A multi-centre in-market evaluation of ALLEVYN◊ Gentle Border

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Abstract

Aims: To assess the performance of ALLEVYN Gentle Border in the management of a range of wounds including pressure ulcers, venous ulcers, diabetic ulcers, burns, donor sites, fungating/malignant wounds and surgically dehisced wounds in a variety of clinical settings. The primary objective was to assess the overall clinical acceptability for the indications treated. Secondary objectives included assessing dressing performance characteristics, determining changes in wound outcomes over the course of treatment, and clinicians' level of satisfaction with product characteristics. *Methods:* A multi-centre clinical evaluation conducted in 2008. *Results:* 153 adult patients were recruited from six countries. A total of 45% of patients (69/153) completed the study period (4–6 dressing change assessments) and 33% (51/153) of patients' wounds had healed before the end of the study period. Clinicians found the dressing to be suitable for the wound type treated in 95% (145/152) of patients. There was significant evidence of a reduction in wound area and depth by the final assessment ($p<0.001$); the median reduction in wound area and depth was 69% and 63%, respectively. There was significant evidence of a reduction in the level of exudate by the final assessment ($p<0.001$) although 87% of the study group had lightly or moderately exuding wounds at the beginning of the study. No pain at dressing removal was reported for 93% of removals. *Conclusions:* The new silicone adhesive hydrocellular foam dressing was effective in improving wound outcomes in conjunction with routine clinical practice. *Conflict of interest:* This study was carried out by Smith & Nephew as part of an in-market evaluation.

KEY WORDS

ALLEVYN◊ Gentle Border
Clinical evaluation
Acute and chronic wounds
Exudate management

The main purpose of a wound dressing is to provide an environment which is conducive to wound healing while also protecting the wound. Covering a wound with a dressing mimics the barrier role of the epithelium (Junqueira and Carneiro, 2005). It is widely accepted that dressings which promote a moist wound healing environment help to increase the rate of epithelialisation (Gates and Holloway, 1992; Helfman et al, 1994). Modern dressings also promote the production of granulating tissue in chronic wounds, can provide a painless method of autolytic debridement in necrotic wounds, prevent environmental and bacterial contamination and help to reduce wound pain.

The choice of dressing should be guided by clinical effectiveness, patient choice and acceptability as well as cost (MeRec, 2008). Overall acceptability of a dressing should include not just the dressing's performance in terms of the management of exudate, maintenance of optimal fluid balance and time to healing, but also patient acceptability and wear time. As dressing removal is often reported by practitioners and patients to be the most painful aspect of wound management, it is important to consider the ease of application and removal and whether this is associated with pain when selecting one dressing over another in clinical practice (Moffatt et al, 2002).

The purpose of this study was to assess the performance of ALLEVYN◊ Gentle Border (Smith & Nephew) in the management of a variety of different wound types in a variety of different settings, including specialist wound clinics, hospitals and community care. ALLEVYN Gentle Border was recently introduced to the market and comprises a polyurethane top film with a high moisture vapour transmission rate, a polyurethane foam absorbent layer and a perforated wound contact layer coated with a silicone gel adhesive. The intended use of ALLEVYN Gentle Border is as an absorbent dressing for the management of a range of wounds healing by secondary intention including chronic or acute, full thickness, partial thickness, or shallow granulating, exuding wounds such as pressure ulcers, venous ulcers, diabetic ulcers, burns, donor sites, fungating/malignant wounds and surgically dehisced wounds.

The primary objective of this non-comparative study was to evaluate the overall acceptability in the

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opinion of the treating clinician of the ALLEVYN Gentle Border dressing for its indicated uses. Secondary objectives included determining the clinicians' level of satisfaction (exceeds expectations/satisfied/dissatisfied) with the dressing performance parameters: exudate management, pain on removal, trauma to the wound/surrounding skin, ease of use, durability, patients' comfort and convenience. A retrospective comparison of the performance of ALLEVYN Gentle Border with the product previously applied for the same parameters (better/same/worse) was also conducted as part of the study. Further secondary objectives were to assess the change in wound outcomes over the course of treatment (healing, exudate, devitalised tissue, condition of surrounding skin) and to assess the dressing performance parameters (e.g. dressing wear time, pain on removal, comfort during wear).

