

Monitoring moisture without disturbing the wound dressing

The cost of chronic wounds is estimated in the UK to be £2.6 billion per annum, with 200,000 patients at any one time having a chronic wound (Posnett and Franks, 2005). The nursing time involved in dressing changes takes up a considerable amount of this cost. A major advance would be to monitor the moisture level at the wound bed while leaving the dressing undisturbed, with changes taking place only when necessary. An initial study of 15 patients with venous leg ulcers demonstrated the effectiveness of a new sensor to monitor moisture levels at the wound bed.

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KEY WORDS

Moisture balance
Wound healing
Clinical judgement
Moisture sensor
Patient empowerment

The concept of moist wound healing (MWH) is relatively new. It was possibly first espoused by John Bull and his co-workers (1948), and later demonstrated experimentally by George Winter (1962) and Howard Maibach (Hinman and Maibach, 1963). While these studies were conducted on experimental, acute wounds in animals (domestic pigs) and humans, their results have subsequently been interpreted as being representative of all wound healing situations. MWH is now accepted as useful in wound care (Dyson et al, 1988; Bryan, 2004; Van Rijswijk, 2004), based

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upon the evidence that cell proliferation and migration (notably of keratinocytes in re-epithelialisation) is facilitated by a moist environment.

Achieving a moist environment relies on good clinical judgement to determine the correct therapeutic levels, since too little moisture will desiccate the wound and too much will lead to maceration of the wound bed and surrounding tissue (Schultz et al, 2005). However, when the aim of wound management is not to progress the wound to healing, such

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as in palliative care where the goal may be to keep the wound dry to minimise dressing changes, holistic assessment is needed to manage symptoms in a way that is acceptable to the patient.

The need for moisture balance has resulted in the availability of a number of wound dressings, including; hydrogels, hydrocolloids, alginates, Hydrofiber® (ConvaTec) and foam dressings (Chen et al, 1992; Sibbald et al, 2000). One of the main objectives of such dressings is to achieve the optimum healing

environment and allow the wound to progress to healing undisturbed. This, in turn, should promote cost-effectiveness both in terms of consumables and staff time to carry out wound care. Indications of excess moisture or strikethrough on such dressings are usually visual changes on backing materials or leakage from the dressing, and it is often difficult to judge if there is too little moisture or if moist conditions exist without removing the dressing and disturbing the healing process.

Until now it has not been possible to combine a practical moisture sensor with a dressing and leave it *in situ* on the patient. This paper introduces a new, disposable sensor, suitable for use with most types of wounds and wound dressings, that can monitor moisture at the wound-to-dressing interface without disturbing the wound.

The possibility of moisture monitoring at the surface of a wound can enhance clinical practice, as decisions regarding dressing changes can be made non-invasively. Systems have been reported that can successfully and non-invasively provide an assessment of moisture *in vitro* (McColl et al, 2007; Young et al, 2007). The *in vivo* sensor system reported here has been tested and shown to be suitable for patient use.

The new device comprises a single-use, sterile, disposable sensor that is

replaced at every dressing change, and a portable, hand-held meter that is applied to the tags of the sensor at the edge of the dressing when the carer or clinician wishes to record moisture levels. The system was developed following several years of study of moisture-monitoring devices on a wound bed model (McColl et al, 2007) and tested on venous leg ulcers (VLUs) *in vivo*, as reported below.

Method of operation

Before applying the dressing the clinician cleanses the wound as per best practice guidelines and places the sensor onto the wound, ensuring that the porous, non-adhesive coating of the sensor is placed downwards. *Figure 1* shows the sensor and its non-adhesive coating. The porous non-adhesive cover is bonded to the sensor pair but can be cut to a smaller size if the dressing chosen for use with the sensor is smaller than the area of the non-adhesive cover. Sensor tags, found at the end of the paired sensor electrodes, are taped down at the edge of the dressing (if an adhesive dressing is used). The longer sensor, as used in this study for leg ulcers, can have the tags tucked into the patient's bandage.

