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Moisture sensor for exudative wounds – A pilot study

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Abstract

Background: Exudative wounds cause discomfort for patients. Introduction of a moisture sensor to dressings could facilitate change of dressings only when needed. The aim of this pilot study was to evaluate the ability of a newly developed moisture sensor to detect moisture in relation to the absorbing capacity of the dressing.**Materials and Methods:** In five patients, with one leg ulcer each, three dressing changes per patient were observed. Interval of dressing change was according to clinical need and healthcare professional's decision. Sensor activation, dressing weight and complications were registered. To investigate the effect of dressing on sensor activation, half of the observations were made without an extra layer of non-woven between the dressing and sensor (Variant A), and half with (Variant B).**Results:** The sensor indicated time for dressing change in six out of fifteen observations. Variants A and B did not differ regarding activation or the timing of the activation.**Conclusions:** The addition of a moisture sensor for facilitating management of exudative wounds is promising. We recommend future larger studies evaluating the potential clinical benefits and risks of the addition of a moisture sensor. We also recommend evaluation of potential home monitoring of wounds by a moisture sensor.

KEYWORDS

exuding wounds, moisture sensor, wound dressings, wound healing

1 | INTRODUCTION

Having a wound can have a major impact on quality of life.¹ Wounds manifest in individual complications such as pain, distress, social isolation, anxiety, time expenditure for dressings, extended hospital stay, chronic morbidity or even mortality.² Treatment of wounds of different aetiologies constitutes about 2%-4% of the total healthcare expenditure costs in Europe, and as the population grows and people live longer, the costs are expected to increase.³⁻⁵

Contrary to what is often common belief, the main part (80%-85%) of the healthcare costs for wound treatment is due to nursing time and hospital or facility costs and not to the cost of dressings,

bandages or medications.² The time needed by nurses to care for wounds is a large expense, and the frequency with which dressing changes are needed is a resourcing concern. For instance, Lindholm et al showed that dressing changes required the equivalent of 57 full-time nurses for a Swedish community of 288 000 people and a typical wound prevalence of 2.4 wounds per 1000 population⁶ and studies performed in Ireland that up to 66% of community nursing time is taken up by wound care.^{7,8}

The most appropriate treatment option of a wound is an individually varying decision but necessarily involves maximising the patient's and wound's healing capacity without interfering with the healing process.⁹ This demands a holistic perspective where

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systemic diseases are considered and involves multiple choices for the caregiver. Wound management initially includes an assessment of the wound and its origin, cleansing followed by removal of non-viable tissue (debridement) to expose healthy tissue with the ability of proliferation to promote healing.¹⁰ After debridement, a wound dressing is applied which can be combined with antimicrobial compounds. Optimal timing and frequency of dressing changes are a complex issue and are influenced by multiple factors.² However, studies show that in the modern healthcare system changes tend to be made with a higher frequency than needed,² interfering with the wound healing process as well as generating increased costs.¹¹ On the other hand, too few dressing changes risk the development of maceration¹² which has negative effects on wound healing. An optimisation of the use of modern absorbent dressings towards fewer dressing changes would help reduce dressing material costs and time spent by nurses to wounds, thus freeing up resources that could be used on other important care activities.¹³ Further, less frequent dressing changes would provide patient benefits by reducing trauma to the wound area and maintain an optimal wound environment. Results would promote wound healing¹⁴ and fewer impositions on everyday life.

The possibilities afforded by "smart dressings" have attracted increasing attention.¹⁵ The addition of a moisture sensor to a wound dressing is one way to approach the question of wound dressing change frequency and has previously been evaluated in preclinical settings.^{16,17} To our knowledge, a moisture sensor adapted to a wound dressing has not been previously evaluated in a clinical context.

The aim of this study was to broaden our knowledge of the function of a moisture sensor adapted to a superabsorbent wound dressing in clinical use and practical operation, and to evaluate the combination of a moisture sensor on a superabsorbent dressing to decide whether the sensor is activated in a satisfactory way regarding the utilisation of the dressing's absorbing capacity whilst avoiding leakage and maceration.