Methods

A multi-centre clinical evaluation was performed between March and November 2008. A total of 153 patients were recruited from the adult (≥18 years) populations routinely seen by the evaluating clinicians from 72 centres in the UK, Ireland, Germany, Spain, Holland and Canada. The study length was set at 4–6 dressings, although some participants' wounds healed before this time. Ethics review of the study documentation was not sought before data collection as the evaluation involved no change to the patients' treatment. The product is available within the countries involved. There were no patient identifiers used in the study data capture and therefore the study did not require review by a research ethics committee. Institutional approval was obtained if required.

The patients recruited had wounds that were suited to the product in accordance with the indications in the standard product insert leaflet and were treated according to the insert leaflet's instructions for use. The centre's standard practice was used throughout the evaluation. Consent was given by patients before participation by using the centre's own consent forms which also included consent for any photographs taken. Patient data was collected using a case report form which allowed the data gathered to be pooled and summarised.

Additional restrictions were not placed on the patient or on their concomitant medication/therapies as a result of taking part in the evaluation.

The following inclusion criteria were specified: men or women aged 18 years or over, patients with chronic or acute exuding wounds, and patients who were able to understand and were willing to consent to the evaluation. Patients were excluded if they had a known history of poor compliance with medical treatment, were pregnant or trying to get pregnant, had participated in this evaluation previously, and or had a known sensitivity to any components of the evaluation product.

Wear time data was derived from information recorded in the case report forms, using duration between clinic assessment and the number of dressing changes between assessments as parameters to determine average wear time. Centres with long wear times were excluded from the wear time summaries since a number of centres had consistently long dressing wear times of greater than seven days across a number of patients. The centres confirmed that the dressings had been changed more frequently than recorded in the case report form. In addition, assessments where data inconsistencies were observed were also excluded from the duration of wear time summaries.

Statistical methods

All data summaries and statistical analyses were conducted using SAS version 9.1. The Wilcoxon signed-rank test was used to assess the percentage reduction in wound area and depth at the final assessment. The Cochran-Mantel-Haenszel test stratified by patient was conducted to test for a change in exudate level at the final assessment. Statistical tests were two-sided and conducted at the 5% significance level.

Results

A total of 153 patients from Canada, the UK, Ireland, Germany, Spain and Holland were recruited onto the study and had at least one silicone adhesive hydrocellular foam dressing (ALLEVYN Gentle Border) applied. A total of 45% (69/153) of patients completed the study period (4–6 dressing changes). A total of 4–6 dressing changes was considered to be sufficient to provide information on product performance. Dressing changes were made at the clinicians' discretion, either for routine reasons (i.e. to assess the wound or for clinical need such as strikethrough or leakage). For 33% (51/153) of patients, the wound had healed, 3% (5/153) of patients left the study as the wound was no longer exuding, and the remaining 18% (28/153) of patients were withdrawn for reasons including change in treatment (n=9), product complaint (n=2), patient's own request (n=2), patient lost to follow up (n=10) and other reasons (n=5) — patient treated from home, treatment interrupted for more than seven days, unable to attend clinic due to hip fracture, patient died, and no more recorded assessments. The median duration for all patients recruited to the study (n=153) was 21 days (range 2–74 days).

It was pre-specified in the statistical analysis plan that all patients who had ALLEVYN Gentle Border dressing applied would be included in the full analysis set. Therefore, all figures for the baseline characteristics and outcomes are based on the 153 recruited patients who had at least one ALLEVYN Gentle Border dressing applied. This represents the definition of the 'intention to treat' population (i.e. full analysis set). This follows regulatory guidelines that state that data should be on the full analysis set (intention-to-treat) population (European Medicines Agency, 1998).

