Interim report on a study to assess the effectiveness and improved fluid uptake of new Allevyn

A new formulation of the Allevyn foam dressings range has been developed. This report details the laboratory testing conducted in order to compare key performance attributes with the previous formulation. The results of these studies showed superior fluid handling performance. Consequently, a large clinical in-market evaluation has been initiated to determine how the formulation changes influence clinical performance, particularly in respect of fluid handling and the associated characteristics of wear time and maceration. These interim results confirm that this new formulation is superior to the previous one.

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Exudate
Wear time
Maceration

Wound care is a dynamic subject which is reflected in the plethora of research, clinical developments and new dressings. Over the past 20 years many new types of wound dressings have been developed and marketed, often with considerable success. Throughout this period some notable dressings have undergone a radical evolution to maintain their clinical performance and cost-effectiveness. Allevyn (Smith & Nephew, Hull) is a range of polyurethane, hydrocellular foam dressings that comprises many variations, both adhesive and non-adhesive. These dressings have been available for more than 20 years and are used for the management of exuding wounds. Most are indicated for use on medium-exuding wounds such as venous leg ulcers. Some have shaped forms for application to 'difficult' areas such as the heel and the sacral area. It is claimed that the exudate uptake function occurs by capillary action, even when used under high compression (Brett, 2006).

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Modern adhesive foams are claimed to be:

- Capable of managing exudate effectively, with 'minimal' risk of maceration
- Able to increase fluid handling by the moisture vapour transmission rate (MVTR) i.e. the capacity of a dressing to absorb fluid into its matrix and then permit fluid loss, by evaporation through the backing material
- Kind to the skin
- Effective at fluid uptake and retention, even under high compression.

As a basis for the clinical in-market evaluation reported here it is useful to consider the main criteria that might reasonably be proposed for an 'ideal' foam dressing:

- Manage exudate according to manufacturer's claims
- Create an 'optimum' moist wound environment
- Function when used under high compression
- Absorb and retain fluid
- Have a low maceration potential
- Be non-traumatic upon removal after a realistic wear time
- Be non-allergenic and non-irritant
- Be easy to apply and remove.

The management of wound exudate is a major clinical challenge. It is important to achieve and maintain an optimum moist wound environment (White and Cutting, 2006). In the event of exudate (particularly from chronic wounds) escaping onto the peri-wound skin, maceration and wound enlargement becomes a major risk (White and Cutting, 2006). The clinical performance of foam dressings in the management of exudate is reported in numerous publications (Harding and Bale, 1991); however, not all give details on the incidence of maceration.

Allevyn was launched in 1987 with a non-adhesive version of the dressing. This was followed by cavity and tracheostomy versions in 1989, and adhesive version in 1995. Shaped forms for sacral and heel areas were introduced in 1999 and a thinner version 'lite' in 2001. Allevyn Adhesive (including plus variants) and Non-Adhesive were reformulated in 2006 to provide enhanced performance. During the period 1987 to present, Allevyn has been compared with other foam dressings in numerous clinical trials, each time proving to be of clinical benefit (Viamontes and Jones, 1993; Harding and Bale, 2003). Furthermore, Allevyn has undergone many modifications over its 20 year lifetime, taking advantage both of new technologies in dressing manufacture and of new materials (Williams, 1995). The latest key technical improvements have been targeted at improving exudate handling through improved 'breathability'

i.e. greater MVTR and conformability while retaining the basic foam. The former has involved the development of enhanced fluid handling and manifests clinically in the creation and maintenance of an 'ideal' moist wound environment resulting in faster healing, longer wear time, reduced risk of maceration, and effective autolytic debridement (Harding et al, 2007; Young, 2007). Improved adhesion to the peri-wound skin also helps with longer wear time by virtue of there being less leakage; it also translates into less skin damage and wound bed trauma, particularly through dressing removal and rucking during wear (Harding et al, 2007; Young, 2007). These technical developments have resulted in improved clinical performance (Harding et al, 2007; Young, 2007).

Aims and objectives

In the first part of the assessment, the new formulation has been evaluated for fluid handling characteristics in defined laboratory tests. These have included a wide range of foam dressings from other manufacturers used for comparative purposes. Based upon positive performance in these tests, a non-comparative multinational clinical in-market evaluation conducted under everyday clinical wound care circumstances was carried out in order to examine the performance of the latest formulations of Allevyn in a clinical setting. The new formulations tested were Adhesive; Plus Adhesive; Plus Sacrum; and Non-Adhesive and the key clinical performance indicators were:

- General appearance of the wound
- Wear time
- Absorbency
- Healing
- Wound infection
- Debridement
- Skin condition
- Ease of application and removal
- Safety (by monitoring any product complaints).

