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Original Citation

Atkin, Leanne, Stephenson, John and Bateman, Sharon (2015) Foam dressings: a review of the literature and evaluation of fluid-handling capacity of four leading foam dressings. Wounds UK, 11 (1). pp. 75-81. ISSN 1746-6814

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Foam dressings: a review of the literature and evaluation of fluid-handling capacity of four leading foam dressings

Posnett and Franks (2008) have calculated that 200,000 people in the UK have a chronic wound, with an estimated treatment cost of between £2.3 billion and £3.1 billion per year. With an ever-increasing ageing population, it can be assumed that costs associated with the management and treatment of wounds will also continue to rise. The Business Service Authority (2014) reported that in 2013 between £160 and £185 million was spent on wound care dressings within primary care services in England, of which foam dressings accounted for £22.6 million of the overall spend. Foam dressings are frequently used in wound care to assist with the management of wound exudate, helping to prevent maceration of the wound bed, protect the surrounding skin and prevent cross-infection caused by strikethrough. The aim of dressings is to provide an optimum environment at the interface with the wound bed to promote wound healing. With limited financial resources within health care, the cost-effectiveness of each type of wound dressing is high on the agenda. It is, however, important that costs are not considered in isolation; the outcomes (general health benefits) associated with interventions (e.g. wound healing and reduction in wound pain) must also be taken into account alongside close collaboration with the patient, and in some cases the carer (Rippon et al, 2008). This article provides a summary of the published literature relating to foam dressings, investigating their impact on healing rates, pain on dressing removal, fluid-handling capacity and their costeffectiveness. It focuses on the independent assessment of the fluid-handling capacity of eight commonly-prescribed foam dressings: four bordered (Cutimed® Siltec B, Mepilex® Border, Allevyn[®] Life and Tegaderm[™] foam adhesive) and four non-bordered (Cutimed[®] Siltec/Cutimed[®] Siltec^{PLUS}, Mepilex[®], Allevyn[®] Non-Adhesive, and Tegaderm[™] foam).

There is a wide range of dressings classified as 'foam dressings'; however, there can be substantial differences in the chemical makeup of different foam dressings. Sussman (2010) distinguishes foams into two separate groups, those being a 'true foam' that draws fluid into air spaces, or 'pseudo-foam' that draws in fluid and physically expands as it retains it. True foams contain hydrophilic polyurethane foam, whereas pseudo-foams contain absorbent materials, such as viscose and acrylate fibres, or particles of superabsorbent polyacrylate designed to increase fluid handling.

The management of wound exudate is one of the key components of an effective wound dressing and

the absorbency and permeability of a dressing have an impact on its fluid-handling capacity (Thomas, 2010). How effectively a dressing manages wound exudate affects a number of factors, including the following:

- Patient quality of life
- Condition of the surrounding skin
- >> Wear time and healing rates.

Manufacturers have sought to produce dressings that provide optimum conditions at the wound bed, such as foam dressings. These are commonly backed with semi-permeable polyurethane film or a thin sheet of closed cell polyurethane foam. In such dressings, wound fluid is initially taken up by the absorbent

KEY WORDS

- ▶ Exudate
- management
- Foam dressings
- ▶ Fluid-handling
- capacity
- ▶ Wound pain

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Trade name	Description
Cutimed Siltec B	Polyurethane foam with a non-adhesive silicone wound contact layer,
	super-absorbers above the foam core and an adherent silicone border
Mepilex	Soft silicone-faced polyurethane foam
Mepilex Border	Self-adhesive soft silicone-faced polyurethane foam island dressing
Allevyn non-adhesive	Hydrophilic polyurethane foam
Allevyn Life	Hydrocellular foam with silicone wound contact layer and surrounding
	border
Tegaderm foam	Polyurethane foam with non-adherent wound contact layer
Tegaderm foam	Polyurethane foam with non-adherent wound contact layer on an island
adhesive	of breathable film backing
Cutimed Siltec	Polyurethane foam with a non-adhesive silicone wound contact layer, super-absorbers above the foam core
Cutimed Siltec ^{PLUS}	Polyurethane foam with with a soft-tack silicone wound contact layer and
	super-absorbers above the foam core
Mepilex	Polyurethane foam with soft silicone wound contact layer
Allevyn Non adhesive	Polyurethane foam with non-adherent wound contact layer
Tegaderm foam	Polyurethane foam with non-adherent wound contact layer

component of the dressing, and some subsequently evaporates through the backing film, extending its useful life. The film also serves as a barrier to bacteria, preventing strikethrough and reducing the risk of bacterial contamination.

