Non-comparative in-market evaluation of ALLEVYN◊ Gentle

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Abstract

Aims: To assess the performance of ALLEVYN◊ Gentle in the management of a variety of wounds including venous, mixed arterial and diabetic foot ulcers. The primary objective was overall clinical acceptability for its indicated uses. *Methods:* A multicentre clinical evaluation conducted in 2008. *Results:* 56 adult patients from five countries were included in the evaluation. Venous leg ulcers were the most commonly treated wounds (18/56, 32%). Median baseline reference wound area was 7.6cm^2, and median depth was 0.3cm. In 95% (52/56) of patients, clinicians reported that the dressing was acceptable for the indication treated. At final assessment, significant evidence reduction in wound area and depth was reported ($p<0.001$). Mean wear time was 3.3 days. Mean material cost per week was £6.68. No pain at dressing removal was reported for 87% of removals. *Conclusions:* The overall results from the study support the use of the dressing in clinical practice. The new soft gel 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
Clinical evaluation
Acute and chronic wounds
Patient acceptance

Despite significant advances in dressing structure and composition over recent years, pain is still widely reported by a number of investigators and is something which has a detrimental impact on patients' quality of life (DeCotiis and Konz, 2008; Kirby, 2008; Wasiak et al, 2008; Woo et al, 2008a; Woo et al, 2008b). Patients with fragile skin and those with burns or wounds on sensitive areas are more likely to experience pain at dressing removal, and represent a challenge in the clinical setting. The actual wound itself may be painful (World Union of Wound Healing Societies [WUWHS], 2004), and this may be exacerbated when dressings are removed or changed. Various studies have reported that the number of patients experiencing pain at dressing change is as high as 50% (Nemeth et al, 2004; Chaby et al, 2007; Guarnera et al, 2007; Woo et al, 2008a). In addition to providing a moist wound environment, properties of the 'ideal dressing' include: minimal adhesion to the wound surface, no impact on the surrounding skin and painless removal (Price, 2005).

ALLEVYN◊ dressings were initially launched in the 1980s. Since that time these dressings have undergone a number of modifications and developments to improve their performance as dressings which provide a moist wound healing environment in the management of a number of different wound types, including ulcers, surgical wounds, burns and donor sites. ALLEVYN Gentle (Smith & Nephew, Hull) was added to the ALLEVYN range in 2008. It is designed to combine the fluid-handling properties of ALLEVYN with advances in soft gel adhesives in an attempt to improve the management of difficult-to-treat wounds in awkward areas of the body and those on fragile skin (Smith and Nephew, 2008; http://global.smith-nephew.com/master/news_launch_allevyn_22204.htm). Using soft gel adhesive technology is one way to limit the potential for pain at dressing removal or change (Price, 2005). ALLEVYN Gentle uses a 'low tack' adhesive on the wound contact side of the product. This adhesive is designed to provide a low level of initial adhesion to allow the dressing to cling to the skin around the wound while secondary dressings or retention bandages are being applied, facilitating easy application in difficult anatomical sites. The safety and performance of ALLEVYN Gentle is supported by the clinical literature supporting the use of ALLEVYN in a wide range of wound types (Baker and Creevy, 1993; Kurring et al, 1994; Williams, 1995; Achterberg and Meyer-Ingold, 1996; Berry et al, 1996; Weiss et al, 1996; Williams and Young, 1996; Price et al, 2001; Vaingankar et al, 2001; Kammerlander and Eberlein, 2003; Viamontes and Jones, 2003).

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The primary objective of this non-comparative clinical evaluation of a soft gel adhesive hydrocellular foam dressing (ALLEVYN Gentle) was to evaluate the overall acceptability of the dressing for its indicated uses. Secondary objectives included dressing performance characteristics (patient wear time, whether the dressing was easy to apply and remove, pain on application and removal, reasons for dressing removal, trauma to the wound and surrounding skin on removal, adherence to the wound/surrounding skin, patient comfort and conformability, exudate management and leakage handling), and assessing changes in the wound over the course of treatment against the following parameters: wound size, exudate level, wound appearance (tissue types), and condition of the surrounding skin. Secondary objectives also included determining the clinician's level of satisfaction with the dressing's overall product performance and a retrospective comparison of performance with the product previously applied in terms of exudate management, pain on removal, trauma to wound/surrounding skin, ease of use, durability, patient comfort and convenience.