Method

Fluid handling capacity

The first part of this review was the laboratory testing of the dressings' fluid handling capacity. It was carried out using both the British standard BS EN 13726-1 for testing absorbency of primary wound dressings and also an equivalent method devised by Smith & Nephew, the only difference between them being the volume of fluid used.

The fluid handling capacity of each dressing was measured using the apparatus shown in *Figure 1*. An ionic solution (primarily saline with calcium added to match the ionic content of exudate) was placed in the cup so that the wound contact surface of the dressing was in contact with the solution. The whole apparatus was then placed in an incubator at 37°C, <20% relative humidity for 24 hours. At the end of this period, the fluid absorbed by the dressing and the amount of moisture vapour transmitted through the sample was measured by evaporimetry and/or weight loss and these values were then used to determine the total fluid handling capacity of the dressing. The results were expressed as weight per 100cm^2 per 24 hours (Smith & Nephew, 2007).

The standard method used 20ml of fluid, which was then increased to 35ml for the internal method. This increase was required to enable dressings with high permeability to ensure that there was excess fluid in the cup at the end of the 24-hour test period. Longer time points were not tested as it was not possible to add sufficient fluid to maintain levels in the cups over a longer period.

Clinical in-market evaluation

The second part of the review was the clinical in-market evaluation, an ongoing multi-centre multinational study with a target treatment population of 250. Patients were recruited from an adult population (>18 years of age) routinely seen by the evaluation clinician from 13 centres in the UK, Ireland, Italy, Spain and France. For each consenting subject an initial assessment was conducted, followed by repeat assessments at every dressing change for a minimum of four weeks until healing up to a maximum of 12 weeks. Throughout the study the following information was recorded:

At the initial assessment:

- Age, gender, relevant medical history, date
- Treatment setting
- Wound category, size, depth, location and duration

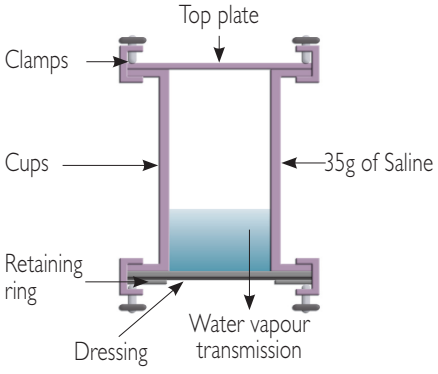

Figure 1. Apparatus set up for fluid handling capacity test.

- Wound bed tissue types, condition of surrounding skin, pain, exudate level, presence of signs of infection
- The choice of dressing variant (i.e. Adhesive; Plus Adhesive; Plus Sacrum; Non-Adhesive)
- Any additional wound products used, including primary or secondary dressings where appropriate.

At every dressing change, the above wound characteristics and choice of product were made as well as the following:

- Reason for dressing change
- Investigator's satisfaction with the level of absorbency of the Allevyn dressing
- Difficulty in application and removal of the dressing determined by the investigator.

At the final evaluation these further assessments were made:

- Date, reason for discontinuation (i.e. healing, 12 weeks of treatment completed, adverse event or other reason)
- Details of any product complaints
- Assessment of satisfaction with the chosen dressing according to various performance parameters and in comparison with old Allevyn dressings and an overall acceptability rating as judged by the clinician.

Primary and secondary objectives

The primary objectives were to assess wear time, absorbency and exudate management. Secondary objectives included the assessment of:

- Healing
- Signs of infection
- Appearance of the wound

- Appearance of the peri-wound skin
- Ease of dressing application and removal
- Reason for dressing change
- Retrospective comparison with the previous Allevyn formulation
- Overall acceptability.

Results

The results of the laboratory fluid handling test (*Figure 2*) confirmed that the new formulation Allevyn has much improved performance when compared with the 'old' version, and to the other products tested. This improvement is by virtue of greatly increased MVTR. This aspect of dressing fluid handling is less likely to engender maceration as the wound exudate is not held in the dressing matrix but lost by evaporation.

Demographics

To date 82 subjects have been recruited from 13 centres in the UK, Ireland, Italy, Spain and France. Data are presented on these subjects from the period October 2006 to May 2007. All subjects provided written, informed consent for participation in this study. The mean age of subjects was 69.6 years (range 25–99) with a gender distribution of 58.5% female, 41.5% male. The majority of subjects were treated in wound clinics (31; 38%), followed by hospital and home (22; 27% in each). Four patients were treated in a nursing home and four by a GP (one patient was cared for at two settings).

