Assessing an adherent silicone foam dressing: a clinical evaluation across five NHS trusts

Abstract

The wound contact layer of UrgoTul Absorb Border (Urgo Medical) foam dressing contains a Technology Lipido Colloid (TLC) Healing Matrix, which includes hydrocolloid and lipophilic substances designed to stimulate fibroblast proliferation and thus promote granulation tissue formation. A multicentre, noncomparative, clinical evaluation of UrgoTul Absorb Border investigated whether use of the dressing promoted granulation tissue formation and the management of wound exudate. Other parameters evaluated included: pain-free dressing changes, protection and improvement of surrounding tissue, ease of application, conformability, ability to remain in place, wear time, effect on peri-wound skin, durability, ease of removal, and patient comfort. There were 43 patients recruited into the evaluation. Results show that 8 wounds (19%) achieved full epithelialisation and 34 (81%) improved. All participating clinicians rated the dressing's overall performance, including its ability to manage exudate, as excellent, very good, or good.

■ foam dressing ■ wounds ■ exudate ■ wound healing ■ silicone

Fibroblast proliferation plays a vital role in helping a wound to progress along a healing trajectory in a normal and timely fashion (Schultz et al, 2005). Fibroblasts enable collagen and extracellular matrix (ECM) synthesis, resulting in the formation of new granulation tissue. A reduction in the number of fibroblasts in the wound would therefore impair healing (Bernard et al 2005, Bernard et al 2007, and Bernard et al 2009).

The Technology Lipido Colloid (TLC) Healing Matrix, which is the key component in Urgo Medical's TLC dressing range, contains hydrocolloid and lipophilic substances that stimulate fibroblast proliferation and thus promote the production of granulation tissue, which assists wound healing (Bernard et al, 2005; Bernard et al, 2009). In in-vitro studies, the TLC Healing Matrix was observed to enhance human dermal fibroblast proliferation (Bernard et al, 2005) and increase the production of hyaluronic acid and collagen, thereby helping to regenerate the extracellular matrix (Bernard et al, 2007). This effect should improve the structure, flexibility and strength of the dermis, thereby contributing to optimal healing (Meaume et al, 2011).

The TLC Healing Matrix is designed to promote moist wound healing: when the hydrocolloid and lipophilic particles contained within the TLC layer come into contact with exudate, they create a lipido-colloid gel that promotes a moist wound environment (White et al, 2015). A large clinical evidence base, drawn from 170 clinical trials involving

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52 889 patients, supports the efficacy of the TLC Healing Matrix. The evidence base has been reviewed and collated into a document by White et al (2015).

UrgoTul Absorb Border (Urgo Medical) is an absorbent foam dressing with a shower-proof silicone adhesive border. The surface of the foam that comes into direct contact with the wound is coated with the TLC Healing Matrix, with a view to promoting a moist healing environment.

The current evidence on UrgoTul Absorb Border comprises a case study by Armstrong and Merlin-Manton (2015), four case studies by Bullough and Merlin-Manton (2014) and an observational study, conducted across a number of health-care organisations, involving 25 patients with a variety of wound types (Merlin-Manton et al, 2015). The latter evaluation presents more in-depth patient information and data analysis, thereby increasing the generalisability of the results. The paucity of evidence reflects the limited time available in which to conduct and publish evaluations since the product's launch in 2014. This evidence base is summarised in *Table 1*.

While this preliminary data suggests that the dressing is safe, larger trials would be useful to demonstrate that the in vitro evidence on the dressing's ability to stimulate fibroblast proliferation (Bernard et al 2005; 2009) can be observed in vivo in terms of improved healing outcomes. This non-randomised observational evaluation was conducted in order to appraise the overall acceptability of UrgoTul Absorb Border (hereafter referred to as the evaluation dressing) in patients with a variety of different wound types and with low to moderate levels of exudate.

Method

Patients with all types of acute and chronic wounds that a clinician deemed suitable for treatment with a silicone foam dressing were recruited into the evaluation from across 5 NHS acute and community trusts over a 6-month period. Settings included acute hospital wards, outpatient departments, patients' homes, wound clinics and care homes. Acute wounds were defined as those of less than 6 weeks in duration and chronic wounds as those present for at least 6 weeks. The inclusion criteria were:

- Age: ≥18 years
- Epithelialising or granulating wounds
- Wounds covered with <50% slough and/or <50% necrosis
- Minimum wound surface area of 10 × 5 mm (no maximum wound surface area was specified)
- Wounds with low to moderate exudate levels (i.e. did not require daily dressing changes)
- Ability to give informed consent.