Materials and methods

A multicentre clinical evaluation was performed between March and September 2008.

A total of 58 patients were recruited from the adult (≥18 years) populations routinely seen by the evaluation clinicians from across 29 centres in the UK, Ireland, Germany, Spain and Holland. Ethics review of the study documentation was not sought before the data collection as the evaluation involved no change to patient treatment. The product is available within the countries involved. There were no patient identifiers (name, date of birth, etc) 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 were appropriate for the product in accordance with the indications and contraindications in the standard product insert leaflet, and throughout the evaluation treatment followed the insert leaflet's instructions for use and standard centre practice. Individual centre's own consent forms were used to gain patient consent before participation, which also included consent for any photographs taken (as per protocol standard for clinical trial). Patient data was collected using a case report form, which allowed the data gathered to be pooled and summarised to provide an understanding of the uses and performance of the products in a clinical setting on multiple indications.

No additional procedures, other than completion of the case report form and photography of the wound (if appropriate and with the patient's consent), were performed during the patient's participation in this evaluation. 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: males or females (not pregnant and using contraception if of reproductive age) of at least 18 years of age; patients with chronic or acute exuding wounds, and patients who were able to understand and were willing to consent to the evaluation.

If the patient met any of the following criteria they were excluded from the evaluation: patients with a known history of poor compliance with medical treatment; patients who have participated in this evaluation previously, and patients with 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. Centres with long wear times were excluded from the wear time summaries. A number of centres had consistently long dressing wear times of greater than seven days across a number of patients. In consultation with these centres, they confirmed that the dressings had been changed more frequently than recorded in the case report form. If this data had been included, the wear times would have been too optimistic (i.e. too positive).

In addition, assessments where data inconsistencies were observed were also excluded from the duration of wear time summaries. UK costs were assigned to the products applied to the reference wound until evaluation discontinuation.

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 reference wound area and depth at the final assessment. The Cochran-Mantel-Haenszel test stratified by patients 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

Disposition of patients

A total of 58 patients were recruited onto the study. One patient was incorrectly entered onto the study as they had not given consent, and a further patient was excluded due to not having any evaluation dressings applied throughout the duration of the study. Therefore, a total of 56 patients were included in this evaluation.

A total of 52% (29/56) of patients completed the study period (4–6 dressing changes). For 21% (12/56) of patients, the reference wound had closed before having 4–6 dressing changes, 5% (3/56) of patients completed the study as the reference wound was no longer exuding, and the remaining 21% (12/56) of patients were withdrawn from the study for the following reasons:

- Change in treatment (4). For one patient, there was a change in their condition (Pseudomonas infection), one patient was transferred to hospital (reason not provided), and the reason for the remaining two patients was not provided
- Product complaint (2). For one

Table 1
Patient treatment setting and wound duration

	Wound type			
	Acute	Chronic	Burn	Total
Patient treatment setting				
Hospital	8 (50%)	10 (27%)	3 (100%)	21 (38%)
Home	4 (25%)	10 (27%)	0	14 (25%)
Nursing home	0	3 (8%)	0	3 (5%)
Wound clinic	4 (25%)	9 (24%)	0	13 (23%)
Other	0	37 (100%)	3 (100%)	56 (100%)
Wound duration (weeks)				
Mean	16.0	107.3	2.0	76.7
Median	6	26.0	2.6	11.7
Minimum	0.3	0.1	0.9	0.1
Maximum	106	1040	2.7	1040
N	15	37	3	55

Other treatment settings were dermatology clinic (1), community (4)

