound dressings. It is found that the developed instrument is able to test different types of dressings effectively for fluid handling capacity. The results obtained by new instrument are found comparable with the existing methods. The existing methods give only single value of fluid handling capacity at the defined hour as compared to the new instrument which gives online continuous results from zero to 48 h. This real time data may be useful for defining the effectiveness of dressings at a particular time interval. The data obtained from the instrument can also be used to know the saturation point and change with time for a particular dressing. The repeatability of results are also proven. Also the instrument is able to test fluid handling capacity of dressings with and without pressure.

Keywords: Absorbency, Fluid handling capacity, Strike through, Wound dressing, Wound exudates

1 Introduction

The modern wound dressings have evolved from simple gauze to multi -functional, multi- layered dressings with combination of different kinds of materials and structures, such as textiles, hydrocolloids, foams, hydro actives, etc. The ideal dressing has to promote wound healing , and reduce pain & healing time.

Different kinds of wound care dressings are being used to treat complicated and even life threatening acute or chronic diabetic wound, burn wound, etc[1]. Recently, several advanced and multi-functional dressings have been developed and introduced in the market with functional materials and structures. In order to adapt them, there is an increasing need to develop standard test protocols to characterize and validate them for intended end use. Several standard methods have been designed to simulate real time conditions for assured consistent performance of the wound dressings. The selection of wound dressing is done by considering the type of wound and the properties of wound dressings, such as exudate management by fluid handling capacity, dehydration rate, moisture vapour transmission rate (MVTR), wicking properties, etc[2,3] . The wound exudate plays very important role in wound healing. The optimum level of exudate provides required moist environment to facilitate epithelialization, which, in turn, increases the rate of wound healing. On the other hand, the excessive exudate can lead to delayed wound healing due to skin maceration and other wound complications[4] . Hence, in the case of heavily exuding wounds, the dressings should absorb excess wound fluid. In case of lightly exuding wounds, the dressings should maintain optimum moist environment and should not absorb much exudate which can dry the wound. In other words, accessing wound dressings fluid handling capacity of wound dressing is an important factor for the effective management[5] .

Most of testing methods and instruments developed for evaluating the characteristics of fluid handling capacity of different types of wound care dressings are based on the material and the structures of dressings, rather than on the function of the product concerned. The developed methods vary from simple ‘dunk and drip’ to better method using specific fluid to know the absorbency of wound dressing. The fluid

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affinity of gel type wound dressings is measured considering the change in weight of wound dressing sample[1] . In another test systems, simulated exudate fluid is pumped in to wound dressing through a hole of a specially designed metallic or acrylic plate. Weight is also applied on the wound dressing to replicate real time pressure on bandages. In the 'demand wettability' method, water uptake of aligned and treated fibres is determined , in which, the dressing absorbs fluid from specially designed apparatus[6-8]. In SMTL (Surgical Materials Testing Laboratory), U.K method, the absorbent capacity of surgical wound dressing was measured electronically , in which a sharp steel like spike was used to determine a point (called strike through where the volume of fluid reaches to the outer surface and edges). The method was discontinued due to the doubt on its validity using sharp steel like spike which was causing distraction to the structure during test[9] .

Most of the existing test methods and instruments provide only a single value for the fluid handling capacity of wound care dressings with a little indication of the performance of the products over a specified period of time. The disadvantage with all these test methods is that the methods are developed for specific types of dressings. Hence, the results of different types of dressings are not comparable. Also, many of the methods are not found fully disclosed or scientifically validated or clinically significant. Most of the standards, specifications and test methods are formulated for specific product structure and are not found suitable for universal use. So, the performance of different types of dressings cannot be compared. Also, mostly these methods were developed without considering pressure / compression on dressings. Hence, the test systems do not predict the real conditions of wear time of different types of dressings. The wound dressings used in treatment of venous leg ulcers are subjected to pressures as high as 40 mm Hg.

The present study is therefore aimed at fabricating a fluid handling capacity tester that assists direct comparison between products that are different in structures and compositions. The instrument records fluid handling capacity of the dressing even under compression over a chosen period. It is possible to relate this information to the clinical use of the dressing.

