

Do all foam dressings have the same efficacy in the treatment of chronic wounds?

The challenge of chronic wounds remains significant both in terms of clinical management, impact on patients and cost to the NHS. Foam dressings are largely used in the treatment of chronic wounds and manufacturers claim to have different product characteristics. However, is there any foam which is better than another in terms of results? This paper analyses some of the studies which have compared the efficacy of different foam dressings in chronic wounds to see if there is any real difference.

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KEY WORDS

Exudate
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Chronic wounds are those that have remained unhealed for more than six weeks and are classified according to their underlying pathology, e.g. pressure ulcers, venous leg ulcers, diabetic foot ulcers and burns. It is estimated that approximately 100,000 people in the UK suffer from leg ulcers (Callam and Ruckley et al, 1985). However, due to the date of this study it could be assumed, given the aging population, that this figure is now considerably higher. The number of patients with pressure ulcers will vary according to region and clinical setting, with most recent estimates being around 10% (Phillips and Buttery, 2009).

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Impact of chronic wounds

Chronic wounds often have a large amount of sloughy tissue, are static or

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non-healing, and have a high volume of exudate, thereby presenting a significant challenge to clinicians and the health service. They also cause problems for the patient such as pain, exudate and odour; all of which have an impact on quality of life and can affect the patient's functionality.

In patients with diabetes, there is a risk of infection, which may also lead to lower limb amputation if optimal treatment protocols are not followed (Diabetes UK, 2009).

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the prolonged treatment period, frequent dressing changes (i.e more nursing time), increased dressing costs and the potential for further deterioration, with estimates running from £2–£3 bn per year (Harding et al, 2007).

As the average age of patients increases, so does the likelihood of comorbidities such as diabetes and cardiovascular disease, which may have a debilitating effect on the patient. It is these patient groups who are likely to present with chronic wounds, such as diabetic foot ulcers, leg ulcers and pressure ulcers.

Dressings used in chronic wounds

By their nature, chronic wounds often have clinical features which are challenging to treat and are complicated by the presence of other comorbidities. These wounds may be large in size, have sloughy or necrotic tissue present, be at risk of infection and may have excessive levels of exudate, although this is not always the case.

Due to their varied presentations, the clinician has to begin with a thorough assessment of the wound and each treatment decision should be based on the findings of this assessment (NHS Quality

Improvement for Scotland [NHSQIS 2009).

Foam dressings are the most common wound care dressing. There are a variety of foam products on the market, most of which aim to manage exudate, provide a moist wound healing environment and promote healing (Thomas, 1993). Adhesive foam dressings are also used as secondary dressings to help primary dressings remain in the wound bed while also assisting with absorbency. Foam dressings are not associated with debriding wounds.

In addition to the main foam component of the dressing, the more advanced products have a breathable outer layer which allows moisture to be evaporated from the dressing (moisture vapour transmission rate [MVTR]), thus improving efficacy and handling of exudate (Thomas, 1993). Foam dressings can also be used under compression bandages for the treatment of venous leg ulceration, due to their ability to retain exudate within the dressing. Most manufacturers will claim that their foam product is superior based on exudate handling, high MVTR and good dressing retention. However, we should be looking at efficacy first.

The range of foams can be confusing to the clinician. This literature review, examining some key studies which analyse the effectiveness of foam dressings (Table 1) to manage exudate in chronic wounds, was undertaken to find out if any particular foam product has proven greater efficacy over the competition.

Foam dressings: a literature review

Weiss et al (1996) undertook a study to determine if venous leg ulcers are best treated with compression and local wound care. This randomised, non-blinded study of 18 subjects with venous ulcers, confirmed by digital photoplethysmography (D-PPG) refill times of less than 25 seconds, was conducted using similar compression and different local treatments. Patients with ulcers of at least two months'

duration and of 1–4cm² in size were included. Patients were excluded from the study if signs of arterial disease were evident (ankle brachial pressure index [ABPI] <0.8). The compression system used in all cases was Jobst® UlcerCare™ stockings (BSN medical).