2 | MATERIALS AND METHODS

The investigation was performed in accordance with the International Standard EN-ISO 14155:2011 and the Declaration of Helsinki and approved by the Regional Ethical Review Board in Linköping (permit number 2019-03560) and the Swedish Medical Products Agency (permit number 5.1-2019-47881). The study protocol was published on ClinicalTrials.gov (05/19/2018, NCT03468816) before the start of the study, and updated according to routine.

2.1 | Subjects

Five patients with one exudative leg ulcer each were included from two different study sites (Department of Dermatology, Linköping

University Hospital, Linköping, Sweden and S2 Wound Healing & Research Clinic, Linköping, Sweden) and followed during three dressing changes each. For inclusion and exclusion criteria, see Table 1. All enrolled patients gave their informed consent prior entry into the study, and all completed the planned three dressing changes.

2.2 | Wound dressings and sensor

The moisture sensor was placed on the superabsorbent wound dressing DryMax Extra Soft (Absorbest AB). The sensor (Absorbest Fuktensor, Absorbest AB) is a non-sterile medical device, with components printed as one unit on a thin, flexible, polymer material with conductive inks (Figure 1.). The sensor consists of three parts: (a) electrodes of carbon-zinc (Zn) and carbon-mangan dioxide (MnO₂); (b) a long conductor cord made of silver (Ag) coiled inside the electrodes; and (c) an electrochromic display attached to the conductor, placed in the middle of the conductor coil. Two combinations of the investigational device and dressing, named Variants A and B, were compared. Variant B had an extra layer of non-woven material between the moisture sensor and the dressing to delay the activation of the sensor compared to Variant A.

2.3 | Sensor principle of operation

Wound exudate contains ions, and as the core of the dressing becomes more saturated, the exudate finds its way out through the backing layer of the dressing to the electrodes of the sensor. When the ions reach the electrodes, a galvanic element forms and produces a small voltage potential and current, activating the display to show a clear blue drop. The study sensor does not require any batteries or software.

2.4 | Study protocol

Patients included in the study were undergoing treatment for exudative wounds and followed local clinical routine for wound management. The frequency of dressing change was decided individually for each patient by the HCP and varied between dressing changes every second day up to a week apart. To complete the study, each patient underwent three dressing changes with the investigational device. Each enrolled patient used both Variant A and Variant B in either the order A-B-A or B-A-B, according to a pre-designed randomised schedule to ensure equal numbers in both study arms. Between dressing changes, the patients were instructed to monitor the display and note and report whether a blue drop (display activation) appeared. At each dressing change, the HCP checked the display for activation, weighed the dressing and recorded the wound status.

The level of saturation of the dressings' absorbing capacities was determined by weighing the dressings before and after use. The level of saturation was prespecified by the manufacturer and defined by

TABLE 1 Inclusion and exclusion criteria. All the inclusion criteria had to be “Yes,” and all exclusion criteria “No” for the patient to be enrolled

Inclusion criteria	Exclusion criteria
Male or female, ≥ 18 y	Known pregnancy at the inclusion visit
Presence of moderate to high exuding leg ulcer, according to the clinician's assessment	Prisoner
The wound is deemed suitable for treatment with study product	Bleeding from the wound surface
The participant has given a written informed consent to participate in the study	The leg ulcer that is relevant for inclusion in the study is larger than 16 x 13 cm
	Known or suspected hypersensitivity to the study products or its components
	Mental inability, reluctance or language difficulties that cause difficulties in understanding the meaning of participating in the study
	The wound is infected
	Illness or treatment of an indication other than the wound and which, according to the study personnel, can affect the wound treatment, the study and/or the dressing

FIGURE 1 Picture of Absorbest Fuktsensor mounted on the backing side of the wound dressing. In this picture, the conductor coil and the display have been pulled out from the middle to be placed outside of the dressing



intervals of weight gain from the previously measured dry weight (Table 2).

The study was designed as a small explorative pilot study. Obtained data were analysed by descriptive statistics and presented as a cross-table.

3 | RESULTS

Detailed demographic data on the five participants can be seen in Table 3. The moisture sensors were activated by wound exudate in six out of fifteen applied dressings. The six dressing changes, using

the 20 x 20 cm dressings, had the highest weights on the used dressings compared to the other dressings, and hence the highest accrued exudate levels. The nine remaining cases, with less exudative wounds, and the 10 x 20 cm dressings, did not receive a sensor activation. For a more detailed description of activation data, see Table 4 (for more data, see Appendix 1).