2 Materials and Methods

2.1 Free Swell Absorptive Capacity Method

The total absorptive capacity, i.e. fluid uptake without load by fibrous dressings such as alginates and other gelling fibres can be tested by EN 13726-1. This test is recommended to assess the characteristics of dressings used for moderately to heavily exuding wounds, where the dressings attain their maximum absorptive capacity within 30 min, under the test conditions. The method is not suitable for dressings dealing with exudates by dual action, such as absorbency and MVTR.

2.1.1 Test Solution

Test solution is prepared using sodium chloride and calcium chloride solution containing 142 mmol of sodium ions and 2.5 mmol of calcium ions as the chloride salts to simulate the ionic composition comparable to human serum or wound exudates. The presence of sodium or calcium ions effects gelling property of alginate. It is prepared by dissolving 8.298 g of sodium chloride and 0.368 g of calcium chloride dihydrate in deionized water and making up to one liter in a volumetric flask.

2.1.2 Test Procedure

The test solution equivalent to 40 times of dressing weight is taken in petri dish. The dressing of 5×5 cm^2 dimension is weighed and immersed in to test solution and kept for 30 min at 37 °C. Then the dressing is taken out and allowed to drain for 30s and reweighed. The mass of the solution retained by dressing per 100 cm^2 per gram is expressed as absorbency.

2.2 Fluid Handling Capacity Method

The test method EN 13726-1 also describes the method for hydrogel and hydrocolloid sheets using paddingnton cup method to know the amount of test fluid retained. The Paddington cup method is not suitable for fibrous or permeable dressings. Paddington cup has been fabricated by The South India Textile Research Association, India (Fig. 1). The Paddington

Fig. 1 — Paddington cup

cup is made up of corrosion resistant material with an internal diameter of 35.7 mm and cross-sectional area of 10 cm^2 having a flange at each end, each able to accommodate 20 mL of test solution. At one end of the cylinder, an annular clamping plate with an orifice area of 10 cm^2 is used. To prevent transpiration through the edges of the dressing, an impermeable tape is used in this area. The end of the cylinder is closed using metal plate. A sealing ring is used effectively to seal the flange. The plates at both ends are clamped in position against the flanges.

2.2.1 Test Procedure

A circular sample, as per template, is cut and clamped over the test instrument. To prevent leakage, it is enclosed with the retaining ring on the outer surface of the dressing. The test method (EN 13726-1) is suitable for wound dressings which are effectively handling exudate through absorbency and MVTR, such as slow fluid handling wound dressings, hydrocolloids, water proof dressings using Paddington method. The cylinder together with the base, clamps and all associated parts is weighed (W1). The weight (W2) is determined after adding 20 mL of test solution. The test is carried out at 37ºC and 20% relative humidity for 24 h and is stabilized at 37ºC for 30 min and weighed (W3). The excess fluid is flushed out and then along with the dressing component it is reweighed (W4). The vapor lost through the dressing (W2 – W3) and the fluid absorbed by the dressing (W4 – W1) are determined. The fluid handling capacity (FHC) is determined based on the fluid absorption (FA) and the water vapour transmission rate (WVTR). Dressings used for low, moderate and highly exudating wounds have been procured and their fluid handling characteristics are studied as per International standard (EN13726-1).

2.3 Design Criteria for Instrument Development

Based on the shortcomings of the existing test methods, design criteria of the instrument has been finalized, as shown below:

(i) The test system should reflect the normal clinical use of the material under examination.

(ii) Fluid should be provided to the test sample by suitable positive flow device.

(iii) The wound bed should be kept in environmental control chamber to reproduce the real condition in the wound for entire duration of test.

(iv) The test should measure fluid-handling capacity profile over time, and not just a single total absorbency.

(v) The instrument should be capable of delivering simulated wound exudates at different flow rates to stimulate real conditions.

(vi) The liquid strike through limit on the other side of the dressings should be measured using suitable systems.

(vii) The instrument should be suitable for testing a wide range of dressings to permit direct comparison of the results.