The main study outcome measured was reduction in ulcer size. Other factors assessed were compliance with the regimen and patients' subjective evaluation of dressing comfort and degree of ulcer pain.

This literature review, examining some key studies which analyse the effectiveness of foam dressings to manage exudate in chronic wounds, was undertaken to find out if any particular foam product has proven greater efficacy over the competition.

The 18 patients were randomly assigned to either a slightly adhesive hydroactive foam (Cutinova™, Smith and Nephew), or a non-adhesive absorptive foam (Allevyn™ Hydrocellular, Smith and Nephew). Dressings were changed every 24–72 hours depending on the volume of exudate.

The study was conducted for a maximum of 16 weeks' duration. Fifteen patients completed the study. Mean time to complete healing was 5.6 weeks for the patients treated with Cutinova, and 6.5 weeks for the Allevyn Hydrocellular group. No statistical analysis was performed due to the low patient numbers. Patient evaluation indicated that all patients found a great reduction in pain.

Banks et al (1997) conducted a randomised controlled trial (RCT) to assess the performance and safety of a polyurethane foam dressing (Lyfoam™ Extra, Mölnlycke Health Care).

The comparator was Allevyn Hydrocellular. A total of 61 patients with different wound types were recruited to the study (20 leg ulcers, 20 pressure ulcers and 21 wounds of different aetiologies).

Wounds were assessed every seven days for exudate leakage, condition of the periwound skin, comfort of dressing and ease of application. The final study assessment was determined by the reduction of exudate volume, where the dressing could be left in place for more than four days during two consecutive assessments.

Forty-one patients completed the study, only two of the 20 withdrawals were related to the study product. Dressing performance was similar in both groups. Assessment of the periwound skin indicated that both dressings performed equally well, with only six cases showing deterioration (three in each group and all due to wound infection). As exudate volume reduced, the dressings stayed in place for longer periods. Absorbency was measured by wear time. The mean wear times were not significantly different (2.21–2.8 days for Lyfoam Extra versus 2.38–2.99 days for Allevyn Hydrocellular). Nurses found both dressings easy to apply and remove.

In a study to compare the effectiveness of two foam dressings in the management of moderate to highly exuding venous and arterial lower leg ulcers, Andersen et al (2002) randomly assigned patients to either Biatain Non-Adhesive dressing (Coloplast) or Allevyn Hydrocellular. A total of one hundred and eighteen participants were enrolled from four centres across Europe. Patients were assessed upon entry into the study and every seven days until their ulcers had completely healed, or the study period of eight weeks was completed. Dressings were changed once every seven days, if exudate leaked, or if an interim assessment was considered necessary. Measurements included wound healing, exudate handling

properties, peri-ulcer skin reactions and patient comfort.

Of the 118 patients enrolled, 99 completed the study. In the study group (Biatain) of 53 ulcers, 18 healed (34%), and in the group of 46 ulcers treated with Allevyn, 18 healed (39%). Both treatment groups showed a significant decrease in ulcer size ($p=0.005$ vs $p<0.0005$). Again,

the efficacy was similar. Dressing absorbency was rated as excellent in 124 of 163 dressings (76%) with Biatain Non-Adhesive, and 12 of 170 (7%) with Allevyn Hydrocellular. Leakage from the dressings was noted at weekly assessment in 64% of the wounds dressed with Allevyn Hydrocellular, and 48% of those dressed with Biatain Non-Adhesive dressing. The number of dressing

changes per week were significantly lower in those being treated with Biatain Non-Adhesive dressing (2.14 versus 3.34; $p<0.0005$). The degree of peri-ulcer skin reaction was low in both groups. No statistical difference was noted in patient comfort between the two dressings.

