An observational evaluation of a new foam adhesive dressing

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Abstract
Following the work of Winter demonstrating the benefits of moist wound healing, there has been a constant stream of wound care products launched into the market to support this concept. This article will describe the findings of an observational evaluation to observe, document and analyse the clinical effectiveness of a new foam adhesive dressing, UrgoTul® Absorb Border (Urgo Medical). The main objective of the evaluation was to define the parameters to allow data capture that would demonstrate the clinical effectiveness of the dressing. Parameters studied and analysed included atrumatic pain-free dressing changes; ease of dressing application; comfort and conformity; exudate management; ability of the dressing to stay in place; and peri-wound skin management. A total of 25 patients with wounds suitable to be dressed using the evaluation product were recruited following a full documented wound assessment by the tissue viability nurse. Participants were selected across the organisation from acute hospital wards and outpatient departments, care homes, wound care clinics and the participants’ own homes. Digital photography was used to demonstrate improvement or deterioration of the wound bed and surrounding skin, and images were assessed by non-participating clinicians to confirm documented observations made within the evaluation. The dressing was found to be clinically effective in both chronic and acute wound types, and had an excellent level of participant acceptance.

Key words: Fibroblast proliferation ■ TLC healing matrix ■ Silicone border ■ Exudate management

New wound care dressings are commonly developed based on the ability to enhance wound healing, while claiming unique features aimed at improving the wound care experience for both the patient and clinician. Wound dressings are known to have various functions including the promotion of patient dignity, enhancement of natural autolysis, moisture management, odour control, improvement of the bacterial balance, and pain relief for patient comfort. All of these elements have a role to play to support the maintenance of the optimum wound healing environment (Thomas, 1997). Some wound care dressings have precise indications, while others are suitable for a much broader range of wound types. However, all wound dressings can influence the way the wound progresses. The clinician must have a clear understanding of the wound healing trajectory and how the properties within the selected wound dressing can enhance this process for the assessed wound (Thomas, 1997).

The technology
Many wound management dressings are available to clinician; hence, this evaluation sought to ascertain the clinical effectiveness of UrgoTul® Absorb Border and investigate its claims of extensive advantages in relation to both participant- and clinician-assessed outcomes (Bullough et al, 2014). The dressing comprises a soft silicone border and a polyurethane foam pad with an additional highly absorbent layer that is covered with a non-adherent technology lipido-colloid (TLC) healing matrix. The TLC healing matrix promotes a moist wound healing environment and contains hydrocolloid and lipophilic particles, which have been shown to promote the proliferation of fibroblasts (McGrath et al, 2014). Additionally, a lipido-colloid gel is created when these particles come into contact with exudate, allowing maintenance of the optimum moist wound healing environment (White et al, 2015).

A number of foam dressings contain a soft, silicone layer across the entire surface to encourage the optimum moist environment while supporting non-adherence of the foam dressing to the wound bed (Bernard et al, 2007). Silicone is hydrophobic (Meuleneire and Rücknagel, 2013); therefore, these dressings will maintain a moist environment, supporting wound healing. Silicone does not interact with the wound in the same way as the TLC healing matrix to enhance fibroblast proliferation (Bernard et al, 2005) and, therefore, only has the ability to absorb fluid while minimising the risk of adherence. Studies have shown that the advantage of a foam with a TLC healing matrix is the interaction within the wound, resulting in the stimulation of fibroblasts during the proliferative phase of healing (Bernard et al, 2005; Fays et al, 2005; Bernard et al, 2009).

Fibroblast proliferation has an essential role in assisting the wound to progress along a normal and timely healing trajectory (Schulz et al, 2005). This is achieved through the fibroblasts that enable collagen and extracellular matrix (ECM) synthesis, which is fundamental to the formation of new granulation tissue. A reduction in the number of fibroblasts present will naturally result in a much slower progression to wound healing (Bernard et al, 2005).

UrgoTul Absorb Border is the only foam dressing that enables direct contact between the TLC technology and the wound bed, which is why the authors considered it necessary to evaluate its advantages. UrgoTul Absorb Border has demonstrated...
an ability to manage exudate (Bullough et al, 2014) and enhance proliferation of fibroblasts by 45% (Bernard et al, 2005; Meuleneire and Rücknagel, 2013), while simultaneously achieving peri-wound skin management, atraumatic removal and pain-free dressing changes (Benbow and Iossen, 2004; Smith et al, 2004; Urgo Medical, unpublished observations).