Demographics and wound characteristics

Patients were treated across a range of

Table 1
Patient demographics

		Total
Age	Mean	73
	Median	80
	Minimum	22
	Maximum	99
	N	151*
Gender	Male	57 (37.5%)
	Female	95 (62.5%)
	N	152*
Treatment setting	Hospital	55 (36%)
	Home	27 (18%)
	Nursing home	11 (7%)
	Wound clinic	56 (37%)
	Other**	4 (3%)
	N	153 (100%)

*Patient age was missing for two patients and gender was missing for one patient
**Other treatment settings were medical practice, day hospital, community hospital

Table 2
Duration of wound before starting the study

	Wound type			
	Acute	Chronic	Burn	Total
Wound duration (weeks)				
Mean	11.3	63.5	1.2	37.0
Median	2.4	8.7	1	3
Minimum	0.1	0.6	0.1	0.1
Maximum	208	2600	2.6	2600
N	72	74	3	149

treatment settings, the majority being in hospital, home and wound clinics (*Table 1*). Surgical and trauma wounds and pressure ulcers were the most commonly treated wound aetiologies. The remaining wound types consisted of malignant wounds, diabetic foot ulcers, venous, arterial and mixed leg ulcers, burns and abscess wounds (*Figure 1*).

Table 1 shows the patients' age, gender and treatment setting. The median baseline wound area over all wounds was 3.8cm^2 (*Table 3*) and the median baseline wound depth was 0.2cm (*Table 4*). Burns generally had a greater wound area at baseline compared with acute (surgical, traumatic, malignant and abscess wounds) and chronic (pressure ulcers, venous, arterial and mixed leg ulcers) wounds (*Table 3*). The median duration of the wound before recruitment was 2.4 weeks for acute wounds and 8.7 weeks for chronic wounds and one week for burns (*Table 2*).

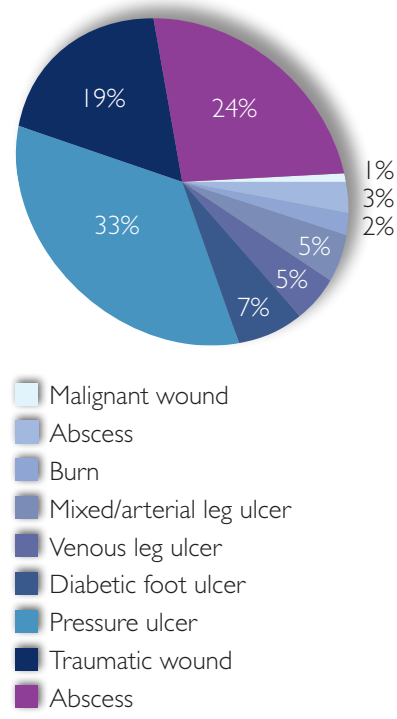

Figure 1. Wound type.

A high proportion of the wounds were located on the sacrum (20/153; 13%), buttocks (16/153; 11%), foot (19/153, 12%) and lower leg (29/153, 19%). The majority of wounds located on the sacrum and buttocks were pressure ulcers, those located on the feet were mostly DFUs and pressure ulcers, and those on the lower leg were mainly a mix of traumatic wounds, VLUs and mixed/arterial leg ulcers. In the majority of patients, the wound was lightly or moderately exuding at the baseline assessment (133/153; 87%). Furthermore, 75% (115/153) of patients experienced some pain from the wound at the baseline assessment — 44% (68/153) experienced mild pain, 24% (37/153) moderate pain, and 7% (10/153) severe pain.

Clinical acceptability (primary objective)

Clinicians rated the dressing as acceptable for the indication treated in 95% (145/152) of patients (clinical

Table 3
Reference wound area

	Wound type			
	Acute	Chronic	Burn	All wounds
Area at baseline assessment (cm^2)				
Mean	6.7	7.2	52.0	7.8
Median	4.0	3.1	34.3	3.8
Minimum	0.02	0.02	11.8	0.02
Maximum	62.8	78.5	110.0	110.0
N	72	76	3	151
Area at final assessment (cm^2)				
Mean	4.0	3.7	39.2	4.5
Median	1.4	0.3	7.7	0.8
Minimum	0	0	0	0
Maximum	62.8	33.0	110.0	110.0
N	72	76	3	151
Percentage reduction in wound area per week				
Mean	28.8	26.9	53.4	28.4
Median	20.5	24.3	60.2	21.7
Minimum	-67.3	-137.5	0	-137.5
Maximum	350	175	100	350
N	72	75	3	150
Percentage reduction in wound area at final assessment				
Mean	52.4	57.0	59.1	54.8
Median	648	75	77.4	68.6
Minimum	-125	-275	0	-275
Maximum	100	100	100	100
N	72	75	3	150

acceptability was not recorded for one patient). Clinicians rated the clinical acceptability for the indication treated as a yes/no answer, at the end of the evaluation.