Viamontes and Jones (2003) evaluated two adhesive foam dressings with the primary objective of assessing skin stripping to periwound skin. An adhesive hydrocellular foam dressing (Allevyn™ Adhesive, Smith and Nephew) and a self-adherent, soft silicone foam dressing (Mepilex® Border, Mölnlycke Health Care) were appraised.

Secondary objectives were to assess wound healing, wound appearance and pain.

Data were collected over a period of one year (June 2001–June 2002) from a ‘real time’ outcomes database containing wound treatment details of patients treated in nursing homes in the USA. All patients in the database who had been treated with either of the study dressings on at least one occasion were included in the evaluation.

Specific assessment included:

- ▶▶ Baseline patient details
- ▶▶ Baseline wound details
- ▶▶ Wound closure
- ▶▶ Evidence of skin stripping.

As this was a non-comparative evaluation, statistical analysis was not included. The results indicated a total of 403 wounds (206 patients) had been treated with either of the study dressings on at least one occasion.

One hundred and sixty-four wounds (41%) were treated with Allevyn Adhesive, while 210 (52%) were treated with Mepilex Border. The remaining 29 (7%) were treated with both. The majority of wounds (385/403; 96%) were pressure ulcers, the remaining 4% (18/403) were traumatic wounds, venous ulcers, ischaemic or diabetic foot ulcers.

Table 1

Foam dressings

Dressing	Properties
Alione Hydrocapillary (Coloplast)	A hydrocapillary pad surrounded by a hydrocolloid adhesive which exposes a non-adherent ulcer contact layer. Covered by a water-resistant, bacteria-proof semi-permeable top film
Allevyn™ Hydrocellular/ Adhesive (Smith and Nephew)	A highly absorbent polyurethane foam dressing with a film backing which allows moisture vapour transmission for superior fluid handling. Available with a silicone gel contact layer to reduce pain at dressing change
Biatain Non-Adhesive dressing (Coloplast)	Hydrophillic polyurethane foam dressing with no wound contact layer. A 3D polymer helps to take fluid away from the wound bed. Waterproof film backing
Cutinova™ (Smith and Nephew)	A self-adhesive sterile wound dressing consisting of two layers — a polyurethane gel matrix and a polyurethane top-film which is waterproof and acts as a bacterial barrier
Lyof foam™ Extra (Mölnlycke Health Care)	A polyurethane foam dressing which has no additional wound contact layer and a high moisture vapour transmission rate
Mepilex®/Mepilex® Border (Mölnlycke Health Care)	Polyurethane foam dressing with Safetac silicone contact layer with a breathable outer membrane which allows transfer of moisture vapour
Tielle™ and Tielle™ plus (Systagenix)	The wound-contact layer comprises hydrophilic polyurethane foam coated with a water and bacteria repellent adhesive membrane of polyurethane. An acrylic fibre weave is located between the wound pad and the membrane
Versiva® XC® (ConvaTec)	A sterile adhesive foam composite dressing with several layers: a perforated hydrocolloid adhesive layer facing the wound covered by non-woven Hydrofiber® layer and a fluid-spreading layer of viscose and polyester covered by an outer polyurethane foam/film layer

Wound size and volume were slightly higher in the group treated with Allevyn Adhesive.

Closure rates were similar with both dressings and there was little evidence of skin stripping with either one. In 2% (7/403) of the wounds, skin stripping was recorded at baseline (three wounds treated with Allevyn Adhesive, four wounds treated with Mepilex Border). At final assessment, normal skin was present in 72% of the wounds treated with Allevyn Adhesive and 70% of those treated with Mepilex Border. Both dressings effectively managed exudate and odour. Patients found both dressings equally pain-free, with 99% reporting no pain associated with the use of either dressing.