(viii) The instrument should permit the application of varying loads to the test samples in order to determine the effect of external pressure.

(ix) The instrument should permit the measurement of moisture vapour transmission by the dressing during the course of the test.

(x) The test should provide an indication of the wear time of a dressing in normal clinical use.

(xi) The instrument should withstand sterilization or disinfection.

3 Results and Discussion

3.1 Aspect of Absorbency

3.1.1 Free Swell Absorbency

Free swell absorbency values of the commercial wound dressings (Tegaderm) and alginate dressing are found 1.2 and 2.6 g/10cm^2 respectively. Alginate dressings absorb fluid and turn into gel. The free swell absorbency of alginate dressings is found nearly two times higher than that of Tegaderm dressings .

3.1.2 Fluid Handling Capacity

Fluid handling capacity of the 3 commercial wound dressing samples are analyzed as per International standard using the existing Paddington cup (Fig. 1) method and the results are given in Table 1. In this

Table 1 — Fluid handling capacity (FHC) of wound dressings over 24 h and 48h

Sample No.	Dressing	Moisture vapour loss g/10 cm^2		Absorbency g/10 cm^2		FHC g/10 cm^2	
		24h	48h	24h	48h	24h	48h
1	Adhesive triple layer	11.28	23.38	3.98	3.90	15.26	27.28
2	Foam dressings with gentle adhesive layer	15.60	28.29	6.92	1.42	22.52	29.71
3	Non adhesive	9.36	19.28	3.86	3.28	13.22	22.56

Fig. 2 — SITRA fluid handling capacity tester (SFHCT)

study, the adhesive triple layer type wound dressing sample is numbered as sample 1, the foam dressing with gentle adhesive is numbered as sample 2 and non adhesive dressing sample is numbered as sample 3. It can be seen from Table 1 that the fluid handling capacity (FHC) of samples increases from sample 3 to sample 1 and then sample 2. Sample 2 shows higher FHC because of its foam like open structure as compared to samples 1 and 3. From all the test results, it is observed that the FHC of testing samples ranges from 13.22 g/10cm^2 to 22.52 g/10 cm^2 after 24 h and from 22.56 g/10 cm^2 to 29.71 g/10 cm^2 after 48 h. Moisture vapour loss is on the higher side at 48h as compared to that at 24 h for all dressings. The fluid handling capacity of all wound dressings is found higher at 48 h as compared to that at 24 h.

3.2 Proposed Fluid Handling Capacity Tester

A novel fluid handling capacity tester (SFHCT) has been designed and fabricated to overcome the limitations associated with the existing test methods (Fig. 2). The novel instrument developed is based upon the design criteria as discussed earlier. The instrument consists of a number of components, such as wound plate, electronic weight measuring device, infusion pump, and strike through detection system.

3.2.1 Wound Plate

A wound plate has been fabricated. The inner part of the SFHCT consists of a stainless steel plate mounted horizontally, bearing a central circular recess (2 mm deep and 50 mm diameter). In the base of this recess, there is a narrow channel (1.25 mm deep) that forms a convoluted path between two ports that open onto the lower surface of the stainless steel plate. Stainless steel is preferred because it is stronger, resists scratching, can be sterilized if required and is unaffected by any organic solvents which are used to remove dressing residues from the surface. Simulated exudates are fed through one of the ports by means of an infusion pump. Exudates travel along the convoluted path and come out through the second port. The exudates fall vertically down through a short and wide-bore tube. This tube discharges into an exudates receiver tank placed upon a pan of an electronic weight measuring device. This device is connected with an electronic data capture device that records changes in the balance reading at predetermined intervals throughout the period of the test. The wound bed together with the infusion pump and weight measuring device are placed in an environmental control chamber. Both the temperature and humidity within the chamber can be recorded using a calibrated meter linked to a data logger.

3.2.2 Electronic Weight Measuring Device

A special type of electronic balance is used to record the weight of the fluid discharged online at pre-determined intervals. The electronic weight measuring device is made of transducer which is used to create an electrical signal whose magnitude is directly proportional to the weight being measured. It is directly controlled by a Programmable Logic Control (PLC) and the weight in grams is displayed on a Human Machine Interfaces (HMI) screen. The accuracy of the electronic weight measuring device is found 0.001 mg.