Reduction in wound area

The median baseline area of the wound over all patients was 3.8cm^2 reducing to 0.8cm^2 at the final assessment. There was significant evidence of a reduction in wound area over all patients ($p<0.001$), with a median reduction at the final assessment of 68.6%. Furthermore, the median reduction per week was 21.7%.

Table 3 shows the baseline, final and percentage reduction in wound area at the final assessment and per week for chronic, acute and burn wounds. There was significant evidence of a reduction in wound area at the final assessment for both acute and chronic wounds ($p<0.001$ for both wound types). A median reduction of 64.8% was observed for acute wounds, and a median reduction of 75% for chronic wounds. Furthermore, a median reduction of 20.5% per week was observed for acute wounds and a median reduction of 24.3% per week for chronic wounds.

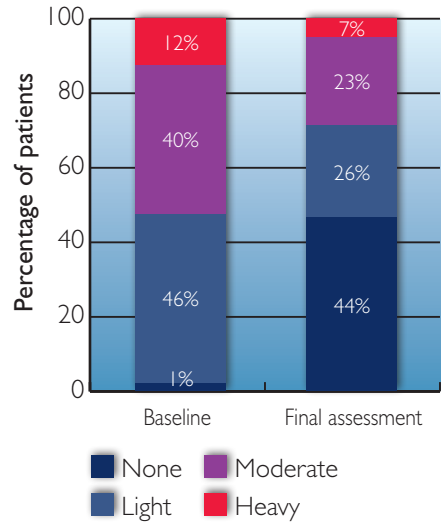

Figure 2. Exudate level at baseline and first assessment.

Reduction in wound depth

The median baseline depth of the wound for all patients was 0.2cm (range: 0–6cm) reducing to a median of 0cm (range: 0–5.5cm) at the final assessment. For patients with non-superficial wounds, there was significant evidence of a reduction in wound depth at the final assessment ($p<0.001$), whereby a median reduction of 63.3% (range: -2000–100%) was apparent. Furthermore, the median reduction per week was 20.6% (range: -875–350%).

Table 4 shows the baseline, final and percentage reduction in wound depth at the final assessment and per week for acute, chronic and burn wounds. There was significant evidence of a reduction in wound depth at the final assessment for both acute and chronic wounds ($p<0.001$ for both wound types); median reduction of 70% (range: -650–100%) for acute wounds and 50% (range: -2000–100%) for chronic wounds. Furthermore, a median reduction in wound depth of 20.6% per week was observed for both acute and chronic wounds (range for acute: -206.8–350%; range for chronic: -875–116.7%). All 46 patients with superficial wounds at baseline had no change in depth at the final assessment.

Wound healing

One-third (51/153; 33%) of the study group healed, corresponding to 26%

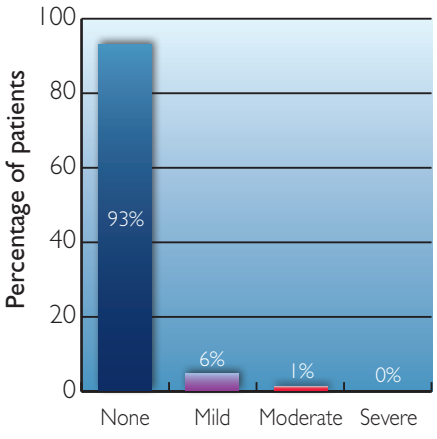

Figure 3. Level of pain on dressing removal.

(19/72) acute wounds, 40% (31/78) chronic wounds and 33% (1/3) burns.

Change in exudate level

There was significant evidence of a reduction in the level of exudate in the wound between baseline and the final assessment ($p<0.001$). In 64% (97/151) of patients, the level of exudate had reduced between the baseline and final assessment, in 30% (45/151) of patients the exudate level did not change from baseline to the final assessment, and in the remaining 6% (9/151) of patients the level of exudate increased by the final assessment. Furthermore, in 44% (67/151) of patients there was no exudate at the final assessment. *Figure 2* shows the distribution of the level of exudate at the baseline and final assessment. Exudate level at final assessment was not recorded for two patients.