In a further study on the same products, the issue of skin stripping was reviewed in a larger cohort of patients (Viamontes et al, 2003). As in the previous study (Viamontes and Jones, 2003), real time data were collected on wound closure, skin stripping, wound infection and product evaluation. The study was retrospective and over a five-year period (May 1997–June 2002). Data on a total of 4200 wounds (1891 patients) were examined. The majority of wounds were pressure ulcers (>94%), with other wound types including traumatic wounds (4%), diabetic ulcers (<1%), inflammatory wounds (<1%), ischaemic ulcers (<1%), postoperative wounds (<1%), and venous ulcers (<1%). Again, wound closure rates were similar for both dressings: 1996 of 3795 (53%) wounds treated with Allevyn Adhesive and 175 of 352 (50%) of wounds treated with Mepilex Border healed during the average treatment period of 71.3 days. Skin stripping was observed in a small number of wounds in each group (13 of 2546 patients treated with Allevyn Adhesive versus four of 227 patients treated with Mepilex Border). Wound infection was noted in 3% of patients treated with Allevyn Adhesive and 9% of patients treated with Mepilex Border. Product evaluation by the nursing staff suggested that Allevyn Adhesive was slightly superior in terms

of ease of application and staying in place without the need for additional adhesive tape.

Vanscheidt et al (2004) compared two foam dressings for the management of venous leg ulcers. This RCT was conducted in 15 centres across North America and Europe. Patients were randomised to either Versiva® (ConvaTec) or Allevyn Adhesive. With the dressing in place, SurePress® (ConvaTec) high compression bandages were applied to the limb. Dressings were changed as clinically indicated, with a maximum wear time of seven days. The treatment protocol was continued for 12 weeks or until the ulcer healed, whichever came first. Data were collected on healing, peri-wound skin, conformability, and ease of application. Of the 107 patients enrolled in the study, 31 withdrew. Possible dressing-related adverse events occurred in 13 patients, but there were no significant differences between the two dressings. There was no statistically significant difference in rate of healing (median Versiva 0.41 cm² and Allevyn Adhesive 0.43 cm²/week), or mean time to complete healing (Versiva 66±3.4 days; Allevyn Adhesive 72.6±3.1 days; $p=0.47$). Average dressing wear time was also not significantly different in either arm of the study (5.6 [SD 1.3] days in patients treated with Versiva, 5.6 [SD 1.2] days in patients treated with Allevyn Adhesive). Investigators reported that Versiva was superior in terms of conformability ($p=0.05$), absence of sensitising reaction ($p=0.02$), and ease of application ($p=0.01$). No statistically significant difference was noted in exudate absorbency, protection of the surrounding skin, non-traumatic removal and ease of removal.

In an open comparative block randomised study carried out on patients with highly exuding leg ulcers, Norkus et al (2005) evaluated the safety and performance of Alione Hydrocapillary (Coloplast), compared to two hydropolymer dressings, Tielle™ and Tielle™ Plus (Systagenix). Ninety-seven patients were recruited

from 12 centres in six European countries. The treatment period was until healing, or for a maximum of 12 months. Compression therapy was used in the majority of patients throughout the study. Wounds were assessed weekly for the first eight weeks, then fortnightly until the end of the study. Dressings could be changed in between times by the study nurses if necessary. Any adherence of the dressing or leakage was noted. Pain was also measured, along with odour, maceration, erythema and eczema. Patients were also asked to evaluate the dressing and compare it to other dressings that they had used. Quality of life was measured at the start and finish of the study.

Again, healing rates were not significantly different in either treatment group (51% in patients treated with Alione Hydrocapillary versus 40% in the patients treated with Tielle/Tielle Plus). No significant difference was noted in leakage, maceration, allergy or erythema between the two treatment groups. Adherence to the wound was reported to occur less frequently in the group treated with Alione Hydrocapillary ($p<0.05$). Study nurses' assessment of the dressings indicated that Alione Hydrocapillary had a superior 'capacity to absorb exudate' ($p<0.05$).

Mean wear time for both dressings was 3.2 days. Alione Hydrocapillary was considered more comfortable by the patients. The median World Health Organization (WHO) quality of life index increased from 60 to 68 in the patients treated with Alione Hydrocapillary, and 48 to 68 in the patients treated with Tielle/Tielle Plus. There was no significant difference in the incidence of wound pain and odour between the two groups.