3.2.3 Infusion Pump

For delivering the wound exudates to the wound plate, an infusion pump with a pressure regulator having Piezo bender technology is used. This infusion pump offers high precision flow control from 0.1 mL to 1000 mL per hour with a low hysteresis, a high repeat accuracy and a low energy consumption. The proportional characteristics of a Piezo bender with direct actuation ensures stable and reliable regulation as well as a stepless pressure rise. The key feature of the infusion pump is that it operates silently.

3.2.4 Strike through Detection System

The fluid handling capacity of wound dressing is determined by the volume of exudates taken up at the time of strike-through occurrence. Strike-through is defined as the point at which the absorbed fluid reaches the outer surface or edges of a dressing. The strike through time is noted from the data logger and the weight of fluid absorbed by the dressing is determined from the appropriate graph at this point.

3.2.5 Strike-through Plate

Vertical strike-through plate is used to detect the presence of fluid on the outer surface of the dressing. It is placed over the wound dressings. It is made of a polypropylene material and is engraved using a copper lamination. A particular level of pressure is generated with the strike- through detector. Strike-through detector is directly controlled by the PLC and the observed level of fluid that is recorded will be stored in the memory automatically. This plate acts as a strike-through detector, moisture vapour absorbing unit and as a pressure plate.

Wound dressing is placed on to the wound plate which is kept in an environmental control chamber. The vertical strike-through plate is placed on the back of the dressing and a suitable weight is added to the back to produce the required level of pressure. The vertical strike-through plate is then connected to the detection instrument. Once the instrument has reached the required temperature and relative humidity, the balance is zeroed and the infusion pump, balance data logger and strike-through data logger are switched on.

The working principle of the SFHCT is explained in flow diagram (Fig. 3). The test fluid is applied to the wound plate convoluted path through one of the port from the infusion pump. Majority of the test fluid will be absorbed up by the dressing. Any unabsorbed fluid continues to pass along the