Devitalised tissue in the wound bed

There was an observed reduction in the median percentage of devitalised tissue by the final assessment in most of the wounds where this was present at baseline assessment, whereby a median reduction of 10% (range: -40–100%) devitalised tissue was observed for acute wounds and 20% (range: -20–100%) for chronic wounds. There was only one burn wound with devitalised tissue at baseline (*Table 5*).

Surrounding skin condition

Table 6 shows the condition of the surrounding skin at the baseline and final assessment for all patients. There was an observed increase in the percentage of patients with healthy skin surrounding the wound at the final assessment (49% and 64% at the baseline and final assessments, respectively), although the final assessment involved a smaller patient group. There was consequently an observed reduction in the percentage of patients with inflamed, macerated and dry and flaky skin surrounding the wound at the final assessment.

Dressing wear time

The mean recorded patient wear time was 3.6 days for patients with reliable wear time data (n=111, range: 0.6–7 days). By wound type, the mean patient wear time was 3.3 days for acute wounds (n=50; range=0.6–7 days) and burns (n=2; range=2–4.5), and 3.9 days (n=59; range=1–6.5) for chronic wounds. The mean patient wear time was observed to be lower for those patients with a moderate or heavy exuding wound at baseline (moderate=2.7 days; n=36; heavy=2.9 days; n=15), compared with those with a light exuding wound at baseline (4.4 days; n=58).

The dressing was fully adhered before dressing removal at 76% (454/596) of dressing change

Table 4
Reference wound depth

	Wound type			
	Acute	Chronic	Burn	All wounds
Depth at baseline assessment (cm)				
Mean	0.8	0.5	0.2	0.7
Median	0.5	0.1	0.2	0.2
Minimum	0	0	0.1	0
Maximum	6	6	0.2	6
N	62	70	2	134
Depth at final assessment (cm)				
Mean	0.5	0.4	0.1	0.4
Median	0	0	0.1	0
Minimum	0	0	0	0
Maximum	5.5	4	0.1	5.5
N	62	71	2	135
Percentage reduction in wound depth per week				
Mean	27.3	-0.6	69.4	15.7
Median	20.6	20.6	69.4	20.6
Minimum	-206.8	-875	38.9	-875
Maximum	350	116.7	100	350
N	43	37	2	82
Percentage reduction in wound depth at final assessment				
Mean	42.6	0.1	75	24.2
Median	70	50	75	63.3
Minimum	-650	-2000	50	-2000
Maximum	100	100	100	100
N	43	37	2	82

assessments. In addition, the reason for dressing change was 'routine' at 83% (494/593) of dressing change assessments.

Product performance characteristics

There was no reported pain on removal at 93% (542/583) of dressing removals (*Figure 3*) and also no trauma to the wound or surrounding skin reported at 98% (574/583) of dressing removals. In 93% (590/632) of dressing change assessments, the clinician rated the dressing as being satisfactory in terms of exudate handling ability given the option yes/no. ALLEVYN Gentle Border was rated as having good conformability on application at 95% (609/638) of dressing applications, and good conformability during wear at 92% (584/637) of dressing change assessments. The dressing was rated as comfortable during wear at 99% (613/620) of dressing change assessments, easy to apply at all of applications (641; 100%) and easy to remove at 99% (578/583) of dressing removals.

Level of clinician satisfaction

Figure 4 shows the clinicians' rating of the level of satisfaction of the dressing at the end of the study. For the majority of patients, the clinician rated the dressing as being satisfactory or exceeding expectations for each of the product performance parameters assessed.

Retrospective comparison with a previously used alternative silicone foam dressing

A total of 80 patients were previously treated with an alternative silicone foam dressing (Mepilex™ Border, Mölnlycke Health Care). *Figure 5* shows the clinicians' opinion on the performance of the silicone adhesive hydrocellular foam dressing in relation to previous experience with an alternative silicone foam dressing. The silicone adhesive hydrocellular foam dressing was rated as better relative to the alternative silicone foam dressing for exudate management and durability in 50% (40/80) of patients, pain on removal in 59% (47/80) of patients, trauma to wound/surrounding skin in 59% (47/80) of patients, ease of use in 48% (38/80) of patients, patient comfort in 58% (46/80) of patients, and convenience in 45% (36/80) of patients.