In a multicentre prospective randomised clinical trial comparing two foam dressings in the management of chronic venous ulceration, Franks et al (2007) included 12 centres across the UK to recruit 156 patients. Allevyn Hydrocellular and Mepilex

Table 2
Effectiveness of different foam dressings

Authors	Wound type	Number of patients	Timeframe	Comparators	Time to healing	Healing rates	Decrease in ulcer size	Conclusion
Weiss et al, 1996	Venous leg ulcers and compression	18 (15 completed the study)	16 weeks maximum	Cutinova vs Allevyn	5.6 weeks vs 6.5 weeks			No statistical analysis carried out
Banks et al, 1997	Leg ulcers, pressure ulcers and others	61 (41 completed the study)	Six weeks	Lyofam Extra vs Allevyn			No statistical difference in reduction in wound size	Similar performance
Andersen et al, 2002	Venous/arterial leg ulcers	118 (99 completed the study)	Eight weeks or until healing	Biatain vs Allevyn	5.2 weeks vs 5 weeks (ns)	34% vs 39%	Significant decrease in ulcer size with both dressings, p=0.005 vs p<0.0005	Similar efficacy
Viamontes and Jones, 2003	Mainly pressure ulcers	206	One year	Allevyn Adhesive vs Mepilex Border	Wound closure rates were similar for both dressings	51% vs 50%		Similar efficacy
Viamontes et al, 2003	Mainly pressure ulcers	1,891	Five years	Allevyn Adhesive vs Mepilex Border	Wound closure rates were similar for both dressings	53% vs 50%		Similar efficacy
Vanscheidt et al, 2004	Venous leg ulcers and compression	107 (76 completed the study)	12 weeks or until healing	Versiva vs Allevyn Adhesive	66+3.4 days vs 72.6+3.1 days, p=0.47	38.2% vs 38.5% (p=0.96)		Similar efficacy
Norkus et al, 2005	Venous leg ulcers and compression	97	12 months or until healing	Alione vs Tielle/Tielle Plus	No statistical difference for time to heal	51% vs 40%	No statistical difference for reduction in wound size	Similar efficacy
Franks et al, 2007	Venous leg ulcers and compression	156	24 weeks	Mepilex vs Allevyn		66.7% vs 61.7%		Similar efficacy

dressings were the comparator dressings and compression systems were either 4-layer or cohesive short-stretch bandages.

Results indicated that complete wound closure was achieved in 24 weeks in 100 (64%) patients, 46 (29.5%) patients withdrew from

the study, nine (5.8%) remained unhealed and one patient died. In the 75 patients who had Mepilex applied to their ulcers, 50 (66.7%) healed. Once again, the Allevyn dressing achieved similar results — a total of 81 patients receiving this dressing and 50 (61.7%) healed. There was evidence that both

dressings improved the levels of pain that patients experienced, as assessed in pre- and post-dressing change analysis at both baseline and four weeks of treatment. Pre- versus post-dressing change pain at baseline reduced significantly (p<0.001) and at four weeks (p<0.001). Over time, the pain reduced significantly

with four-week scores lower than at baseline. The researchers suggest that compression therapy could also have played a part in alleviating symptoms.

Effectiveness of different foam dressings

Several measures were used to indicate effectiveness of the products. *Table 2* summarises the key information on efficacy.

... studies cited above suggest that there is little difference in clinical efficacy between the products examined, which may indicate that clinicians choose dressings for other reasons, including patient comfort, dressing retention, dressing profile and ease of use.

Conclusion

The role of foam dressings in the treatment of chronic wounds is well established, and it would appear that clinicians are happy with their efficacy. The provision of a moist warm wound healing environment and good exudate handling properties are essential when treating patients with chronic wounds, and foam dressings are one of the best available treatments (Thomas, 1993).