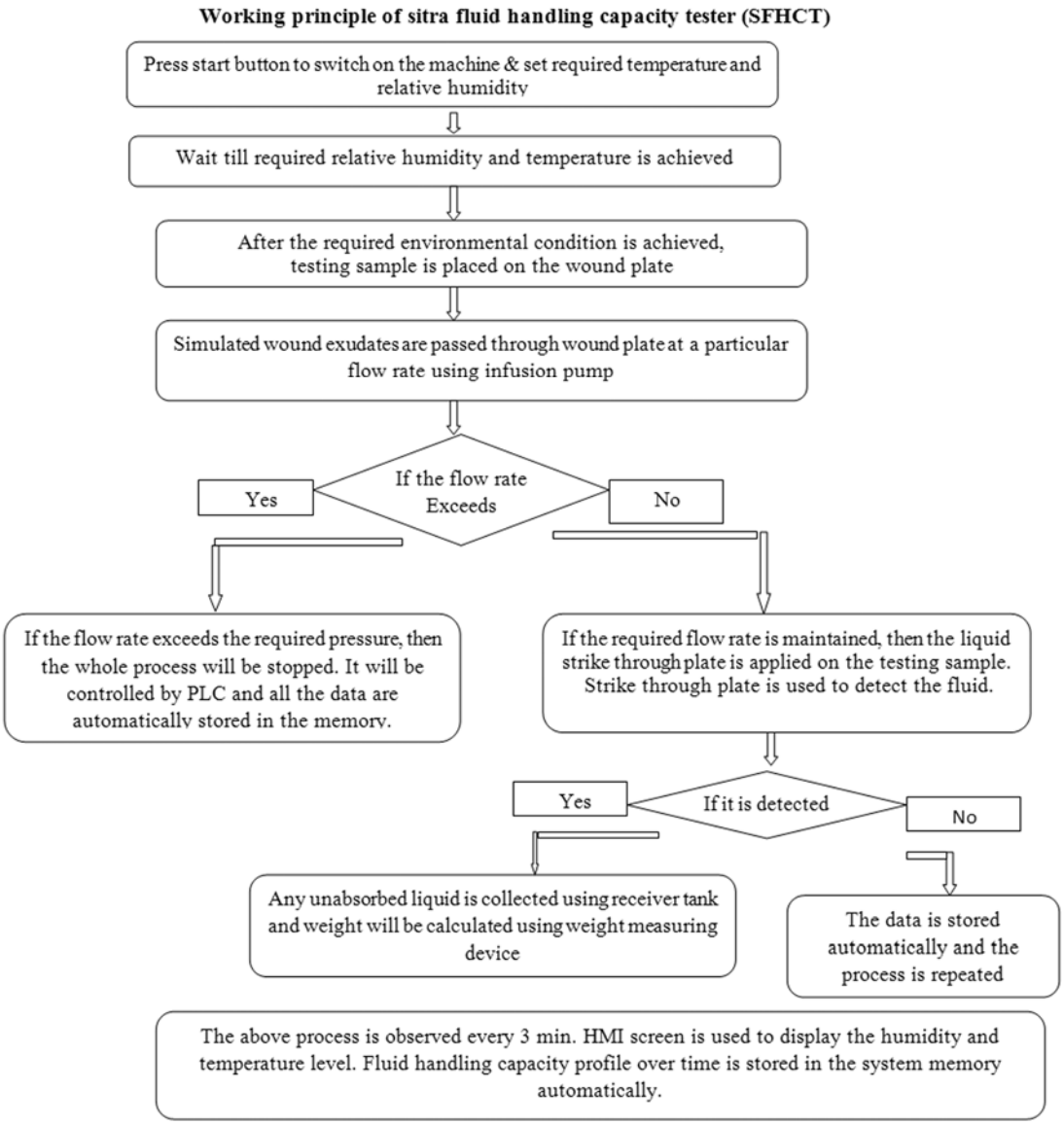

Fig. 3 — Flow chart of SFHCT operations

convoluted path. Finally, it passes through the second port of wound plate into the fluid receiver which is kept in weight measuring device, causing a change in the balance reading. The amount of fluid absorbed in this way is inversely proportional to the absorbency of the dressing. The weighing balance readings will be recorded by the data-logger. A highly absorbent dressing will take up all the liquid that is applied to it, while the less absorbent dressing will absorb only for a short time or absorb a little liquid, to achieve maximum absorbency. During a test, therefore, the maximum weight of fluid that can be taken up by a dressing is determined by the flow rate of the infusion pump. The instrument is calibrated by running blanks, replacing the test dressing with a totally occlusive non-absorbent film. This provides a measure of the dead volume within the system and an accurate measure of the flow rate, details of which are required for meaningful interpretation of the data.

3.3 Testing Different types of Dressings

For testing cavity wound dressings or hydrogel dressings, a simple modification is made in the instrument. A piece of circular acrylic tube is fixed around the recess in the centre of the plate to form a chamber into which the dressing is placed. Although strike-through measurements are not appropriate with such dressings, it is possible to apply pressure to cavity dressings, such as alginate packing by means of a weighted piston, which forms a loose fit in the acrylic tube. In all other respects, the test procedures remain the same. When testing hydrogel dressings, the open end of the chamber is sealed with a piece of aluminium foil held in place with impermeable plastic tape to prevent evaporation.

3.4 Data Analysis

In order to make the graphical results easier to understand and facilitate comparisons between different products, it is necessary to analyse these data to calculate weight of fluid absorbed from the calibrated flow rate (the weight of fluid applied) and the time at which each reading is taken. This is done automatically by the computer using the simple formula shown below:

Assume: 1 mL of fluid weighs 1 g

$$\mathrm{FHC} = \mathrm{FR} * \mathrm{T} - \mathrm{BR}$$

where FHC is the fluid handling capacity; FR , the calibrated flow rate in mL/min; *T*, the testing time in min; and BR, the balance reading at time *T* .