To read the moisture level, the tags are freed from the edge of the dressing or bandage and the portable meter is clipped onto them. The meter applies a low, alternating current to the sensor. The sensor is made up of a pair of small, silver chloride electrodes. The low current applied through the paired sensor electrodes does not interfere with local tissue or patient comfort and after ten to thirty seconds a reading of moisture level is obtained, based on the value of electrical impedance across the sensor electrodes. As ions and other charged molecules move in the wound exudate under the influence of electric current, it is possible to relate electrical impedance readings to five useful clinical bands of moisture level at the wound interface. Dry environments do not allow charges to move around and cause high electrical impedance readings, wet environments lead to easy charge movement and low impedance readings. The desired 'moist' condition is a range of impedance located between the high and low values.

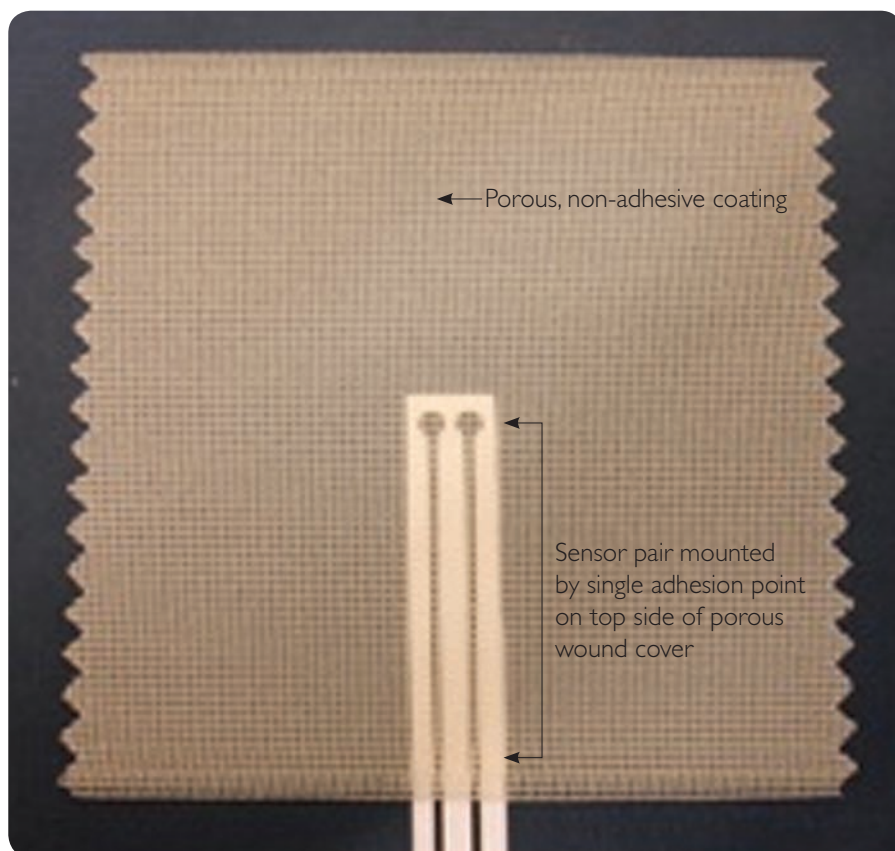


Figure 1. Disposable sensor which is placed on the wound during dressing change.

The five moisture bands discernable from the sensor readings are:

- ▶▶ Dry: electrically high impedance
- ▶▶ Dry to moist: impedance falling from high levels to mid-range
- ▶▶ Moist: mid-range impedance
- ▶▶ Moist to wet: impedance tending to low
- ▶▶ Wet: low impedance.

The clinician can use the moisture band reading to decide if a dressing change is appropriate. For example, a 'wet' reading should trigger a dressing change. A 'moist to wet' reading might not trigger a dressing change and result in advising the patient that the dressing can stay *in situ* for longer. The clinician can use the moisture band to decide if a dressing change is needed or not, tailored to suit ward or clinic routine, or to limit changes due to patient expectations/demand. Dowsett reported that, 'frequent dressing changes are often inconvenient for the patient and costly for the health services in terms of clinician time and dressings product usage' (Dowsett, 2008).

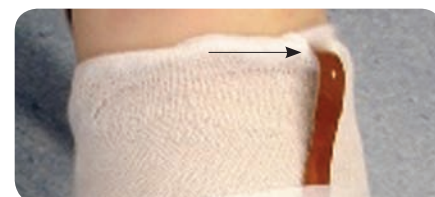


Figure 2. Venous leg ulcer with compression bandage. Arrow indicates end of sensor tag, in this case tucked into the bandage and taped.