The exclusion criteria were:

- Patients with a history of poor adherence to their wound-care regimen
- Infected wounds
- Patients with a progressive neoplastic lesion treated by radiotherapy or chemotherapy, or receiving ongoing treatment with immunosuppressive agents or high-dose corticosteroids
- Patients with a history of sensitivity to any of the dressing's components
- Pregnant women

Table 1. Summary of the clinical published evidence on UrgoTul Absorb Border foam dressing

Author	Sample size	Publication	Wound type	Outcomes			
				Condition of peri-wound skin	Exudate level	Conformability	Comfort
Armstrong and Merlin-Manton (2015)	*n*=1	Poster	Non-healing neuropathic foot ulcer	Improved	Exudate decreased and wound improved	Conformed and stayed in place for 1 week	N/A as neuropathic ulcer
Bullough and Merlin-Manton (2014)	*n*=4	Poster	Two pressure ulcers (categories II and IV); one thumb wound and one skin tear	Not specified	No maceration	Not specified	Not specified
Merlin-Manton et al (2015)	*n*=25*	Publication	19 chronic wounds and 4 acute wounds	20 (87%) improved	At baseline, 16 wounds (70%) had low-exudate levels. 22 staff (96%) rated the dressing's ability to absorb exudate as excellent or very good	22 staff (96%) rated this as excellent or good	22 staff (96%) rated this as excellent or good

*Data missing for two patients

- Wounds with suspected malignant changes
- History of deep venous thrombosis or venous surgery within the previous 3 months.

Treatment protocol

The clinical governance departments within each of the NHS trusts approved the evaluation process and tools, and all patients gave their written informed consent. The treatment protocol stipulated that the patients should continue with their current wound management regimen, with the only adjustment being that the evaluation dressing should be used instead of the previous foam dressing or applied if the patient was a new referral. The follow-up period was 6 weeks (or less if the wound healed sooner), with a proposed minimum of weekly dressing changes.

The Urgo clinical lead offered all clinicians participating in the evaluation specific guidance on how to use the dressing, guided by the manufacturer's instructions for use. She also explained the dressing's mechanism of action and indications for use to the clinicians at each of the evaluation sites. A piloted bespoke evaluation tool was used, with the aim of eliciting standardised data. In order to improve consistency, data collection was limited to tissue viability nurses, wound clinic leads and tissue viability link nurses.

Patient demographic data and relevant past medical history were recorded on entry. In addition, the following parameters were assessed at the start of the evaluation and at each dressing change:

- Wound type
- Wound size
- Wound bed characteristics
- Exudate level (based on clinician evaluation)
- Conformability of the dressing
- Dressing change frequency and rationale
- Ability to stay in place
- Condition of the peri-wound skin
- Ease of application
- Ease of removal
- Patient experience, including pain.

The protocol stipulated that wounds should be photographed at the start of the evaluation and at each dressing change. Independent clinicians not involved in the evaluation subsequently assessed these images.

Results

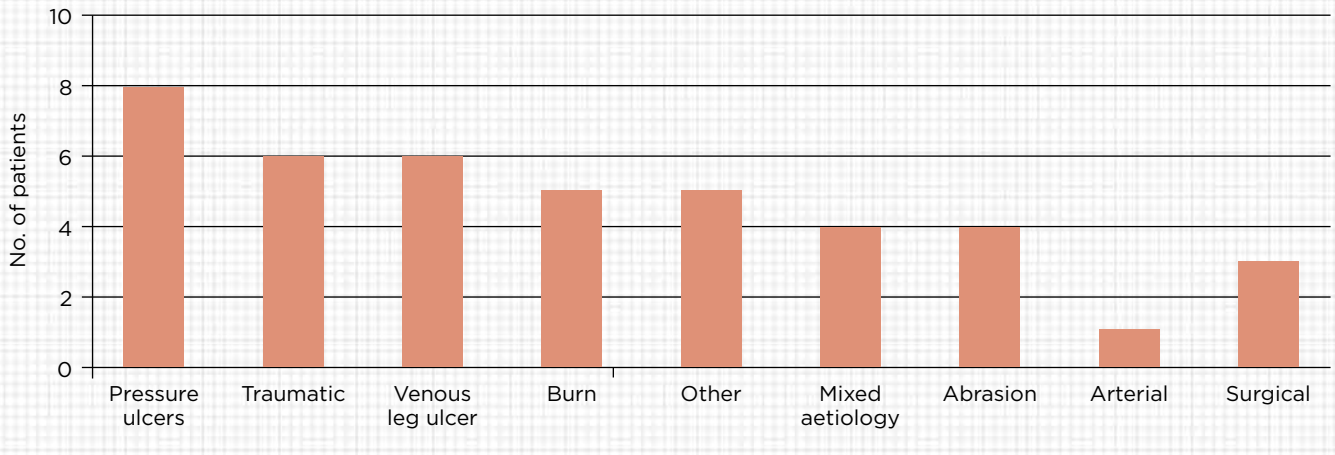
A total of 43 patients were recruited into the evaluation with 43 data sets. However, one patient moved away from the evaluation site mid-way through the evaluation, and so was withdrawn, as only the baseline data and first-assessment data were captured and recorded. The remaining 42 patients completed the evaluation.