3.5 Interpretation of Test Results

As the test system continuously records the weight of fluid taken up by a dressing over a chosen period of typically 48 h, it is possible to relate this information to the clinical conditions for the dressing. Most of the leg ulcers examined produce ~ 0.5 g of exudate /cm^2/24 h. A smaller number of ulcers, however, produces volumes of exudate that is approximately twice this value (1 g/cm^2/ 24 h). These two values are taken to represent moderate and heavily exuding wounds. If these exudate rates are combined on a single graph with the absorbency profile of a particular dressing, it becomes possible to estimate how long the product may remain effective during normal clinical use.

3.6 Results Validation Studies

3.6.1 Phase 1— Versatility of Tester

Three different types of commercial dressings (sample 1, sample 2 and sample 3) as shown in Table 1 are tested to examine the versatility of the SFHCT also. The graphs (Fig. 4) depict the fluid handling ability of three commercial wound dressings. As may be seen (Fig. 4), there is a marked differences in the ability of each of the three dressings to absorb and retain the test solution. Sample 3 is found with lower fluid handling capacity as compared to other two products (i.e. Sample 1 and 2). It can also be seen that the results of Table 1 at respective hours are

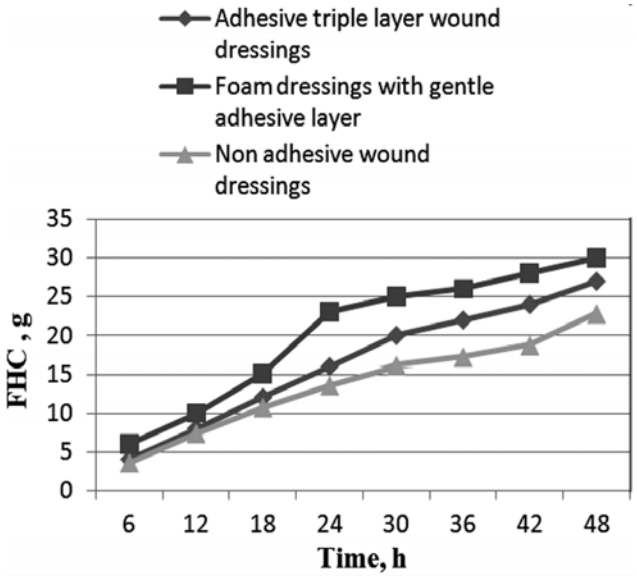

Fig. 4 — FHC of wound dressings

matching with SFHCT data in Fig. 4. The FHC of sample 1 is found 15.26 g/10 cm^2, sample 2 is found 22.52 g/10 cm^2 and sample 3 is found 13.22 g/10 cm^2 after 24 h using existing Paddington cup method.

The FHC results of Paddington cup method are comparable with FHC result of SFHCT at 24 h (samples 1, 2 and 3 show 16 g/10 cm^2, 23 g/10 cm^2 and 13.5 g/10 cm^2 respectively). Similarly results obtained using Paddington cup at 48 h are also found comparable with FHC of SFHCT results of 48 h. The data produced by instrument is showing real time online data between fluid handling capacity *vs* time. These data can be useful in knowing the dressing saturation time. This will be helpful in deciding dressing change time. Also it can be used to decide which dressing is suitable for a particular type of wound (i.e. highly exudating or low exudating). And it can also be helpful to know whether different types of dressing can be used interchangeably for a particular type of wound dressing.

3.6.2 Phase 2 — Reproducibility of Results

In order to prove reproducibility of result, three commercial samples (sample 4a, sample 4b and sample 4c) of similar type of foam dressings with gentle adhesive layer have been tested. The results are shown in Fig. 5. The results clearly identify that the repeatability of the test results of the fluid handling capacity tester is competent.

3.6.3 Phase 3— Result Validation with Effect of Compression

The fluid handling ability of the wound dressing under pressure / compression is also an important factor in wound care management, for example. in case of the management of venous leg ulcers, significant level of compression (often as high as 40mmHg) is applied. Simple foams (such as bath sponges) initially take up large volumes of fluid, but a large amount of the retained liquid is lost if the sponge is gently compressed. If allowed to stand in one position, fluid will drain away due to the effect of gravity. Different kinds of foam dressings are developed as per the required absorbency, such as polyurethane, hydrocellular, composite, etc. It is necessary to know the performance of such foam dressing under compression and without compression. The developed instrument is found helpful for the same.