Venous leg ulcer (VLU) study

In the authors' study, the sensor was tested on 15 patients recruited at the beginning of compression treatment for a VLU, normally a six-week regimen. No clinical intervention was made based on the sensor readings, as the object of the study was to show that readings of the sensor in the five moisture bands listed above corresponded with clinical observations of the wound.

The aims of the study were:

- ▶▶ To test the application of the disposable sensor in conjunction with an accepted bandaging system
- ▶▶ To compare the moisture band reading by the meter with visual inspection of wounds

- ▶ To gain the patient's perspective on wound monitoring via a sensor as part of treatment.

Materials and methods

Ethical approval

The study was conducted through a single VLU clinic situated within NHS Greater Glasgow and Clyde at the Clydebank Health Centre. All dressings were changed by trained nursing staff who were also given a short training on the use of the meter. As this was a clinical trial of a medical device, NHS ethics and Medicines and Healthcare products Regulatory Agency (MHRA) approval were sought and obtained before starting the study.

Subjects

To determine the viability of the wound monitor according to the volume of wound exudate produced, all the subjects selected had a non-infected, granulating VLU. Consent forms were provided and subjects were given the opportunity to ask questions before enrolment in the study.

Measurement system

A flexible, sterile moisture sensor, attached to a simple, non-adherent porous wound dressing, was included as part of standard care for managing a venous leg ulcer. The active part of the sensor was centred over the wound and then bound in place with a compression bandaging system comprising a two-layer absorbent padding system and an Actico short-stretch bandage (Activa Healthcare) (Figure 2).

Meter measurements were performed daily (Monday–Friday), usually in the patient's home, by a research nurse over a four-week period. Each measurement taken with the portable meter required about 10–30 seconds, and provided a numerical value that could be related to hydration. Wound dressings were replaced weekly at the clinic, regardless of the meter reading, where the wound size was measured to track healing and photographs were taken to validate the hydration measurements visually.

Questionnaire

Each subject was asked to complete a

short, multiple choice questionnaire at the end of the trial to give an insight as to how the device was received. The scoring scale was from one to four: one indicating a positive response and four a negative one.

Results

In total, 15 patients were enrolled in the study, of which eight were men (29–94 years of age) and seven were women (60–88 years of age). Nine of the study group (60%) completed the observations with the monitor. Two subjects (13%) were withdrawn from the trial for non-compliance and four subjects (26%) were withdrawn after they were judged to have wound or other infections that required antibiotic treatment. The wound infections that were encountered in this group were judged by the clinical staff to be related to previously unswabbed lateral ankle ulcers, not to the use of the sensor system. All of the patients who demonstrated a healed VLU in the trial did so within a maximum of four weeks.

Moisture observations

Dry, moist and hydrated wounds were observed during the study and these corresponded well with the critical 'moisture bands' obtained from the meter readings, as shown by the following cases.

Case one: excess exudate, moisture band 'wet'

The patient had a wound on the medial side of the right shin, half-way down the leg. This wound had been treated for four weeks before enrolment in the study.

At the end of week one the meter was applied to the tags on the sensor for sixty seconds before the bandage was removed. This gave a low impedance reading corresponding to 'wet'. This is indicative of excess wound exudate at the surface of the wound, which was evident from visual inspection.

Figure 3 shows the wound at the end of week one (immediately after removal of the dressing and before cleaning).

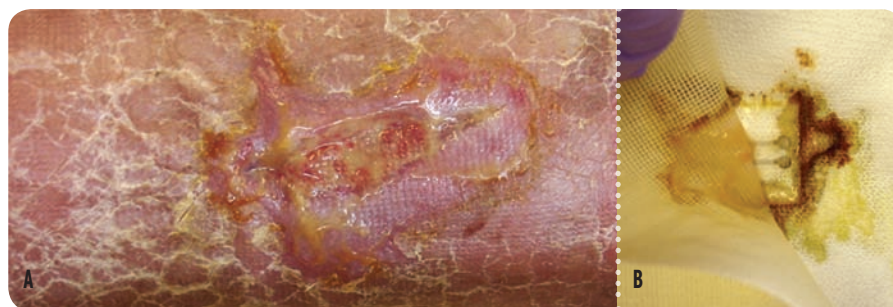


Figure 3. Photographic record of patient at dressing change. A shows the patient's wound with a visible layer of exudate upon dressing removal. B shows the porous contact layer which had been pushed back from the sensor electrodes, showing the spread of exudate.