The study set out to investigate the tolerability and acceptability of the dressing, and included the assessment of a variety of wound types by their aetiology and with specific patient-focused parameters. These parameters for observation included comfort, healing rates, absorption, and the ability of the dressing to remain in situ while enabling the participant to continue with their normal, daily activities without the need for dressing interference.

Method

Before the initiation of the multi-site observational evaluation, it was registered with the procurement department of the trust for authorisation to undertake this work across Walsall Healthcare NHS Trust. Clinical photographs were taken and full informed patient consent was gained before definitive recruitment. Participants were recruited across a number of care settings within the integrated organisation including care homes, wound clinics, patients’ own homes, outpatient departments and acute hospital wards.

The consultant tissue viability nurse, in conjunction with the honorary contract tissue viability nurse, developed the bespoke evaluation data-collection tool to capture detailed baseline information and parameters to be evaluated. This tool was designed to ensure a consistent approach by all involved, as participating clinicians ranged from tissue viability nurses and wound care clinic nurse leads, to community nurses, district nurses and care home nursing staff. The intention was to recruit patients over a 6-month period from the care settings identified. The data-collection tool was initially piloted on five patients from across the Walsall healthcare economy prior to full implementation. Following this pilot period, no amendments were deemed necessary as all participant parameters were included. The tool design supported standardised data-capture and ease of completion to allow for the range of clinicians who would be involved in documenting their findings.

The inclusion criteria were:

- Presence of epithelial and/or granulation tissue
- \(<50\%\) slough
- \(<50\%\) necrosis
- Minimum wound surface area of 10 mm x 5 mm
- Ability to give informed consent
- No maximum wound surface area
- Low-to-moderate exudate levels
- Patients aged 18 years or older

All wounds were considered suitable for inclusion, regardless of duration. Acute wounds were defined as less than 6 weeks old and chronic wounds as over 6 weeks in duration.

The exclusion criteria included:

- Any patient not able to give written and verbal consent
- Presence of infection within the wound bed
- A wound that required more active treatment, such as desloughing or debriding

Irrespective of previous dressings used, any patients who met the selection criteria were recruited into the evaluation. Before use of the evaluation dressing, previous products used by the participants were either thin hydrocolloid dressings or silicone adhesive foam. As these patients’ wounds had not progressed

<table>
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<th>Table 1. Evaluation parameters</th>
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<td>Wound</td>
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<th>Table 2. Likert scale</th>
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![Figure 1. Wound locations](image1.png)

- Abdomen (n=1)
- Lower limb (n=13)
- Sacrum (n=3)
- Breast (n=1)
- Foot (n=2)
- Hip (n=1)
- Knee (n=1)
- Ankle (n=1)

![Figure 2. Wound aetiologies](image2.png)

- Pressure damage (n=6)
- Venous leg ulcer (n=7)
- Arterial leg ulcer (n=1)
- Mixed aetiology leg ulcer (n=4)
- Traumatic wound (n=2)
- Dehisced surgical wound (n=2)
- Palliative wound (n=1)

Patients who were less than 18 years of age.
The honorary contract tissue viability nurse delivered training to all staff regarding application and removal techniques for the evaluation product before commencement of the evaluation. A standard evaluation pack was left with each recruitment site and the completion monitored by the lead author. The authors recognise the subjectivity of this data but aimed to minimise this through guidance on how to complete the evaluation form and ongoing monitoring.

Data were collected at each dressing change with a full wound review documented. In addition to this, a digital photograph was taken. To ascertain the level of patient acceptability, a sequence of comfort-related questions were verbally asked by the clinician making the assessment using the Likert scale (Table 1).

The clinicians were asked to rate the assessment based on their observation of dressing application, ability to stay in place and handle exudate, conformability, ease of removal and condition of the patient’s peri-wound edge. Patient comfort on dressing removal was assessed using the visual analogue pain scale (Collins et al, 1997).

The photographs were evaluated by the tissue viability team. However, in order to limit the potential for bias, non-participant clinicians were asked for their opinions on the wound status at baseline and on completion of the evaluation. These clinicians were tissue viability team members who were not involved in the evaluations. On completion of the evaluation period, all data-collection tools, photographs and supporting documentation were returned to the tissue viability team for data entry.