As the data set was small, no statistical difference could be calculated for Variants A and B regarding activation or no activation. The non-woven material that was used between the sensor and the dressing in Variant B did not seem to influence on the timing of the activation.

Wound size was measured at the inclusion visit and at each of the dressing changes and the wounds included in this analysis

either remained unchanged or decreased slightly in size during the study period. There was no implication that the combination of DryMax Extra Soft and Absorbent Fuktensor had a negative impact on the wound healing process. The wound status, the wound edges and the surrounding skin did not change for any of the patients during the study period. Thus, the addition of the sensor did not affect the healing process in a negative way, but four adverse events in three patients with a possible connection to the study product did occur. In one case, the dressing adhered to the wound, and in three cases, the dressing edges or the sensor cord (Figure 2) caused mechanical imprints on healthy skin at the edge of the wound. Other adverse events noted in one patient were increased pain, growth of *Pseudomonas aeruginosa* and inflamed

surrounding skin. All events were graded as mild in intensity and unrelated to the study device.

In the six cases when the display indicated a dressing change, the moisture sensor was used on heavily exudative wounds. The sensor indicated for a dressing change just hours after a new dressing version had been applied. The display indication was then lost overnight, and the display returned to its initial state. Therefore, when the patients arrived at the clinic for the scheduled dressing change, the sensor display had lost its indication. The only exception was at one dressing change, where a faint blue drop was still visible.

4 | DISCUSSION

The combination of a moisture sensor adapted to a superabsorbent wound dressing to obtain an indication on timing of dressing reapplication has for the first time been evaluated in a clinical context.

Maintenance of a moist environment is widely accepted as the "ideal" environment for wounds to heal.¹⁸⁻²⁰ Exudate in the right amount can bathe the wound with nutrients and actively cleanse the wound's surface. The amount of exudate which is produced is individual to the wound however always tends to rise during the inflammatory phase and if infection is present. A delicate balance to keep the correct amount of fluid at the wound interface needs to be achieved.²¹ To handle wound exudate, advanced wound dressings have been developed with improved absorption and retention capacities.²² Whilst optimal dressing choice is important in achieving good healing progression, it is also important to minimise the frequency of dressing changes to allow healing to occur undisturbed.^{23,24} Despite the research and evidence to support the concept of leaving dressings in place, there remains a tendency for HCP to remove dressings unnecessarily.^{23,25} Patients and HCP could therefore benefit from a moisture sensor indication to help in the decision when to change wound dressing.²⁶ The healthcare system could also benefit from a moisture sensor in cases where the volume of wound fluid is difficult to anticipate and thus complicates the planning of continued care, such as estimating time for revisits and dressing changes. The caregiver and patient must, however, always consider the individual features of the wound and the overall assessment of the patient's

TABLE 2 The level of saturation for each dressing type was prespecified by the manufacturer and defined by intervals of weight gain in grams from the dry weight

Dressing size	Weight of dressing (g)		
	Changed too early	Interval for correct change	Changed too late
10 x 10 cm	<11	11-26	>26
10 x 20 cm	<17	17-62	>62
20 x 20 cm	<26	26-109	>109

TABLE 3 Detailed demographics of the participants in the study

Patient ID no.	Age	Sex	Type of leg ulcer	Position of wound
1	74 y	Female	Mixed venous/arterial	Above right ankle
2	60 y	Female	Venous	On left shin
3	77 y	Male	Likely venous	On left shin
4	78 y	Female	Venous	Inside of right shin
5	86 y	Female	Mixed venous/arterial	Most of left calf

TABLE 4 Cross-table showing number of dressing changes, variant used, sensor display indication at home and at scheduled hospital visit, leakage and strike-through in relation to correct or too late dressing change

				Display indication											
				Home			Visit ^a								
	Variant									Leakage		Strike-through			
	A	B	Sum	Yes	No	Sum	Yes	No	Sum	Yes	No	Sum	Yes	No	Sum
Changed too early	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Correct change	6	6	12	3	9	12	-	11	11	2	10	12	4	8	12
Changed too late	1	2	3	3	-	3	1	2	3	1	2	3	1	2	3
Sum	7	8	15	6	9	15	1	13	14	3	12	15	5	10	15

^aDue to a "not sure" answer, there are only 14 observations in the Visit group.