Foams can be used as a primary or secondary dressing on wounds, and can be left in place for up to seven days. They can be used on a range of wound types, including:

- » Moderate-to-heavily exuding pressure ulcers
- >>> Venous ulcers (with compression)
- Pre-tibial lacerations
- » Superficial and cavity wounds
- Infected ulcers
- Diabetic foot lesions
- ➡ Skin tears
- >> Skin grafts
- Donor sites
- ✤ Surgical sites
- ▹ Acute trauma
- >> Pilonidal sinuses.

As with any type of wound product, care is required when applying and removing any dressing that has adhesive properties if the skin is fragile, particularly in the very young, elderly, cachectic and obese. For this reason, there is a range of silicone-coated foam dressings (e.g. Mepilex) that aim to prevent trauma on removal.

PERFORMANCE

Franks et al (2007) undertook a multi-centre prospective randomised clinical trial to compare Allevyn Hydrocellular and Mepliex® on a sample of 156 patients with chronic venous ulceration. Patients were randomised from 12 clinical centres with a median ulcer size of 4.33 cm² (range 0.33-123.10 cm²). After 24 weeks, a total of 100 (64.1%) patients had complete ulcer closure, 46 (29.5%) had withdrawn from the trial, nine (5.8%) had ulcers that remained unhealed and one patient had died. Of the patients randomised to Mepilex, 50 out of 75 (66.7%) had complete ulcer healing compared with 50 out of 81 (61.7%) on Allevyn. This difference was not statistically significant (P=0.521). The hazard ratio for healing after adjustment for bandage type and trial centre was 1.48 (95% CI 0.87-2.54; P=0.15), which only marginally changed following adjustment for baseline variables, neither of which achieved statistical significance (P=0.16). Withdrawal rates were similar between groups, with 23 patients (30.7%) leaving the Mepilex group and 23 (28.4%) leaving the Allevyn group, of these 14 patients from the Allevyn Group and 17 in the Mepilex group withdrew due to wound deterioration; other reasons for early withdrawal included patient request, lost to follow-up, and bandage-related issues. Anderson (2002) performed a similar study investigating 118 randomised patients to receive either a hydrocellular foam dressing (Allevyn) or a polyurethane foam dressing (Biatian) when used in combination with short stretch bandages for patients with venous ulcerations. After 8 weeks they found no difference in time to healing, with mean time to healing in the hydrocellular foam group 5.0 weeks compared to 5.2 weeks in the polyurethane foam. Pérez et al (2011) conducted an observational study focusing on the use of silicone foam dressings (Mepilex Lite) in patients who had undergone radiation therapy. The main objective of the study was to measure healing (defined as complete re-epithelialisation of the wound) and injury progression during radiation therapy; 20 patients were included in the study and all the wounds 20/20 (100%) progressed to full healing with the mean total time to healing being 9.5 days (range 3-22 days). Secondary objectives were the measurement of:

- >> Trauma caused by dressing removal
- Convenience and comfort
- >> The patient's aesthetic perception

- ➡ Ease of use
- ► Adaptability
- >> Length of time the dressing stayed in place.

These objectives were all considered important, as inadequate treatment of moist/wet radiodermatitis may cause treatment discontinuation, with a subsequent impact on disease progression. During the evaluation of convenience and comfort, patients reported that the dressing did not cause trauma during application or removal (20/20, 100%); that health professionals and family members, who occasionally had to provide treatment, found it easy to use (20/20, 100%); it adapted easily to difficult-tocover areas (20/20, 100%); additional fixation was rarely required (20/20, 100%); it relieved some of the symptoms associated with radiodermatitis (pruritus, stinging, itching and erythema) (20/20, 100%) and it was preferred to conventional dressings (20/20, 100%).