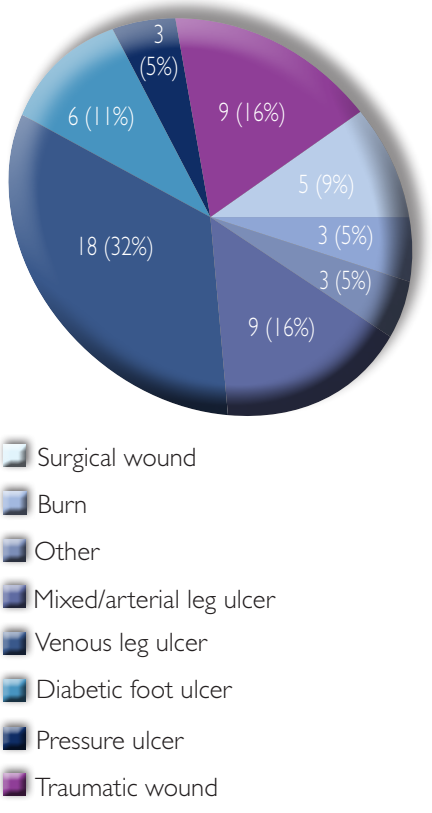

Figure 1. Wound type.

patient, the dressing curled and there was damage to the skin, while the other patient had pain under the dressing and new reddening around the wound
- Patients' requests (3). One patient felt that her skin had a reaction to the dressing whereby the peri-wound was red and tender. A further patient declined subsequent treatment (no reason provided). No reason was given for the remaining patient
- Patients lost to follow-up (2)
- Patient admitted to hospital for cellulitis (1).

The median duration on the study was 17 days (range of 0 to 53 days).

Demographics and wound characteristics

The mean age of the patients was 69 years (range of 29 to 90 years). A total of 32% (18/56) were male and 68% (38/56) were female. Patients were treated across a range of treatment settings, the majority being in hospital, home and wound clinics (*Table 1*). Venous leg ulcers were the most commonly treated wound indication (18/56, 32%). Surgical and traumatic wounds, arterial and mixed leg ulcers, diabetic foot ulcers, pressure ulcers and burns were also treated — and the remaining wounds treated were a foot ulcer of mixed aetiology, a malignant graft site, and a wound resulting from gout. *Figure 1* shows the distribution of wound indications treated.

The median baseline reference wound area over all wounds (not just those patients that healed) was 7.6cm^2, and the median baseline wound depth was 0.3cm. The median duration of the reference wound was six weeks for acute wounds (defined as surgical, traumatic wounds, malignant graft site, and a wound resulting from gout), 26 weeks for chronic wounds (defined as pressure ulcers, diabetic foot ulcers, venous leg ulcers and mixed/arterial leg ulcers) and 2.6 weeks for burns (*Table 1*). A large proportion of acute and chronic reference wounds were located on the lower leg, ankle and foot (48/53, 91%), and the burn cases were located on the hand, arm and anterior trunk (3/3, 100%). Wounds located on the lower leg were venous, arterial and mixed leg ulcers and also surgical and traumatic wounds. Wounds on the ankle were venous leg ulcers and traumatic wounds, and wounds on the foot were mostly pressure ulcers, diabetic foot ulcers and surgical wounds. In the majority of patients, the reference wound was moderately exuding at the baseline assessment (38/56, 68%). Furthermore, 84% (47/56) of patients experienced some pain from the reference wound at the baseline assessment, whereby 45% (25/56) experienced mild pain, 34% (19/56) moderate pain, and 5% (3/56) severe pain.

Clinical acceptability (primary objective)

Clinicians rated the soft gel adhesive hydrocellular foam dressing as acceptable for the indication treated in 95% of patients (52/55, information on clinical acceptability was not recorded for one patient). For the three patients in which the clinician rated the soft gel adhesive hydrocellular foam dressing as not acceptable, the reference wounds were moderate to heavily exuding at baseline.