Results
A total of 25 patients were selected for inclusion into the observational evaluation. The data for two patients were not included owing to lost paperwork, leaving a total of 23 participants whose data are included in the findings. The mean age was 82 years old with a female-male split of 57% (n=13) and 43% (n=10), respectively. The wound duration ranged from 3 days to greater than 2 years, with a mean chronic wound age of 48 weeks. Chronic wounds accounted for 83% (n=19) of the participants, while the remainder had acute wounds (n=4). The area of the body affected by the wound varied but included some difficult-to-dress areas, such as the breast, hip and knee (Figure 1), with a number of wound aetiologies (Figure 2). Wound size ranged from the minimum wound size for inclusion (10 mm x 5 mm) to the largest, some of which were circumferential on the lower limbs.

Of the 23 participants, only 3 (13%) were self-caring and able to bathe or shower independently. However, when questioned on dressing adherence, all stated the ability of the product to remain in situ for three showers within a 7-day period.

Figure 3 shows the condition of the peri-wound skin on initial assessment in the evaluation. At the end of the evaluation, a total of 87% (n=20) of the participants showed an improvement to this surrounding area.

The optimum moist wound healing environment relies on effective management of excess exudate. Exudate levels recorded varied from light/low levels to high, with the majority (70%; n=16) being within the light-to-low category. By the end of the evaluation, all participants had either
none or light-to-low levels of exudate demonstrating an improvement. Data analysis of the dressing's ability to manage exudate indicates that the clinicians have rated 96% (n=22) of the evaluations as either ‘very good’ or ‘excellent’. The remaining 4% were recorded as ‘good’.

All participants received a minimum of six evaluation dressing changes with the exception of 17% (n=4) who achieved full healing within a 5-week period.

The results (Figure 4) demonstrated a wide range of notable outcomes. A total of 135 dressing changes were completed across the 23 wounds, suggesting a mean of 6 dressing changes per participant. Where the community nurse teams and care home staff were completing the dressing changes, they were responsible for ensuring the evaluation documentation was complete. In 96% (n=22) of the wounds observed, the clinicians rated the conformability of the dressing as ‘very good’ or ‘excellent’ with the remaining 4% (n=1) rated as ‘good’. At no time was it documented that the dressing adhered to the wound or caused any trauma, either while in situ or on removal. As a result of non-concordance from one patient, the dressing remained in place for 14 days and despite a recommended average wear-time of up to 7 days, the wound improved.

Further results reported for the parameter, ‘patient comfort during wear’ included 4% (n=1) rated as ‘good’, and 96% (n=22) rated as ‘very good’ or excellent. For the parameter, ‘ability to remain in position’, 87% (n=20) were reported as ‘excellent’ or ‘very good’ by clinicians.

This included 30% (n=7) of the total wound dressings, which used compression therapy in addition to the primary evaluation dressing. On removal of the compression, the dressing remained in situ with no evidence of slippage under the bandage and was removed by the clinician with ease. One clinician documented...
PRODUCT EVALUATION

Case Study 3
A 54-year-old female patient presented to the wound clinic with a traumatic wound to her left foot. On initiation, the wound measured 1 cm x 1 cm with minimal depth and had been present in excess of 9 months with no improvement seen. Previous treatment included a foam adhesive dressing with silicone in contact with the wound bed. The wound care nurse chose to use the UrgoTul Absorb Border for this patient owing to the direct contact between the TLC healing matrix and the wound bed and surrounding skin, with the rationale to minimise the current pruritis, offer extra absorbency and stimulate wound healing. The patient attended the wound clinic on a weekly basis for dressing changes and despite

that she felt she had used an inappropriate dressing size for a difficult-to-dress wound area and once this was amended, her parameter rating for 'ability to stay in place' increased.

Four case studies representing the different wound types and locations included in the evaluation are described.

Case Study 1
A 54-year-old female patient presented to the wound clinic with a traumatic wound to her left foot. On initiation, the wound measured 1 cm x 1 cm with minimal depth and had been present in excess of 9 months with no improvement seen. Previous treatment included a foam adhesive dressing with silicone in contact with the wound bed. The wound care nurse chose to use the UrgoTul Absorb Border for this patient owing to the direct contact between the TLC healing matrix and the wound bed and surrounding skin, with the rationale to minimise the current pruritis, offer extra absorbency and stimulate wound healing. The patient attended the wound clinic on a weekly basis for dressing changes and despite

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Case Study 2
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showering a minimum of three times per week, the dressing remained in situ. UrgoTul Absorb Border alleviated the pruritus and improved the peri-wound skin, which has been prone to irritation from previous wound dressings.