All the studies cited above suggest that there is little difference in clinical efficacy between the products examined (*Table 2*), which may indicate that clinicians choose dressings for other reasons, including patient comfort, dressing retention, dressing profile and ease of use. However, we should be really looking at efficacy of these dressings.

This review of the literature suggests that while there may be differences in characteristics of foam dressings, none were superior in terms of wound efficacy. Given

the results of these studies, it is possible that the high level of matrix metalloproteinases (MMPs) found in chronic wound fluid (Tregrove et al, 1999) is not being reduced sufficiently by foam products alone, and that using protease inhibitors may have an impact on these protease levels, which could promote healing as a result. Ideally, a foam incorporating a protease inhibitor may have different interesting results. **WUK**

References

Andersen KE, Franken CPM, Gad P, et al (2002) A randomized, controlled study to compare the effectiveness of two foam dressings in the management of lower leg ulcers. *Ostomy Wound Management* 48(8): 34–41

Banks V, Bale S, Harding K (1997) Evaluation of a new polyurethane foam dressing. *J Wound Care* 6(6): 266–9

Callam MJ, Ruckley CV, Harper DR, et al (1985) Chronic ulceration of the leg: extent of the problem and provision of care. *Br Med J (Clin Res Ed)* 290: 1855–6

Diabetes UK (2009) *Putting Feet First, a guide*. Diabetes UK, London

Franks PJ, Moody M, Moffatt CJ, et al (2007) Randomised trial of two foam dressings in the management of chronic venous ulceration. *Wound Rep Regen* 15: 197–202

Harding KG, Gray DG, Timmons JP and Hurd T (2007) Evolution or revolution? Adapting to complexity in wound management. *Int Wound J* 4(Supplement 2): 1–12

NHS Quality Improvement for Scotland (2009) *Guide to Wound Assessment*. NHSQIS, Edinburgh. Available online at: www.tissueviabilityonline.com/wound-assessment

Norkus A, Dargis V, Thomsen JK, Harding KG, Ivins N (2005) Use of a hydrocapillary dressing in the management of highly exuding ulcers: a comparative study. *J Wound Care* 14(9): 429–32

Phillips L, BATTERY J (2009) Exploring pressure ulcer prevalence and preventative care. *Nurs Times* 105(16): epub ahead of print

Thomas S (1993) *Foam dressings: a guide to the properties and uses of the main*

Key points

- ▶▶ Chronic wounds significantly impact on patient quality of life. They can be painful, are at risk of infection and can affect the patient's functional ability.
- ▶▶ Treatment of chronic wounds often involves absorbent foam dressings to help manage exudate, including in leg ulcers under compression. Foam dressings all have different product characteristics which can make the choice confusing.
- ▶▶ Different foam dressings were found to be equally effective to manage exudate in chronic wounds in the literature review.

foam dressings available in the UK. *J Wound Care* 2(3): 153–6

Tregrove NJ, Stacey MC, MacAuley S, et al (1999) Analysis of the acute and chronic wound environments: the role of proteases and their inhibitors. *Wound Rep Regen* 7(6): 442–52

Vanscheidt W, Sibbald G, Eager CA (2004) Comparing a foam composite to a hydrocellular dressing in the management of venous leg ulcers: A controlled clinical study. *Ostomy Wound Management* 50(11): 42–55

Viamontes L, Jones AM (2003) Evaluation study of the properties of two adhesive foam dressings. *Br J Nurs* 12(11): s43–s49

Viamontes L, Temple D, Wytall D, Walker A (2003) An evaluation of an adhesive hydrocellular foam dressing and a self-adherent soft silicone foam dressing in a nursing home setting. *Ostomy Wound Management* 49(8): 48–52, 54–6, 58

Weiss RA, Weiss MA, Ford RW (1996) Randomised comparative study of Cutinova foam and Allevyn with Jobst UlcerCare Stockings in the treatment of venous stasis ulcers. *Phlebology* 1: s14–s16