Reduction in wound area

The median baseline area of the reference wound over all patients

Table 2
Reference wound area

	Wound type			
	Acute	Chronic	Burn	All wounds
Area at baseline assessment (cm^2)				
Mean	19.3	21.3	26.0	21.0
Median	6.9	7.1	32.1	7.6
Minimum	0.8	0.1	11.8	0.1
Maximum	157.1	131.0	35.3	157.1
N	16	37	3	56
Area at final assessment (cm^2)				
Mean	6.1	13.7	0	10.7
Median	0.8	3.3	0	1.3
Minimum	0	0	0	0
Maximum	51.8	116.0	0	116.0
N	16	35	3	54
Percentage reduction in wound area				
Mean	63.0	39.7	100	49.9
Median	70.8	33.9	100	48.9
Minimum	-25.0	-133.3	100	-133.3
Maximum	100	100	100	100
N	16	35	3	54
Percentage reduction in wound area per week				
Mean	28.1	14.9	60.7	21.2
Median	23.6	11.7	58.3	16.6
Minimum	-5	-51.9	53.8	-51.9
Maximum	77.8	58.3	70	77.8
N	15	35	3	53

was 7.6cm^2, reducing to 1.3cm^2 at the final assessment. There was significant evidence of a reduction in reference wound area over all patients ($p<0.001$), with a median reduction at the final assessment of 49%. Furthermore, the median reduction per week was 17%, calculated for all patients that had an area value at both baseline and final assessments and a study duration of at least one day (53 patients in total).

Table 2 shows the baseline, final and percentage reduction in reference wound area per week, for chronic, acute and burn wounds. There was significant evidence of a reduction in reference wound area at the final assessment for both acute and chronic wounds ($p<0.001$ for both wound types). A median reduction of 71% was observed for acute wounds, and a median reduction of 34% for chronic wounds. Furthermore, a median reduction of 24% per week was observed for acute wounds and a median reduction of 12% per week for chronic wounds.

Reduction in reference wound depth

The median baseline depth of the reference wound over all patients was 0.3cm reducing to a median of 0.1cm at the final assessment. There was significant evidence of a reduction in reference wound depth at the final assessment ($p<0.001$), whereby a median reduction of 40% was apparent. Furthermore, the median reduction per week was 15%.

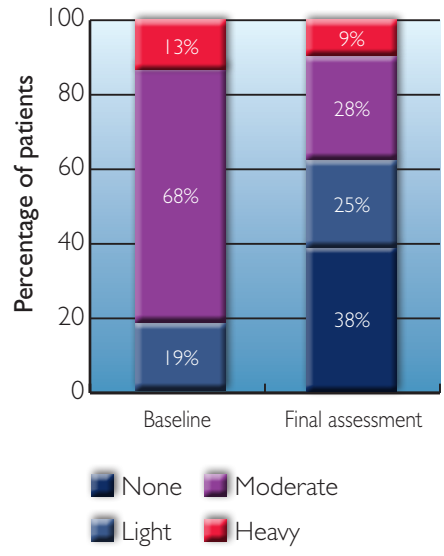

Figure 2. Exudate level at baseline and final assessments.

Table 3 shows the baseline, final and percentage reduction in reference wound depth per week for chronic, acute and burn wounds. There was significant evidence of a reduction in reference wound depth at the final assessment for both acute ($p=0.031$) and chronic wounds ($p=0.005$); a median reduction of 100% was observed for acute wounds and 33% for chronic wounds. Furthermore, a median reduction in reference wound depth of 27% per week was observed for acute wounds, and 14% for chronic wounds. A total of three patients with superficial wounds at baseline had no change in depth at the final assessment, and the remaining one patient had an increase in wound depth of 0.1cm by the final assessment.

Reference wound healing

A total of 21% (12/56) of patients healed by the end of the evaluation, corresponding to 25% (4/16) acute wounds, 14% (5/37) chronic wounds and 100% (3/3) burns.

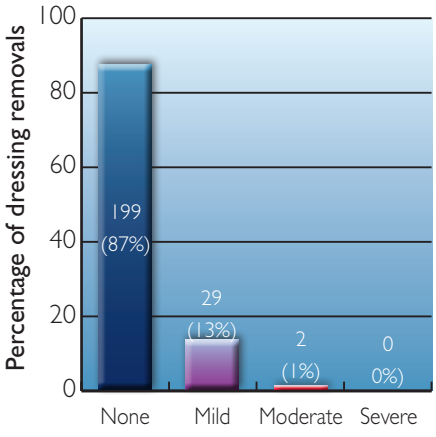

Figure 3. Level of pain on dressing removal.