Dressing applications and wound types

For the patient population treated so far, 26(32%) received Allevyn Adhesive, 6(7%) Allevyn Plus Adhesive, 2(3%) Allevyn Plus Sacrum, and, 43(53%) Allevyn Non-Adhesive; five were unclassified as there was no predominant dressing type used throughout the evaluation. The protocol specified that the decision to use Allevyn Adhesive or Allevyn Non-Adhesive should have been made before considering the patient for inclusion in the evaluation. The distribution across wound types is shown in *Table 1*. Allevyn Non-Adhesive was mostly used on the lower leg (23;

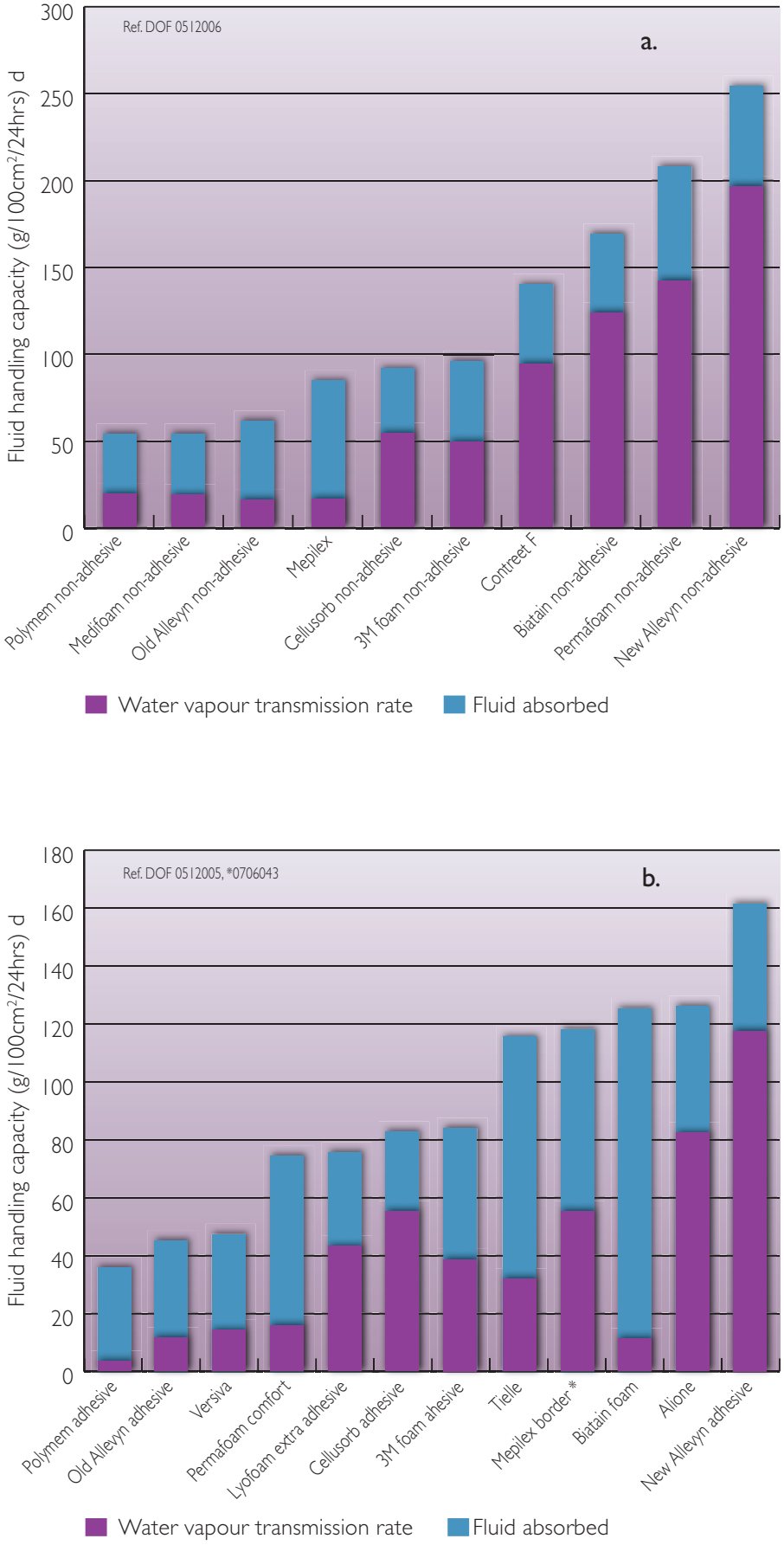

Figure 2. Results of the laboratory fluid handling test. a. Non-adhesive dressings and b. adhesive.