An intervention review examining the use of foam dressings for the healing of diabetic foot ulcers (Dumville et al, 2011) included six studies containing a total of 157 participants. Meta analysis of two of the studies found no statistical difference between foam dressings and basic wound contact dressings, and pooled data from two studies revealed no significant difference in ulcer healing between the foam and alignate dressings. They concluded that there was no research evidence to suggest that foam wound dressings are more effective in healing foot ulcers in patients with diabetes than other types of dressings; however, they do recognise that the trials were very small.

Minimising costs, i.e. the unit cost of each dressing and the number of visits (time taken for a nurse to dress the wound), and limiting the pain associated with dressing change are key priorities for all healthcare environments. Allevyn Gentle Border Heel was evaluated by Moody and Bielby, (2009) on 20 patients; they considered ease of use, wear time, fluid-handling, conformability, comfort, change in wound characteristics and the condition of the peri-wound skin. They concluded that the dressing was easy to apply to the hard-to-dress heel area, and prevented maceration due to the pooling of exudate. Waring et al (2008) compared the adhesive properties of Allevyn Adhesive and Mepilex Border and evaluated a number of parameters relating to trauma. Strips of the dressings were applied to the skin of 22 healthy volunteers, and the forces required to peel them off were measured 48 and 72 hours after dressing application. Dressings were also applied to the forearms of the participants and removed one day after application, when they were asked to rate the severity of pain on removal. After removal, the dressings were examined by scanning electron microscopy and subjected to protein analysis. Allevyn Adhesive was associated with a significantly higher level of pain on removal than Mepilex Border (P<0.001) and analysis of the dressings after removal showed clear differences, with significantly less cellular material and protein deposits attached to Mepilex. This is mainly due to the soft tacky hydrophobic nature of silicone dressings in contrast to traditional acrylic adhesives

In another study, Allevyn silicone adhesive shaped heel dressing was evaluated on 20 patients (Hampton, 2010). Based on clinicians' subjective data, it was concluded that the wounds improved, the dressing was atraumatic to the wound bed and was easy to remove. All of the patients also reported an improvement in the level of pain experienced. Similarly, in a multi-centred evaluation of Allevyn Gentle with 153 patients from six countries, Hurd et al (2009) concluded that 95% of patients found the dressing suitable for the wound type, and that it achieved good results in conjunction with routine clinical practice. In a randomised controlled trial, Franks et al (2007) noted that pain improved following treatment with both Allevyn Hydrocellular and Mepilex dressings (P<0.001), but observed no difference between dressings. Furthermore, Bateman (2014) undertook a 38-patient evaluation of the Cutimed* Siltec range of foam dressings on a variety of acute and chronic wounds in a patient group ranging in age from one year to 98 years. Due to the success of treatment on this moderate number of patients, the evaluation was extended to incorporate a further cohort of 112 patients, enabling a 150-patient evaluation to be analysed. This comprehensive evaluation, which has yet to be published, shows positive holistic outcomes in a number of aspects, including:

- Exudate containment
- Maintenance of a moist wound bed
- ▶ Peri-wound skin protection
- » Atraumatic dressing application and removal
- >> Patient and clinician perception
- » Subsequent choice of product.

No statistical analysis of the results, however, has been conducted to date

METHODS OF STUDY Fluid-handling capacity

The fluid-handling capacity, defined as the sum of moisture vapour loss plus absorbency, of four bordered dressings and four non-bordered dressings were compared (Box 1). The size of all pads was the same: 10 cm^2 (internal diameter = 35.7 mm). The bordered products were Cutimed Siltec B, Mepilex Border, Allevyn Life and Tegaderm[™] foam adhesive. The non-bordered products were Cutimed Siltec/ Cutimed SiltecPLUS, Mepilex, Allevyn Non-Adhesive, and Tegaderm foam. The fluid-handling properties of the dressings were examined using SMTL test method TM-390 (British Standards Institution, 2002), which is written in accordance with European Standard BS EN 13726:1:2002 (Surgical Materials Testing Laboratory, 2002). In this test, samples of each dressing were applied to Paddington cups, to which were added 20ml of sodium/calcium chloride solution containing 142 mmol/litre of sodium ions and 2.5mmol/litre of calcium ions. The cups were weighed to the nearest 0.0001g using a calibrated analytical balance and placed in a temperature- and humidity-controlled incubator, which was used to maintain an environment of 37±2°C and a relative humidity level below 20% for a period of 24 hours. At the end of the test, the cups were removed from the incubator and allowed to equilibrate at room temperature for a period of 30 minutes prior to reweighing to the nearest 0.0001 g. The base of each cup was then removed, and any remaining fluid was allowed to drain. After a period of 15±2 minutes, the cup was then reweighed, and the weight of the fluid retained by the dressing calculated by difference. The loss in weight due to the passage of moisture vapour through the dressing was thus determined. For each product, five sample measurements were obtained.