Change in exudate level

There was significant evidence of a reduction in the level of exudate in the reference wound between baseline and the final assessment ($p<0.001$). In 58% (31/53) of patients the level of exudate had reduced between the baseline and final assessment, in 38% (20/53) of patients the exudate level did not change from baseline to the final assessment, and in the remaining 4% (2/53) of patients the level of exudate increased by the final assessment. Furthermore, in 38% (20/53) 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 assessments.

Devitalised tissue in wound bed

There was an observed reduction in the median percentage of devitalised tissue by the final assessment in most acute and chronic wounds where devitalised tissue was present at the baseline assessment. A median reduction of 55% was observed for acute wounds and 20% for chronic wounds (*Table 4*).

Surrounding skin condition

Table 5 shows the condition of the surrounding skin at the baseline and final assessment over all patients. There was an observed increase in the percentage of patients with healthy skin surrounding the reference wound at the final assessment. There was consequently an observed reduction in the percentage of patients with inflamed and dry and flaky skin surrounding the reference wound at the final assessment. However, there was a slight increase overall in the percentage of patients with maceration at the final assessment; for the 5/46 (11%) patients who developed maceration by the final assessment (and who had maceration recorded at both these assessments), the level of exudate remained moderate for three patients and reduced to moderate or light for the remaining two patients (for ten patients a response for condition of the surrounding skin was not recorded, thus only 46 patients were included).

Table 3
Reference wound depth

	Wound type			
	Acute	Chronic	Burn	All wounds
Depth at baseline assessment (cm)				
Mean	1.0	0.3	0.1	0.5
Median	0.5	0.3	0.1	0.3
Minimum	0	0	0.1	0
Maximum	4	1.5	0.1	4
N	13	33	3	49
Depth at final assessment (cm)				
Mean	0.3	0.2	0	0.2
Median	0	0.2	0	0.1
Minimum	0	0	0	0
Maximum	2	1.5	0	2
N	10	33	3	46
Percentage reduction in wound depth				
Mean	71.9	21.4	100	38.2
Median	100	33.3	100	40.0
Minimum	0	-400	100	-400
Maximum	100	100	100	100
N	8	27	3	38
Percentage reduction in wound depth per week				
Mean	47.6	6.9	60.7	17.1
Median	26.9	13.7	58.3	15.2
Minimum	0	-186.7	53.8	-186.7
Maximum	77.8	58.3	70	77.8
N	7	27	3	37

Dressing wear time

The mean recorded patient wear time was 3.3 days (N=37, range: one to seven days). By wound type, the mean patient wear time was 3.1 days for acute wounds (N=9, range: 1.6, 4.1), 3.2 days for chronic wounds (N=25, range: 1, 7), and five days for burns (N=3, range: 4, 6).

The soft gel adhesive hydrocellular foam dressing was fully adhered before dressing removal at 80% (185/231) of dressing change assessments. In addition, the reason for dressing change was 'routine' (i.e. twice-weekly or as required by wound assessment) at 95% (208/220) of dressing change assessments.

Cost per week

The mean soft gel adhesive hydrocellular foam dressing cost per week was £6.68, and the mean cost of other dressings and products used was £9.58. The corresponding mean total material cost per week was £16.27. *Table 6* shows the material cost data for each wound type.

Table 7 shows a breakdown of the components forming the mean cost of other dressings and products which was higher than for the soft gel adhesive hydrocellular foam dressing.

Nurse time required for dressing changes was not measured in this study, but on the basis of evidence from other published studies, a mean of 13 minutes per dressing change represents a conservative estimate (Drew et al, 2007; Vowden et al, 2009). Nurse costs according to the Personal and Social Services Research Unit (PSSRU) are estimated at £22 per contact hour, giving a weekly cost of £10.11 in nurse time alone (PSSRU, 2008). The mean total cost per patient per week is therefore £26.37, of which the mean cost of the soft gel adhesive hydrocellular foam dressing constitutes £6.68, other products is £9.58 and nurse time is £10.11.