**Case Study 2**

An 84-year-old female patient presented to the wound clinic with a circumferential venous leg ulcer to her left leg. The wound had areas of maceration evident and had been present in excess of 3 months with no improvement seen. Previous treatment included a wound contact layer and absorbent pad beneath a short stretch bandage. The tissue viability nurse chose to use the dressing, with the rationale being to alleviate maceration of the wound, offer extra absorbency, stimulate wound healing and allow pain-free dressing changes. Use of a short-stretch bandage was continued to promote venous return.

**Case Study 3**

An 85-year-old male patient was recruited for the study as his chronic abdominal wound was not progressing as expected with a silicone foam dressing. Exudate levels were not being efficiently managed with this dressing. Therefore, enhanced fibroblast proliferation and absorbency were the specific considerations for this patient. The wound measured 4.5 cm x 6 cm on commencement with UrgoTul Absorb Border and, within 7 days, the exudate was effectively managed and the wound measurements reduced to 6 cm x 2 cm (at the widest point), representing a 56% reduction in wound surface area. Before his care was transferred out of the area, the final wound measurements were 5 cm x 1.9 cm at day 28, equalling a total surface area reduction of 64% within 4 weeks.

**Case Study 4**

A doubly incontinent, 80-year-old female patient with a pressure ulcer on her sacral area was initiated by a member of the tissue viability team and followed up by the district nursing team, who had previously prescribed a silicone foam dressing which caused distress to the patient on removal. Although pressure redistribution was a contributing factor, this had been continually in place during the previous dressing regime where there had been no healing progression.

**Discussion**

The ability to maintain normality and patient acceptability are key criteria for any clinician carrying out an evaluation of a new product. This study recruited 22 participants to evaluate UrgoTul Absorb Border within an integrated healthcare organisation. The clinical effectiveness has been demonstrated by the encouraging results; however, the authors acknowledge that the sample size was small and further clinical outcomes may be explored with more specific data capture, particularly in relation to wound surface area and levels of exudate. The bespoke evaluation tool could also be enhanced to capture more in-depth patient parameters as this would enable a more comprehensive understanding with comparative data capture. To depict a much broader range of wounds by aetiology with larger participant numbers would be more accurately representative of the local demographics within the integrated healthcare organisation’s population.

Incorporating the TLC healing matrix layer into the adhesive foam dressing (UrgoTul Absorb Border) that interacts with the wound bed has the benefit of enhancing fibroblast proliferation. Foam dressings containing silicone that have direct contact with the wound bed do not offer this advantage.

The measurement of the participants’ experience of pain can be very subjective; therefore, use of a visual pain scale attempts to capture levels of pain via a more consistent means. With the capacity to remain in place, manage moisture and avert further trauma to the patient and wound, UrgoTul Absorb Border has been shown to meet patient and clinician expectations, and has the potential to achieve economic benefits by reducing dress-change frequency and accelerating healing times.

**Conclusion**

This observational evaluation found UrgoTul Absorb Border to be a versatile dressing as it demonstrated effectiveness across a selection of both acute and chronic wounds when used as a primary dressing. It demonstrated the ability to manage wound exudate levels and improve surrounding skin.

Throughout the evaluation period, all wounds showed an improvement and progression to healing. The atraumatic, pain-free dressing removal was reported by participants who also found the dressing to be comfortable and reported that it allowed them the freedom to carry out their normal activities of daily living, such as having a shower.

Both clinicians and participants involved in the study confirm that none of the dressings used adhered to the wound bed, making this dressing an suitable choice for a wide range of both acute and chronic wounds.

**Conflict of interest:** This study was made possible by an educational grant supported by Urgo Medical Ltd. UrgoTul Absorb Border is a registered trademark of Urgo Medical Ltd. Elizabeth Merlin-Manton was an Urgo Medical employee when this evaluation was conducted and written. Michelle Greenwood became an Urgo Medical employee after this evaluation was completed.

Winter GD (1962) Formation of the scar and the rate of epithelization of superficial wounds in the skin of the young domestic pig. Nature 193:293–4
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