The data were summarised descriptively. Single-factor analyses of variance (ANOVA) were conducted to assess evidence for a difference in fluid-handling capacity within the bordered dressings. A similar procedure was undertaken for the non-bordered dressings. Prior to analysis, the suitability of the data for these procedures was verified using exploratory data analysis procedures. Planned comparisons were undertaken following the ANOVA procedure, as an alternative to post hoc testing, in which the Cutimed Siltec B and Cutimed Siltec/Cutimed Siltec^{PLUS} dressings were compared against other dressings (using linear

contrasts). The value of each individual contrast and a corresponding effect size were also calculated.

PATIENT AND CLINICIAN EVALUATION

A product review was also undertaken exploring 150 ward-based patients presenting with acute and chronic exuding wounds. The proposed benefits of a foam dressing were reviewed alongside a preset education regimen for both the patient and clinician. The outcomes of the evaluation were exudate management, protection of the peri-wound skin, atraumatic application and removal, nonadherence and the benefits of using an information leaflet within the dressing regimen. In this study, the patients who were referred with exuding wounds were recruited over 4 months. Monitoring was over a 28-day period or until patient discharge, if earlier. Data collection related to patient demographics, objectives of therapy, previous treatments used, wound status, and patient and clinician experience of the product and its education leaflet. Both patient and clinician were asked what their highest priority of management was at day 1, with options being 'reduction and avoidance of maceration to peri-wound skin', 'exudate management' and 'pain at wound site'. The significance and strength of the association between personnel (i.e. clinician or patient) and their priority was tested using the chi-square test for association. Patients and clinicians were also asked whether they wished to continue using the product they were assigned and whether the related education leaflet was helpful.

RESULTS – SMTL

Fluid-handing capacity of bordered dressings

Summary statistics indicated Cutimed Siltec B to have a mean fluid-handling capacity between 34% and 76% greater than other bordered dressings; however, the Cutimed Siltec B values were more variable than those of other dressings (*Table 1*). Exploratory analyses confirmed that the data fulfilled all necessary assumptions for the statistical testing to be undertaken.

The ANOVA test indicated a significant difference between products. Planned comparisons indicated significant differences between Cutimed Siltec B, and each of the other bordered products (*P*<0.001 in all cases). Cutimed Siltec B had a greater fluid-handling capacity than the all other tested products, with effect sizes being large in all cases. Cutimed Siltec B was also

Table 1: Fluid-handling capacity of bordered dressings		
Bordered dressing	Mean fluid-handling capacity, g/10 cm (SD)	
Cutimed Siltec B	21.7 (1.68)	
Mepilex Border	16.2 (0.412)	
Allevyn Life	12.3 (0.545)	
Tegaderm foam adhesive	14.0 15.6 (0.498) 00	

found to have a significantly greater fluid-handling capacity than a combination of the other products in a deviance linear contrast, (P<0.001). The fluid-handling capacities of bordered products and their effects, and corresponding significance levels for the comparisons, are summarised in *Table 2*.

Fluid-handing capacity of non-bordered dressings summary statistics indicated that Cutimed Siltec/ Cutimed Siltec^{PLUS} had a mean fluid-handling capacity of between 18% less than and 138% greater than other non-bordered dressings. Cutimed Siltec/Cutimed Siltec^{PLUS} exhibited comparable variability to other dressings (*Table 3*). Exploratory analyses confirmed that the data fulfilled all necessary assumptions for the statistical testing to be undertaken.