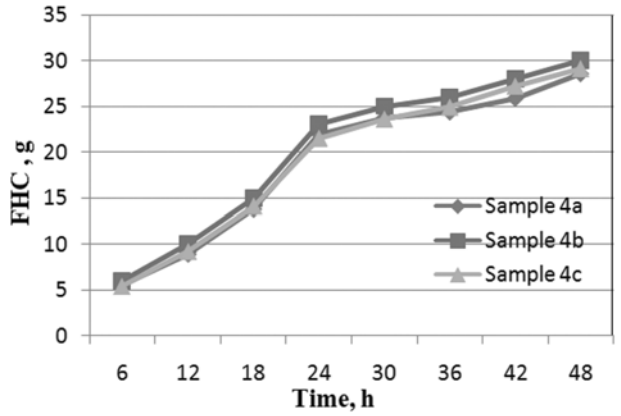

Fig. 5 — Reproducibility of test results (same kinds of three foam dressings Sample 4a, 4b and 4c)

• Absorbency under Compression

In order to simulate levels of compression simulating to the clinical situation, each sample is typically loaded with 40 mmHg. Two different types of commercial foam dressings for wound care have been tested to demonstrate the important effects of externally applied pressure on dressing performance. The results of samples 5 and 6 without compression are labeled as sample 5_wc and 6_wc and under compression are labeled as sample 5_c and 6_c. For this investigation, each dressing is tested under the compressed and uncompressed state, to identify whether they perform differently under compression. From Fig. 6, it is observed that he fluid uptake capacity of the wound dressings is reduced significantly under compression in both the cases. In case of both Sample 6_c and sample 5_c, the graph shows lower fluid uptake as compared to sample 6_wc and sample 5_wc. Hence, as compression increases

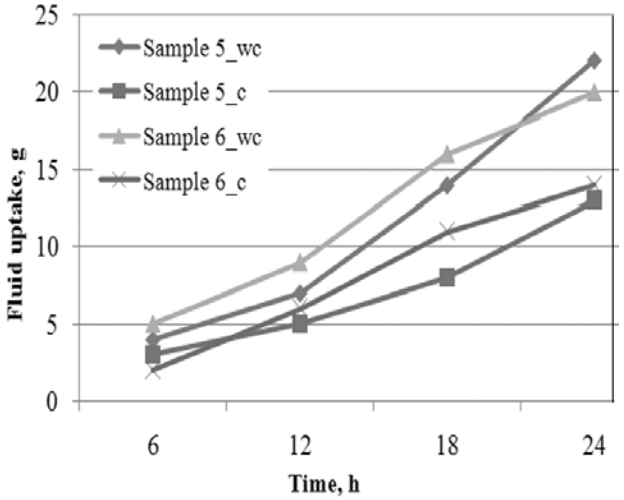

Fig. 6 — Fluid uptake over time for two different types of foam dressings (Sample 5_wc is without compression and 5_c is with compression; and Sample 6_wc is without compression and 6_c is with compression)

more reduction in fluid handling capacity can be seen compared to uncompressed sample.

4 Conclusion

A novel instrument has been designed and fabricated to assess the fluid handling capacity of materials used in the wound dressings. The test method can be used to generate data on the fluid handling properties of most types of dressings which will enable to get some basic predictions to be made about likely wear time.

In the clinical situation, when treating heavily exuding wounds, such as venous leg ulcers, it will be appropriate to select a product for exudate management that has been shown to perform well when subjected to clinically relevant levels of compression. For measuring or comparing the absorbent capacity of dressings in the laboratory, it is essential to take account of the effects of compression if the results of the investigation are to have any clinical relevance. The test system described in the present study clearly facilitates such comparisons, and appears to be able to detect significant differences in performance under compression.

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