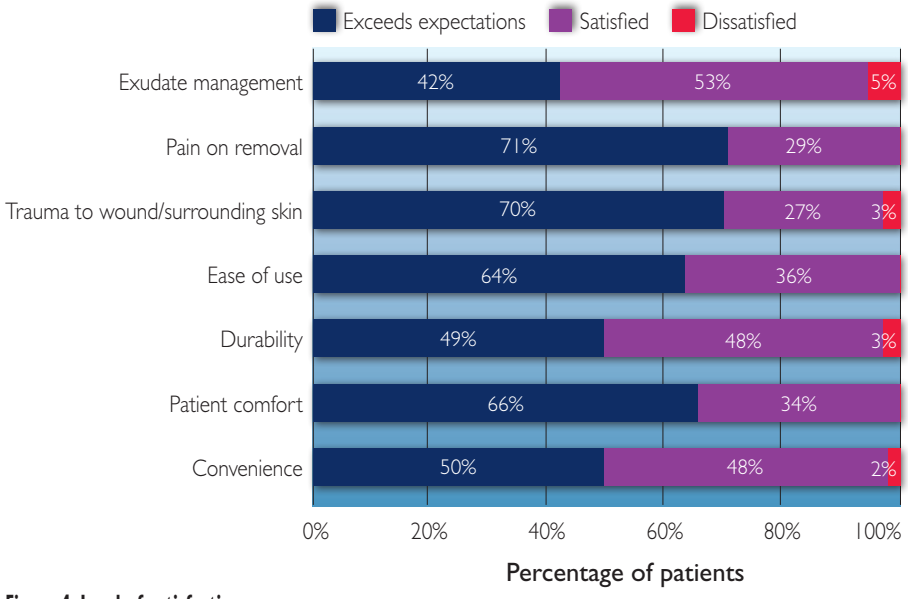

Figure 4. Level of satisfaction.

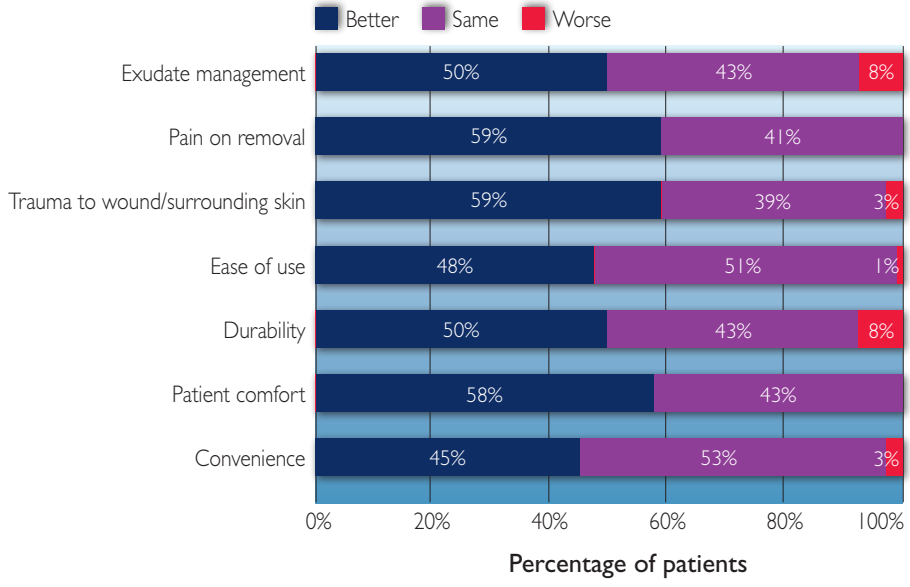

Figure 5. Product performance relative to an alternative silicone foam dressing.

Safety

There were two complaints reported from two patients throughout the evaluation. One patient had an allergic reaction to the dressing and eczema was evident, and the second product complaint was deemed not to be related to the dressing as it was an infection of the hair follicles. The study consisted of 932 dressing applications across 153 patients. This equates to a low level of exposure and suggests no concerns with the safety of the silicone adhesive hydrocellular foam dressings.