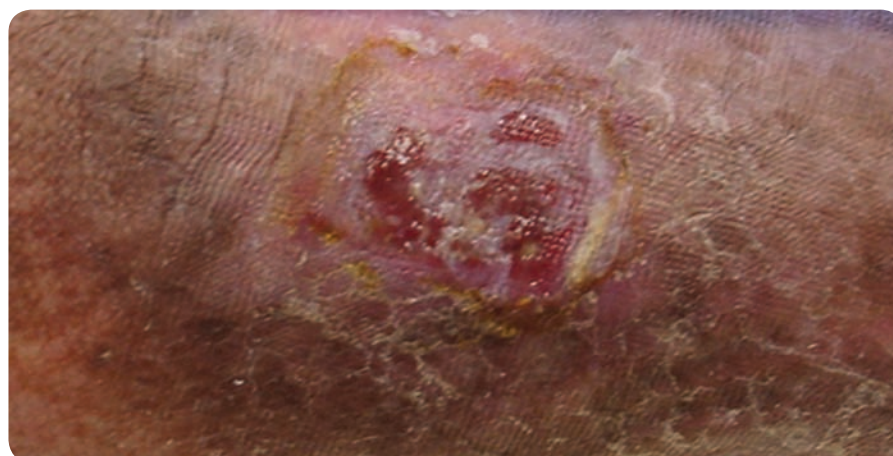


Figure 4. Photographic record of patient in case two at dressing change at the end of the second week of observation. Moist, granulating wound, corresponding to a 'moist' meter reading.

Case two: moist wound, moisture band 'moist'

The patient, who had been receiving treatment for two weeks before the start of the trial, presented with a moist wound on the front of the right leg.

Figure 4 shows a moist, healing wound with no evidence of excess moisture at the end of the second week of observation, immediately after removal of the bandage. Likewise, the reading on the meter immediately before removal of the dressing corresponded to 'moist', indicating the presence of moisture at the wound surface.

Case three: dry wound, moisture band 'dry'

A reduction in exudate level is a good indicator of healing for venous leg ulcers. In a non-healing wound, exudate production may continue and be excessive due to ongoing inflammatory or other processes (World Union of Wound Healing Societies [WUWHS], 2007). In this case the wound healed during the trial with the wound monitor. The patient had been receiving treatment for four weeks before enrolment in the study. Figure 5 shows the wound immediately after the dressing was removed at the end of week four of the trial. Little evidence of moisture was found on the dressing. The corresponding moisture band from the meter reading immediately before dressing removal was 'dry', indicating a dry environment at the sensor-to-wound interface.

Questionnaire

The wound monitor was well received by the subjects, with the average

Table 1

Results of patient questionnaire, post study

Wearing the wound monitor	Mean	Not at all	A little	Quite a bit	Very much
Did you experience any discomfort with the sensor?	1.3	86%	7%	0%	7%
Would you have any objection to wearing the sensor as part of your ongoing treatment?	1.2	93%	0%	0%	7%
Did you feel that the sensor inhibited you doing anything that would otherwise be possible in your daily life?	1.2	86%	7%	7%	0%
Were you consistently aware of the presence of the sensor?	1.4	79%	14%	0%	7%
Did you find the ends of the wires caught on your clothing during the day, or on your bedding at night?	1.1	93%	7%	0%	0%
Did you feel any sensation when the monitor was connected and in use?	1.0	100%	0%	0%	0%
Did you experience any additional discomfort specifically in the wound area?	1.5	71%	14%	7%	7%
Did you feel that the sensor was the cause of any additional discomfort when the dressing was changed?	1.3	79%	14%	7%	0%

question score never rising above 1.5 (Table 1). Overall, the percentage of positive responses was always 71% or greater. It is particularly worth noting that 100% of the subjects did not feel any sensation when the wound monitor was in operation. In addition, all but one of the subjects had no objection to wearing the sensor as part of their ongoing treatment.

Discussion

Observations with impedance

The study demonstrated that the moisture band that can be assigned to a reading obtained from the meter when connected to the sensor is linked to the moisture at the wound surface. There is a marked difference between dry and moist in electrical measurement terms, so the bands of dry, wet and moist are well separated. This would suggest that the monitor can be used to aid clinical judgement as to when a wound dressing should be changed, without disturbing the dressing.