The ANOVA test indicated a significant difference between products. Planned comparisons indicated significant differences between Cutimed Siltec/ Cutimed Siltec^{PLUS}; and Mepilex and Tegaderm Foam. No significant difference was found between Cutimed Siltec/Cutimed Siltec^{PLUS} and Allevyn Non-Adhesive. Cutimed Siltec/Cutimed Siltec^{PLUS} exhibited greater fluid-handling capacity than the other tested products except Mepliex; and also exhibited greater fluid-handling capacity than a combination of other tested products in a deviance linear contrast.

The fluid-handling capacities of non-bordered products, their effect sizes and associated significance levels for the comparisons are summarised in *Table 4*.

RESULTS – CLINICAL EVALUATION

Written information along with verbal explanation helps patients and clinicians to make informed choices about a product's benefits, uses and application and removal criteria. It also helps in deciding whether to continue with or discontinue product use. Table 5 summarises the responses to questions in the product review that were given by clinicians and patients relating to their baseline priorities. It may be observed that while clinicians' primarily prioritise exudate management, a much higher proportion of patients are concerned about pain at the wound site. The association between personnel (i.e. clinician and patient) and main priority was found to be statistically significant ($\chi^2_{(2)}$ =46.8; P<0.001). The magnitude of the effect was moderate, as measured by the ϕ coefficient of 0.559.

Table 6 summarises some of the comments provided by patients as part of the wound evaluation.

Table 2: Comparison of the fluid-handling capacity of bordered products, the size of their effect and the associated significance level

Products being compared	Value ¹	Effect size	P-value
Cutimed Siltec B versus Mepilex Border	+5.55	0.954	< 0.001
Cutimed Siltec B versus Allevyn Life	+9.44	0.948	< 0.001
Cutimed Siltec B versus Tegaderm foam adhesive	+6.09	0.951	< 0.001
Deviance contrast: Cutimed Siltec B reference	+7.02	0.942	< 0.001

A positive value indicates a higher fluid-handling capacity exhibited by Cutimed Siltec B

Table 3: Fluid-handling capacity of non- bordered dressings	Mean fluid handling capacity, g/10cm, (SD)
Cutimed Siltec/Cutimed Siltec ^{PLUS}	23.8 (1.10)
Mepilex	29.1 (1.03)
Allevyn Non-Adhesive	22.4 (2.22)
Tegaderm foam	10.0 (0.261)

Table 4: Comparison of the fluid-handling capacity of non-bordered products and the size of their effect			
Products being compared	Value ¹	Effect size	P-value
Cutimed Siltec/Cutimed Siltec ^{PLUS} versus Mepilex	-5.33	0.842	<0.001
Cutimed Siltec/Cutimed Siltec ^{PLUS} versus Allevyn Non-Adhesive	+1.40	0.379	<0.120
Cutimed Siltec/Cutimed Siltec ^{PLUS} versus Tegaderm foam	+13.70	0.970	<0.001
Deviance contrast: Cutimed Siltec/Cutimed Siltec ^{PLUS} reference	+3.26	0.761	<0.001

A positive value indicates a higher fluid handling capacity exhibited by Cutimed Siltec/Cutimed[®] Siltec^{PLUS}

Table 5: Patient and clinician priorities at day 1		
Which of the following is the highest priority	Clinicians (n=150)	Patients (n=150)
to you?		
Maceration to periwound skin	30 (20%)	9 (6%)
Exudate management	80 (53.3%)	43 (28.7%)
Pain at wound site	40 (26.7%)	98 (65.3%)

Table 6: Patients commenting on Cutimed Siltec PLUS and Cutimed Siltec B: "They said, we listened":