FIGURE 2 Mechanical imprint from sensor cord seen in one subject due to incorrect application of the sensor

situation and not only rely on the sensor reading to determine dressing change frequency.

The community expenses³⁻⁵ and patient suffering² related to wound care are of increasing interest. Strategies aimed at standardised wound care can support the quest for equal but still individualised care. Monitoring wound dressing moisture saturation and distribution is multifactorial depending on dressing absorption, position dependent to gravity, wound contact area in relation to dressing and the wound itself. In a laboratory setting, optimal dressing changes can be determined,¹⁶ but need to some extent be individualised clinically. In the nine cases in the present study where the sensors were not activated, all patients had less exudative wounds as indicated by absorbed exudate weights in the lower range of the pre-determined weight requirements for a “correct” change (17–62 g). The dressing weights after use ranged from 18 to 35 g, with no occurrence of leakage.

In six cases, the moisture sensor indicated the need for a dressing change just hours after the latest change, with the signal then fading away over time. Premature activation of the sensor would be an issue in clinical use and was noted as a device deficiency by one of the HCP. A plausible explanation to the phenomena is that a large excretion of exudate from the wound is absorbed vertically²⁷ by the DryMax Extra Soft dressing and flows through the dressing towards

the sensor. As there is a slight delay before the absorbing core of the dressing reaches its full absorption capacity, heavily exuding wounds may initially “flood” the core material, allowing moisture to reach the backing of the dressing. The moisture coming through activates the sensor electrodes, resulting in a premature sensor activation. As the backing material of the dressing is not designed for holding liquids, evaporation or re-absorption by the core may occur, thus causing the sensor electrodes to dry out and deactivating of the display. The extra layer between the sensor and the dressing in Variant B was expected to delay the activation in comparison with Variant A. However, no difference in activation between the variants could be found in this limited subject sample. Further research on factors affecting the sensor activation is therefore a possible area of product development, together with consideration of the importance of signal fading, caused by exudate drying.

The sensor cord caused a mechanical imprint with mild discomfort in one patient (Figure 2). This was due to an error in the application process by a nurse who afterwards was given clearer instructions not to place the cord directly towards the skin. However, it is not desirable from a comfort perspective and better instructions for application of the dressing with the moisture sensor including the sensor cord are suggested for future product use. The remaining adverse events reported are common problems for hard to heal wounds, and the study product was not likely to be the cause even if that cannot be ruled out.

This study is limited by the small number of subjects. We recommend future studies to include a larger population with more observations to evaluate the reliability of the sensor's ability to detect excessive wound fluid and further recognise the clinical aspects. The study is further limited since the exact timing of the activation of the sensors was not registered.

5 | CONCLUSIONS

This pilot study concludes that the combination of dressing and moisture sensor is promising. We recommend future larger studies evaluating the potential clinical benefits and risks of the addition of a moisture sensor. We also recommend scientific evaluation of potential home monitoring of wounds by a moisture sensor.

CONFLICT OF INTEREST

Author JS is an employee of the study sponsor Absorbest AB, Kisa, Sweden. The study was financed by Absorbest AB.

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APPENDIX 1

Results at dressing change 1, 2 and 3; weight of used dressing, categorised after interval set up in the clinical investigation plan, and display indication, leakage and strike-through

ID No.	Dressing size (cm)	Dressing wear time (d)	Weight of dressing (g)			Variant	Display Indication			Strike-through
			Changed too early	Correct change	Changed too late		Home	Visit	Leakage	
1	20 x 20 cm	3		78		A	Yes	No	No	Yes
		4			125	B	Yes	No	Yes	Yes
		4		100		A	Yes	No	Yes	Yes
2	10 x 20 cm	2		35		B	No	No	No	No
		2		30		A	No	No	No	No
		3		35		B	No	No	No	Yes
3	10 x 20 cm	3		25		B	No	Not sure	No	No
		3		21		A	No	No	No	No
		4		18		B	No	No	No	No
4	10 x 20 cm	4		23		B	No	No	No	No
		4		23		A	No	No	No	No
		3		22		B	No	No	No	No
5	20 x 20 cm	3			120	A	Yes	Yes (faint)	No	No
		5			111	B	Yes	No	No	No
		3		103		A	Yes	No (Very faint)	Yes	Yes