In turn, this impedance sensor system may also provide a clinical indicator of any rapid increase in moisture due to infection, indicating that further wound assessment is required. Consistent wet readings may also highlight an inappropriate choice of dressing and that a more absorbent product is required.

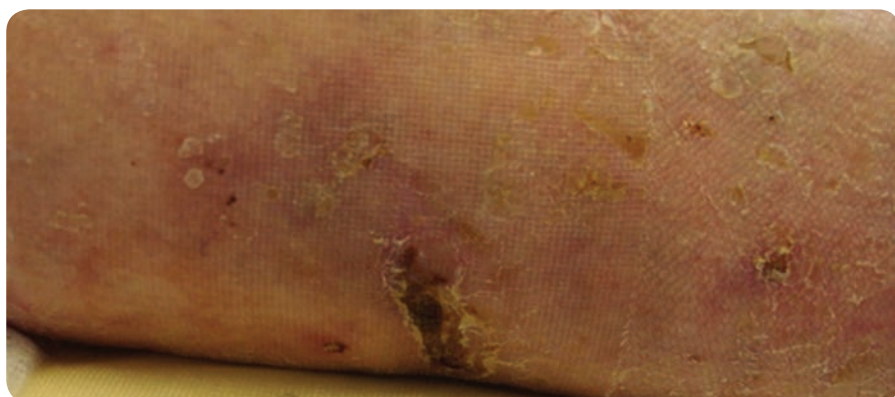


Figure 5. Photographic record of dry, healed ulcer at the end of four weeks of treatment. The reading from the meter corresponded to 'dry' immediately before dressing removal.

Questionnaire

The results of the questionnaire were encouraging with few subjects indicating that they felt additional discomfort while wearing the sensor. Those who experienced the greatest amount of discomfort from the sensor had a venous leg ulcer on the lateral side of the leg. A study conducted by Savic et al (2007) looking at the perceptual thresholds in subjects, revealed that the lateral part of the leg is more sensitive than the medial aspect, which could explain the higher scores in these patients (Savic, 2007).

Limitations

In general, the wound monitor provided an accurate indication of the moisture conditions under the wound dressing. There were relatively few occasions when the reading provided by the meter was in contrast to the visually observed wound condition, the most common being immediately after the dressing was replaced. In this instance, the meter would provide a high level of impedance suggesting a dry wound, whereas the photograph taken prior to bandaging suggested that the wound was moist. This high reading relates to the time taken for the porous dressing on the sensor to fully absorb the wound moisture. In most cases the impedance lowered as the sensor equilibrated and wound exudate was produced, and readings taken by the research nurse the next day usually indicated a moist wound.

At dressing changes there was close agreement between the meter measurements and the visual observations. The most common reason for discrepancies was slippage of the dressing and sensor from the wound area, particularly in the younger, more active subjects, and for those who had wounds on the lateral side of the ankle.

Conclusions

The wound monitor was used to indicate the presence of moisture at the surface of wounds underneath compression bandages without disturbing the wound environment.

By identifying varying degrees of moisture, the wound monitor could

become a useful tool in assessing the progress of treatment and in aiding clinical judgement of dressing changes. The tool has the potential not only to be a valuable adjuvant to cost-effective management of wounds for the clinician, but to empower patients who are being managed at home to determine whether they need to attend clinic or arrange for the district nurse to call to carry out dressing changes.

The device could be implemented in a variety of new studies, such as examining if this moisture measurement technology reduces the incidence of peri-wound maceration due to its prompting of timely dressing changes. In addition, it would be interesting to study the device's effect on patient empowerment.

Future work

The sensor and meter will be commercially available for clinical and home use in the EU and Middle East from October 2009, marketed by Ohmedics Ltd (www.ohmedics.com). It is hoped that the system will attain widespread use in supporting clinical decisions in wound management. **WUK**

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Key points

- ▶▶ Excess exudate from a wound can have a detrimental effect on the wound bed and surrounding peri-wound margins.
- ▶▶ Moisture control to avoid desiccation or excess exudate during wound healing is part of accepted best practice in wound management.
- ▶▶ Patients found the new sensor technology unobtrusive and the device was well tolerated in a venous leg ulcer study.