Pain	"Before trial patient needed Entonox to help with pain during dressing changes. With this product it no
	longer needed Entonox and didn't hurt at all after second dressing." "Those dressings helped my mum's legs
	in that they didn't hurt when the nurse took them off." "The pain around my wound is the worst I have ever
	experienced, I was scared to try a new dressing but glad I did, no pain after the second one, which is great." "No
	one knows what the pain feels like unless you have the wound yourself." "No pain on removal and didn't leave a
	sticky residue on skin." "With previous dressing pain was 5/5, with this new dressing my pain reduced to 0."
Maceration/	"Less change and no inconvenience of it leaking." "Didn't stick to the scabby areas." "Feels soft and strong." "I
Comfort	trust the dressing not to stick to my wound." "No problem on baby's skin." "Didn't cause damage to the red,
	inflamed skin borders." "The other dressing kept slipping off my sore skin edges, making it worse." "Didn't curl
	up and leak like my other one." "I could flex my hand and it stayed in place." "Didn't move under bandages."
	"Stays in place better than my other dressings, especially when I walk." "Dressing sat comfortable around my
	chest drain." "I like the feel of the dressing, it's nice and soft."
Exudate	"Patient felt safe and trusted the dressing wouldn't leak." "Doesn't leak like the other one." "Kept my skin dry."
	"Less visits to GP practice nurse - could go back to work." "I chose this dressing because I liked the thickness of
	it, it would hold more water."

SUMMARY

The analysis has shown that Cutimed Siltec B exhibits the greatest fluid-handling capacity of the tested bordered products. The differences between Cutimed Siltec B and other bordered products were large in magnitude and statistically significant, despite the limited number of replicates used in the testing process. Of the non-bordered products, Mepilex exhibited the greatest fluid-handling capacity. There was a considerable and statistically significant difference between Mepilex and Cutimed Siltec/ Cutimed Siltec^{PLUS}. Significant differences between

Mepilex and other non-bordered products were not established directly, but could be inferred from this finding, as Cutimed Siltec/Cutimed Siltec^{PLUS} has been shown to perform at least as well as other nonbordered products.

It is disappointing to note from the patient evaluation that the priorities of the clinician and patient differ greatly, particularly within the remit of exudate management and pain at the wound site. This is evidenced both by the greater proportion of patients indicating pain at the wound site to be a priority, and the strength and diversity of comments provided by patients on this subject, with many patients commenting favourably on apparently unexpected reduction in pain, while greater levels of pain had been expected, possibly as a result of previous experience of inadequately functioning dressings. The results of the product evaluation demonstrated positive endpoints for exudate containment, moist wound bed maintenance, peri-wound skin healing and protection, and atraumatic application/removal. All 150 patients and clinicians said that they would continue with Cutimed Siltec PLUS/Cutimed Siltec B. The implementation and evaluation of an absorbent foam product in conjunction with an educational leaflet tailored to the patient is a welcome addition to the ever-changing wound care 'tool box' which is essential for tissue viability nurses and clinicians alike in the challenging arena of exudate management for both acute and chronic wounds. The leaflet stayed with the patients throughout their journey so they could refer back to the product information, and future clinicians within their care package could also be updated, which aids consistency in care approaches.

The close tripartite relationship between patient, healthcare professional and industry as a collaborative union is key to ensuring that product evaluations, outcomes and subsequent decision-making encompasses the wants, needs and preferences of the patients to ensure holistic wound care is provided. Listening to patients and their carers is vital if product production, procurement and availability is to positively evolve.

There will always be the need for on-going exploration and evaluation of innovative products that provide atraumatic application/removal, nonadherence to the wound bed, adequate absorption and moist wound bed maintenance properties. These products need to be cost-effective, appeal to both the patient and the clinician, and come with useful patient information leaflets. However, patients' experience and perceptions should be incorporated within this process, enabling our patients to collaborate within decision-making processes from an informed standpoint. We need to be mindful that our patients may not choose the product that has been scientifically shown to absorb more fluid in a laboratory but one that is comfortable, aesthetically pleasing in appearance and from a brand or a company with which they have had previous positive experiences. Compliance with product usage from a

healthcare perspective is absolutely paramount to a product's success alongside data from the literature and laboratory and evidence of its cost-effectiveness.

CONCLUSION

When clinicians, procurement officers and allied healthcare workers are selecting products to be included on local wound formularies, the concept of foam dressing fluid-handling capacity needs to be considered alongside all factors related to wound care if the right product for the right patient at the right time is to be achieved.

CONFLICT OF INTEREST

Non-restrictive education grant from BSN medical

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