Product performance characteristics

There was no reported pain on removal at 87% (199/230) of soft gel adhesive hydrocellular foam dressing removals (*Figure 3*), and also no trauma to the wound or surrounding skin at 96% (221/230) of dressing removals. In 96% (233/242) of dressing change assessments, the clinician rated the soft gel adhesive hydrocellular foam dressing as being satisfactory with the exudate and leakage handling ability. The soft gel adhesive hydrocellular foam dressing was rated as having good conformability on application at 91% (234/258) of dressing applications, and good conformability during wear at 90% (220/244) of dressing change assessments. The soft gel adhesive hydrocellular foam dressing was rated as comfortable during wear at 98% (231/235) of dressing change assessments, easy to apply at 98% (256/260) of applications and easy to remove at all (230, 100%) dressing removals (data only being recorded for 230 removals).

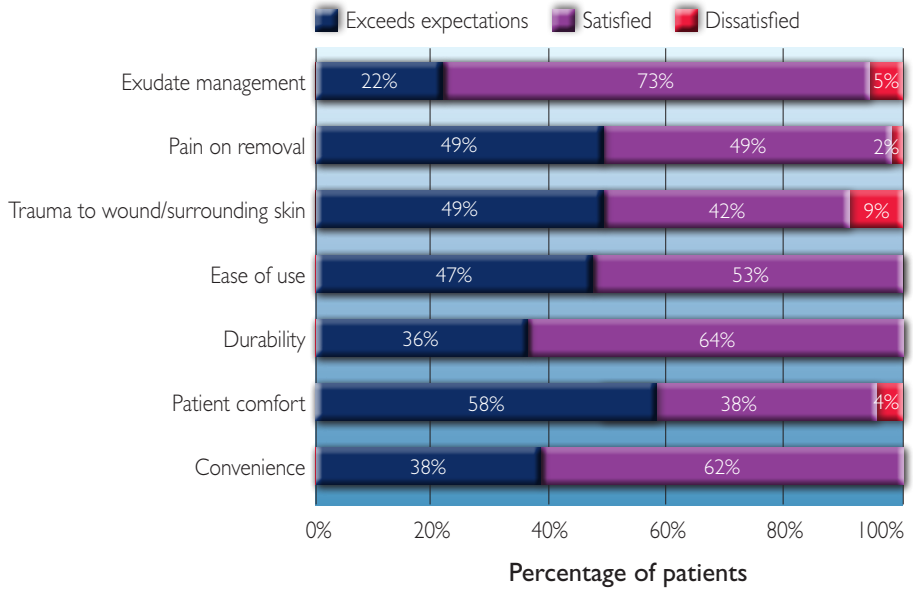

Figure 4. Level of satisfaction was recorded for a total of 55 patients. This included a reporting on the level of satisfaction for those patients that were withdrawn.