Patient demographics and wound characteristics

The mean patient age was 76 years (range 36–101), and just over half of the evaluation group was male (n=23, 55%). An equal number of patients (n=21) were treated across both the acute and community settings. The wound types were representative of those usually seen in acute and community settings and included pressure ulcers, leg ulcers, traumatic wounds/surgical wounds/abrasions and burns. A full breakdown is shown in *Figure 1*. Patient demographics data, including significant comorbidities and medications given, are summarised in *Tables 2a* and *2b*.

The wound duration ranged from 3 days to 2.5 years. The evaluation dressing was used as the primary dressing in 32 wounds (76%) and as the secondary dressing on 9 wounds (21%) (data are missing for one patient).

Primary dressings/ointments worn prior to entry into the evaluation included TLC Healing Matrix dressings, alginates,



Note 1. Of the 8 pressure ulcers, 6 were categorised as follows: 1 as a category 1 ulcer, 3 as category 2 ulcers, and 2 as category 3 ulcers (National Pressure Ulcer Advisory Panel et al, 2014). The categories 2 and 3 pressure ulcers were defined as chronic wounds.
Note 2. Other wound types comprised: one pressure injury on the left caused by a medical device, one rash that resulted in loss of skin integrity, two moisture lesions, and one radiotherapy-induced skin reaction for a nonrelated cancer. These were all classified as acute wounds.

Figure 1. Wound types included in the evaluation

Hydrofibers, hydrocolloids, foams, silicone foams, iodine, low adherent dressings and a silver-based cream. Due to poor patient adherence, only three of the six patients with venous leg ulcers had used compression therapy before the evaluation. Those tolerating compression therapy continued wearing this throughout the evaluation period. Use of other adjunctive therapies was not analysed.

Rationale for dressing change

Reasons given for the dressing change at week 1 were:

- Routine dressing change (*n*=24, 57%)
- To complete a wound assessment (*n*=5, 12%)
- Other reasons (not stated) (*n*=2, 5%)
- Reason not recorded (*n*=11, 26%)

This set the precedent, with mostly routine dressing changes performed during the evaluation period.

Condition of the wound

The results showed that the majority of the wounds responded quickly to the dressing, with most showing consecutive improvements at weeks 1 and 2. At week 1, the clinicians subjectively reported that half of the wounds (*n*=21, 50%) had improved, with only five (12%) showing no change and one deteriorating (15 datasets missing). A similar number (*n*=22, 52%) improved further still over the next week, with only six (14%) staying unchanged (14 datasets missing). At the final dressing change, 8 wounds (19%) had fully epithelialised and 34 (81%) improved, including 1 where the clinician stated that the wound had 'almost healed' (*Figure 2*).

Table 2a. Demographic data

Age of patients (in years)	Mean	76
	Median	80
	Range	36–101
Gender	Male	23
	Female	19

Table 2b. Patient characteristics

Patient characteristics		No. (%)
Significant comorbidities	Diabetes	9 (21)
	Peripheral arterial disease	3 (7)
	Incontinence	7 (17)
	Rheumatoid arthritis	2 (5)
	Venous disease	8 (19)
Medication	Steroid	3 (7)
	Analgesics	17 (41)
	Antibiotics	5 (12)
	Other*	5 (12)

*Other medication included paracetamol, flucloxacillin, furosemide, Ibuprofen, metformin, and clopidogrel.