Cost per week

The mean cost per week of the dressing was £7.69 per patient and the mean cost of other dressings and products used was £8.18 (*Table 7;* UK Drug Tariff, 2009) based on costs of dressings in the UK making a mean total material cost per week of £15.87. *Table 7* shows the material cost data for each wound type. *Table 8* shows a breakdown of the components forming the mean cost of other dressings and products.

Nurse time required for dressing changes was not measured in this study, but based on evidence from other published studies, a mean of

about 13 minutes per dressing change across a range of dressings represents a conservative estimate (Vowden et al, 2009). Nurse costs according to Personal and Social Services Research Unit (PSSRU, 2008) are estimated at £22 per contact hour, giving a weekly cost of £9.25 in nurse time alone. The mean total cost per patient per week is therefore £25.12, of which the mean cost of silicone adhesive hydrocellular foam dressings constitutes £7.69, other dressings and products is £8.18 and nurse time is £9.25.

Discussion

The data from this study supports the use of ALLEVYN Gentle Border hydrocelluar dressing in a variety of wound types and clinical settings. Currently, foam dressings are among the most widely used type of absorbent dressing for the management of exuding wounds (Carter, 2003). The cellular structure of foams allows them to absorb and evaporate exudate from the wound bed, thereby decreasing maceration compared with traditional gauze products (Chaby et al, 2007). The majority of wounds included in the study had light or moderate exudate. The significant reduction in the level of exudate, even in chronic and malignant wounds of long duration, confirms the ability of the new dressing to handle exudate well. At final study assessment, >70% of the wounds included in the study had no or light levels of exudate. Wound size and depth also improved over the study period, and one-third of patients had wounds which had healed (n=51), corresponding to 40% chronic wounds, 26% acute wounds and 33% burns.

Half of the patients included in the study had inflamed, macerated or dry and flaky skin surrounding the wound at baseline. It has been widely reported in the literature that compromised skin condition surrounding a wound can increase patient discomfort, particularly at times of dressing change (Szor and Bourguignon, 1999; King, 2003; Manfredi et al, 2003; Nemeth et al, 2004; Jorgensen et al, 2006; Guarnera et al, 2007; Gunes, 2008). Patients in the study reported no pain on dressing removal or trauma to the surrounding skin upon dressing removal in 542/583 (93%) dressing changes. These factors add to the patient's acceptability of the dressing. By the end of the study period nearly two-thirds of patients had healthy skin surrounding the wound area and the number of patients with inflammation had halved. These factors undoubtedly contributed to the high level of acceptability reported in the current investigation. The mean time to

Table 5

Changes in levels of devitalised tissue in wounds that had devitalised tissue at baseline assessment.

	Wound type			
	Acute	Chronic	Burn	Total
Percentage of devitalised tissue at the baseline assessment				
Mean	35.8	60.4	50	50.8
Median	20	60	50	50
Minimum	5	5	50	5
Maximum	100	100	50	100
N	26	41	1	68
Percentage of devitalised tissue at the final assessment				
Mean	16.5	27.3	0	22.8
Median	0	0	0	0
Minimum	0	0	0	0
Maximum	90	80	0	90
N	26	41	1	68
Reduction in percentage of devitalised tissue at the final assessment				
Mean	19.3	33.0	50	28.0
Median	10	20	50	20
Minimum	-40	-20	50	-40
Maximum	100	100	50	100
N	26	41	1	68

Table 6

Surrounding skin condition at baseline and final assessment

Surrounding skin condition	Baseline	Final assessment
Healthy	75 (49%)	72 (64%)
Inflamed	30 (20%)	11 (10%)
Macerated	28 (18%)	14 (13%)
Dry and flaky	22 (14%)	10 (9%)
Other	17 (11%)	7 (6%)
N	153	112

Table 7
Material cost per week

	Wound type			
	Acute	Chronic	Burn	Total
Silicone adhesive hydrocellular foam dressing cost per week (£)				
Mean	8.24	6.97	15.11	7.69
Median	6.34	4.98	15.11	5.51
Minimum	2.70	2.15	3.42	2.15
Maximum	36.51	24	26.80	36.51
N	50	59	2	111
Other product costs per week (£)				
Mean	11.77	5.26	4.65	8.18
Median	3.99	0	4.65	1.94
Minimum	0	0	0	0
Maximum	68.49	37.44	9.31	68.49
N	50	59	2	111
Total cost per week				
Mean	20.01	12.23	19.76	15.87
Median	10.02	8.55	19.76	9.47
Minimum	3.20	2.59	3.42	2.59
Maximum	100.70	56.72	36.11	100.70
N	50	59	2	111