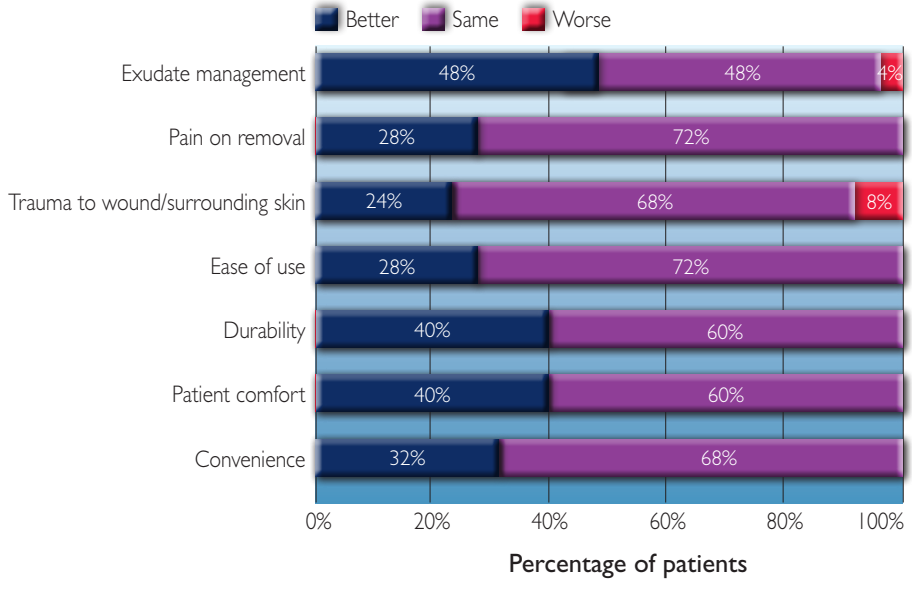

Figure 5. Relative frequency of product performance for 25 patients who previously had an alternative silicone dressing applied, regardless of reason for discontinuation.

Level of satisfaction

Figure 4 shows the clinicians' rating of the level of satisfaction of the soft gel adhesive hydrocellular foam dressing at the end of the evaluation. 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

Figure 5 shows the clinicians' opinion on the performance of the soft gel adhesive hydrocellular foam dressing in relation to previous experience with an alternative silicone foam dressing. The soft gel adhesive hydrocellular foam dressing was rated as better relative to the alternative silicone foam dressing for exudate management in 48% (12/25) of patients, durability and patient comfort in 40% (10/25) of patients, pain on removal and ease of use in 28% (7/25) of patients, trauma to

wound/surrounding skin in 24% (6/25) of patients, and convenience in 32% (8/25) of patients. Only 25 patients had previously used the specified alternative silicone foam dressing. Therefore, the retrospective comparison was based on these 25 patients. Patients were included regardless of whether they were withdrawn early or not — even patients who were withdrawn early were in the evaluation sufficiently long enough for the clinician to rate the performance of the product relative to the product previously applied.

Safety

There were a total of three complaints reported across three patients throughout the evaluation, only one of which was formally reported as being related to the soft gel adhesive hydrocellular foam dressing. This patient complained of pain, and the clinician noted more exudate with irritation and flushed skin under the dressing. The study consisted of 289 dressing applications across 56 patients. This equates to a low level of exposure and suggests no concerns with the safety of the soft gel adhesive hydrocellular foam dressings.

Discussion

The results of the current study suggest that the soft gel adhesive hydrocellular foam dressing is acceptable to both practitioners and patients in the clinical setting. In the current product in-market evaluation, in 87% of dressing removals, patients experienced no pain at dressing removal, which is higher than levels previously reported in the literature for non-silicone based adhesive dressings (Phillips et al, 1994; Hofman et al, 1997; Nemeth et al, 2003). The results of the current evaluation fulfil the criteria of an 'atraumatic dressing' first described by Thomas in 2003. The dressing also meets the objectives of minimising pain during wound dressing procedures laid out in the European Wound Management Association Position Document (EWMA, 2002) and consensus statement of the World Union of Wound Healing Societies (WUWHS, 2004). The later consensus document recommends the use of dressings that maintain moist wound healing, are atraumatic to the surrounding skin, are absorbent and have a low potential to stimulate an allergic reaction. The soft gel adhesive hydrocellular foam dressing fulfils these criteria. The combination of triple action technology and soft gel adhesive also provided a mean patient wear time of 3.3 days. The majority of dressing changes in the current study were for routine clinical reasons, rather than slippage or leakage of exudate. These are important factors in the day-to-day management of wounds,

Table 4

Percentage of devitalised tissue (wounds with devitalised tissue at the baseline assessment)

	Wound type			
	Acute	Chronic	Burn	Total
Percentage of devitalised tissue at the baseline assessment				
Mean	60.5	46.3	5	49.1
Median	60	47.5	5	50
Minimum	5	10	5	5
Maximum	100	100	5	100
N	10	24	1	35
Percentage of devitalised tissue at the final assessment				
Mean	8	18.9	0	15.0
Median	0	7.5	0	0
Minimum	0	0	0	0
Maximum	40	90.9	0	90.9
N	10	22	1	33
Reduction in percentage of devitalised tissue at the final assessment				
Mean	52.5	28.9	5	35.3
Median	55	20	5	30
Minimum	5	-20.9	5	-20.9
Maximum	80	100	5	100
N	10	22	1	33