Exudate handling and condition of the peri-wound skin

At the final evaluation, clinicians were asked to rate the dressing in terms of its ability to handle exudate. All clinicians rated it as excellent, very good or good, with a large majority (*n*=37, 88%) describing it as excellent (*Figure 3*).

The condition of the peri-wound skin improved in 36 patients (86%) and remained unchanged in the remaining patients. At the baseline assessment, only a quarter of the sample (*n*=11, 26%) reported that their peri-wound skin was healthy, whereas at the end of evaluation, 37 (88%) stated that it was excellent. One patient (2%) had erythema at the final assessment, compared with five (12%) at baseline. The use of barrier protectants was not recorded.

Acceptability

At the final evaluation, the participating clinicians rated the dressing on the basis of a number of parameters (*Figures 4* and *5*).

- Ability to stay in place: all clinicians reported that this was excellent, very good or good. During the 6-week follow-up period, on only four occasions was a dressing change required because a dressing had fallen off, with three of these incidents occurring in the same patient
- Ease of application and removal: again, almost all clinicians rated this as either excellent (*n*=24, 57%) or very good (*n*=17, 41%), with one (2%) rating it as good. Almost all clinicians (*n*=39, 93%) stated that it was excellent, with the remainder (*n*=3, 7%) regarding it as very good.
- Comformability: all but one clinician rated this as excellent
- Comfort during wear and during dressing removal: most clinicians rated comfort during wear as excellent or good. All but one clinician rated comfort during dressing removal as excellent.

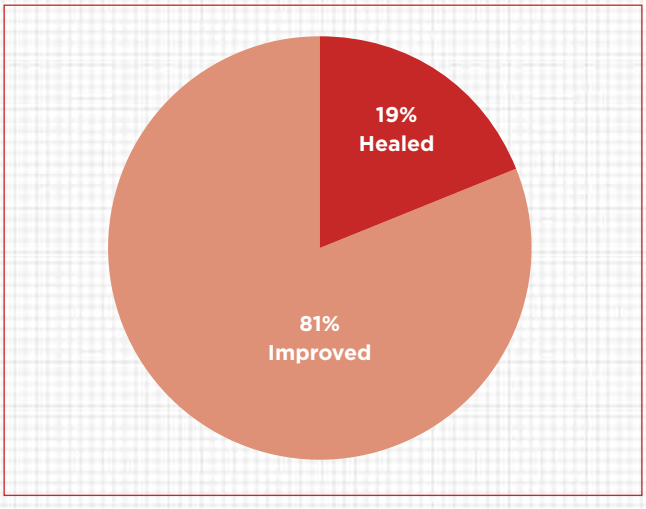


Figure 2. Wound healing outcomes

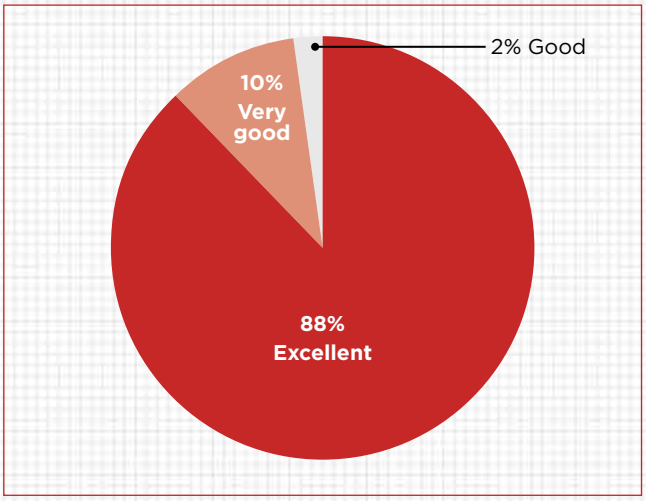


Figure 3. Clinicians' ratings of dressing's ability to handle exudate

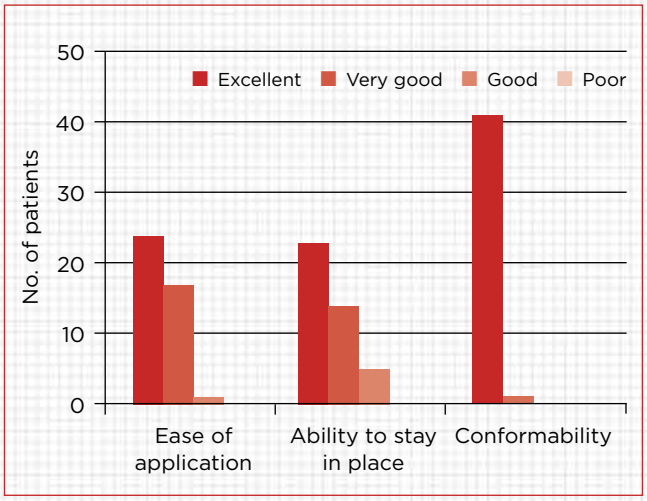


Figure 4. Final evaluation ratings on ease of application, ability to stay in place, and conformability