Table 8
Other products used

Product type	Product brand
Foam	Contreet™ *(Coloplast)*
Gel	INTRASITE◊ Aquaform™ Gel *(Unomedical)* Flaminal™ *(Ark Therapeutics)* Prontosan™ Gel *(Braun Medical)*
Ointment	FLAMAZINE◊ CADESORB◊ IODOSORB◊ Timodine™ Cream *(Reckitt Benckiser)*
Cavity dressing	Aquacel™ *(ConvaTec)* Aquacel™ Ag *(ConvaTec)* Seasorb™ Soft *(Coloplast)* ALGISITE◊ M Aquacel™ Ag Ribbon *(ConvaTec)* IODOFLEX◊ Sorbsan™ *(Pharmaplast)* ALLEVYN◊ Cavity Aquacel™ Ribbon *(ConvaTec)* Sorbsan™ Ribbon *(Unomedical)* Sorbsan™ Silver *(Unomedical)*
Other	Adaptic™ *(Johnson & Johnson)* Activon™ honey *(Advancis Medical)* Inadine™ *(Johnson & Johnson)* Cavilon™ *(3M)* ACTICOAT◊ Absorbent ACTICOAT◊ BACTIGRAS◊ Hydrocortisone 1% Iodozyme™ *(Archimed)* Promogran™ *(Systagenic Wound Management)* INTRASITE◊ Conformable Tubigrip™ *(Mölnlycke Health Care)* Catrix™ *(Catrix)* Mepitel™ *(Mölnlycke Health Care)* ALLEVYN◊ Ag

dressing change was lower in patients with moderate or heavily exuding wounds at baseline compared with wounds with light exudate, with an overall mean patient dressing wear time of 3.6 days. Seventy-six percent of dressings were fully adhered at the time of dressing change. Furthermore, the majority of dressing changes (83%) were performed in order to conduct routine wound assessment, rather than because of clinical need such as failure of the dressing to stay in place, leakage or strikethrough.

The high level of acceptability reported by clinicians participating in the current study suggests that the inclusion of a silicone adhesive in the ALLEVYN Gentle Border may enhance patient comfort. Only 5% of dressings in the current study were reported as unacceptable due to exudate management, the need for tape to hold the dressing in situ or failure of the dressing to remain in place (on a wound located on the right axilla). The majority of wounds included in this evaluation were pressure ulcers, surgical and traumatic wounds, which are often difficult to treat and associated with high levels of patient discomfort. Physical bulk and cushioning properties may also add to patient comfort while the dressing is in place (Amione et al, 2005). It seems possible that the additional cushioning provided by the dressing was a contributing factor to the high level of satisfaction reported in the current study, although further clinical studies are needed to verify this hypothesis.

Information on costs per week in this study shows that the cost of other associated dressings and products was actually higher than the silicone adhesive hydrocellular foam dressing. It is therefore essential for payors to include this additional cost in any budget impact analysis. Nurse time also forms an important component of the

overall cost and again is higher than the silicone adhesive hydrocellular foam dressing. This can often be ignored by payors due to the emphasis on reducing material costs.

The data from the current study demonstrates that the product has been acceptable for use among the majority of this study group and that the changes made to the product have successfully translated into positive clinical outcomes in conjunction with routine clinical practice.

Conclusion

Clinicians rated ALLEVYN Gentle Border as acceptable for the indication treated in 145/152 (95%) of patients. The dressing was shown to be effective in conjunction with routine clinical practice in improving wound outcomes, in particular, reducing wound area and depth and level of exudate. WUK

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Key points

- In an in-market evaluation carried out by the manufacturers, clinicians recorded the performance of ALLEVYN Gentle Border as acceptable in 95% of patients (145/152).
- In conjunction with routine clinical practice, the dressing was effective in improving clinical outcomes.
- ALLEVYN Gentle Border provides practitioners with a useful addition to their choice of dressings.