Table 5

Surrounding skin condition assessed as present or absent by the clinician at baseline and final assessment

Surrounding skin condition	Baseline	Final assessment
Healthy	12 (21%)	20 (44%)
Inflamed	18 (32%)	5 (11%)
Macerated	12 (21%)	12 (26%)
Dry and flaky	21 (38%)	10 (22%)
Other	4 (7%)	4 (9%)
N	56	46

Table 6
Material cost per week

	Wound type			
	Acute	Chronic	Burn	Total
Soft gel adhesive hydrocellular foam dressing cost per week (£)				
Mean	6.14	7.05	5.27	6.68
Median	4.86	7.29	6.28	6.28
Minimum	2.37	1.23	1.72	1.23
Maximum	11.30	13.27	7.81	13.27
N	9	25	3	37
Other product costs per week (£)				
Mean	9.21	10.58	2.38	9.58
Median	11.10	10.31	3.11	9.84
Minimum	0.65	0.97	0.75	0.65
Maximum	17.34	23.41	3.28	32.41
N	9	25	3	37
Total cost per week				
Mean	15.35	17.63	7.65	16.27
Median	13.87	16.35	9.57	13.87
Minimum	3.33	4.37	2.47	2.47
Maximum	22.98	36.68	10.91	36.68
N	9	25	3	37

Table 7
Other products used

Product type	Product brand
Ointment	Iruxol® Mono Hydrocortisone 1% WV Flamazine◊ (Smith & Nephew)
Cavity dressing	Urgosorb® Silver (Urgo) Aquacel® Silver (ConvaTec)
Other	Acticoat◊ (Smith & Nephew) Activon honey (Advancis) Algisite◊ AG (Smith & Nephew) Catrix® FuciBET® (Leo) Aquacel™ (ConvaTec) Inadine® (Systagenix) Iodoflex◊ (Smith & Nephew)
Compression therapy	Profore◊ (Smith & Nephew) Tubigrip (Mölnlycke Healthcare) Class 1 stocking (circular) Class 2 stocking (circular) Profore Lite◊ (Smith & Nephew) Proguide◊ (Smith & Nephew)
Retention bandage	Tubular blue line Klinifix bandage
Tape	Sanipore Fix
Other	OpSite◊ Flexifix (Smith & Nephew) Propax (crepe) Wool

especially when patients are located in the community where there may be minimal or infrequent access to healthcare practitioners to perform dressing changes.

Information on costs per week in this study shows that the cost of other dressings and products was higher than the soft gel adhesive hydrocellular foam dressing. It is therefore essential for payers to include this additional cost of other products used in combination with the soft gel adhesive hydrocellular foam dressing in any budget impact analysis. Nurse time also forms an important component of the overall cost, which can often be ignored by payers due to the emphasis on reducing material costs.

Although the numbers of patients enrolled in the evaluation were relatively small and the evaluation was conducted in various centres in different countries where daily practices may differ, the number of patients in which the clinician rated the dressing as 'better' to previous management with an alternative dressing further supports the use of the dressing in clinical practice. Further controlled comparative studies are needed to confirm these data.

Conclusion

Clinicians rated the soft gel adhesive hydrocellular foam dressing as acceptable for the indication treated in 95% of the patients (clinical acceptability was still recorded for those patients that were withdrawn from the evaluation as the product was used for a sufficient time for the clinician to assess whether or not the product was clinically acceptable). 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 as acceptable in 95% of patients (52/55).
- At final assessment, significant reduction in wound area and depth were reported ($p<0.001$).
- No pain at dressing removal was reported for 87% (199/230) of dressing removals.
- ALLEVYN Gentle provides practitioners with a useful addition to their choice of dressings.