Discussion

The results of this 42-patient evaluation, undertaken across five NHS organisations and involving clinicians from a variety of health-care settings, support those reported in previous papers on this dressing. All provide preliminary data indicating that the clinicians found it acceptable in terms of its absorbency, conformability and comfort. In the present evaluation, eight wounds (19%) healed and 34 wounds (81%) improved. In addition, all of the clinicians rated the dressing positively in terms of its ability to manage exudate, although it would be beneficial to measure this in relation to dressing wear time, so that the financial implications can be analysed. The dressing also scored highly in terms of ease of dressing application, conformability and ability to stay in place. However, the case of the patient on whom the dressing was found to have not stayed in place at three consecutive dressing changes warrants further exploration, with consideration as to why this occurred, including the skin-care regimen used. These findings could be used to improve the wear time of this dressing. Similarly, there were high scores for the dressing in terms of patient comfort and ease of pain on removal, but these were scored subjectively and so warrant more in-depth objective analysis.

Study limitations include the small sample size and failure to present the data for each individual patient. Data were complete only for the first evaluation, so a full data analysis was not possible as some mid-point data were missing. The author acknowledges that a longer follow-up period would have allowed for all of the wound outcomes to be evaluated, while a future evaluation would benefit from including data on the wound surface area.

The clinicians' practice of undertaking routine dressing changes makes it difficult to demonstrate a reduction in costs, other than on the basis of unit price, for this dressing in comparison with other foam dressings. Further analysis is therefore required. This is common practice and has been

Figure 5. Clinician's views on ease of use at the final evaluation

reported in relation to other silicone foam product evaluations (Stephen-Haynes et al, 2011), and so should be reviewed and challenged (Ousey et al, 2013).

While there is a benefit of analysing data from a number of sites, it is important that the evaluation is coordinated appropriately and that full data is obtained. In this evaluation, full baseline and endpoint data were obtained, but there are gaps in the mid-point data. In spite of this, these findings indicate an appropriate approach to a dressing evaluation, and further research is needed to determine the outcomes, with a deeper analysis including the improvement in wound size, wear time and exudate management as well as patients' views on ease of application, removal, and comfort during wear.

The overall aim of holistic wound management is to manage factors such as exudate, infection and devitalised tissue, to improve patients' quality of life, promote healing and make the best use of health-care resources. It is important to achieve a wound bed that is sufficiently moist to promote healing

as well as avoid complications, such as maceration and peri-wound damage.

It is essential that clinicians have the knowledge to plan treatment and ongoing wound management. They should be aware that no single dressing is appropriate for the management of all wound types, and few dressings are appropriate for the treatment of a wound during all the stages of healing.

Wound care is complicated. Clinicians need to know and understand the healing process, pain, dressing products, asepsis, microbiology, pharmacology, psychosocial factors and ethics; they also need good communication skills (Stephen-Haynes et al, 2011).

Insufficient knowledge and a lack of careful consideration in dressing selection can lead to wound management being ineffective as well as uneconomical in terms of both time and physical resources.

Dressing choice should be influenced by wound healing and exudate management as well as patient factors, including comfort and conformability and ease of dressing removal.

This clinical evaluation has demonstrated positive outcomes for individuals with wounds. It also recognises that further exploration of the outcomes and a larger sample size is needed, as is further analysis of wear time and the financial costs of dressing types.

Conclusion

This clinical observational evaluation with limited numbers adds to the evidence base on UrgoTul Absorb Border foam dressing, demonstrating that it is acceptable to both clinicians and patients, and appears to promote healing. However, further evaluations, with a larger sample size and more objective assessment criteria, are needed to substantiate this. **CWC**

Declaration of interest: Urgo Medical supported the provision of the data collection tool and supply of the dressings for this clinical evaluation.

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