Table 1
Number of patients receiving dressings by wound type

Dressing type	Malignant wound	Surgical wound	Traumatic wound	Pressure ulcer	Diabetic foot ulcer	Venous leg ulcer	Mixed leg ulcer	Arterial leg ulcer	Full-thickness burn	Other	Total
Allevyn Adhesive	0	4	3	12	3	3	0	1	0	0	26
Allevyn Plus Adhesive	0	3	0	2	0	1	0	0	0	0	6
Allevyn Plus Sacrum	0	0	0	2	0	0	0	0	0	0	2
Allevyn Non-Adhesive	1	0	8	5	7	10	6	1	1	4	43
Total (All dressings)*	1	7	12*	24*	10	15*	6	2	1	4	82*

* Includes unclassified patient (no one dressing was applied predominantly throughout the evaluation)

Table 2
Level of exudate and type of dressing used

	Allevyn Adhesive	Allevyn Plus Adhesive	Allevyn Plus Sacrum	Allevyn Non-Adhesive	Total*
Overall dressings					
None	33 (14.3%)	15 (27.3%)	0	52 (12.6%)	102 (13.3%)
Slight	103 (44.6%)	16 (29.1%)	11 (57.9%)	128 (31.0%)	264 (34.5%)
Moderate	69 (29.9%)	20 (36.4%)	8 (42.1%)	174 (42.1%)	296 (38.6%)
Heavy	26 (11.3%)	4 (7.3%)	0	59 (14.3%)	104 (13.6%)
n (%)	231 (100%)	55 (100%)	19 (100%)	413 (100%)	766 (100%)

* Includes unclassified patients

54%), and applied in wound clinics (27; 63%). A number of patients received more than one variant of Allevyn. The main wound types treated were pressure ulcers (24 [29%] subjects); venous leg ulcers (15 [18%] subjects); and diabetic foot ulcers (10 [12%] subjects). Other wound types treated included arterial and mixed aetiology leg ulcers, malignant, surgical, traumatic and burns.

Wear time

With such a complex permutation of wound types and dressing variants, the wear time and duration of treatment details have been summarised for the major wound types. Thus, the longest duration of treatment with a single variant was obtained in those subjects mainly treated with Non-Adhesive (mean = 46.9 days), followed by Adhesive (mean = 35.7 days). For all dressing variants, the shortest mean duration of treatment was for pressure ulcers (31.9 days), followed by 43.3 days for VLU, 43.6 days for traumatic wounds, and 55.7 days for diabetic foot ulcers.

Wear time and xudate management

The wear time should always be interpreted in the context of other important factors such as exudate level, primary or secondary dressing usage and the site of the wound. In this evaluation the mean wear time for all dressings was 4.4 days. This varied from 3.8 days for wounds with 'heavy' exudate at baseline level up to 5.5 days for those with 'slight' exudate at baseline level. There was also a variation in wear time according to wound size with those greater than 7cm^2 achieving a mean of 4.0 days and those less than 7cm^2 a mean of 4.9 days. The detailed exudate levels are presented in *Table 2*. While most dressings were applied to wounds with 'slight' or 'moderate' exudate levels, some (Allevyn Adhesive = 11.3%; Allevyn Non-Adhesive = 14.3%) were applied to heavily exuding wounds.

Size of the wound

The wound areas, calculated by means of maximum length and width, showed an overall reduction throughout the treatment period. Only two subjects did not achieve full healing during the 12-week treatment period, these patients both had large pressure ulcers which did reduce in size (*Table 3*).

Signs of infection

During the study four subjects developed clinical signs of infection in their wounds.

Appearance of the wound

For each dressing, the percentage of devitalized tissue (i.e. slough and necrosis) reduced from a mean baseline value of 47.6% to a mean of 10.6% at the final assessment. This applied to all wound types and all dressing variants and amounted to a mean reduction of 37.8%. There were a number of wounds in this data set which were totally cleared of devitalised tissue through the promotion of autolytic debridement.

Appearance of the peri-wound skin

At the baseline assessment the peri-wound skin condition was assessed. Overall, only 22 subjects (26.8%) had healthy skin; 43 (52.4%) had inflamed skin; 16 (19.5%) had maceration, and 13 (15.9%) had dry/flaky skin. At the final assessment, the proportion with healthy

Table 3
Median reduction of wound size according to dressing group

	Allevyn Adhesive (n=26)	Allevyn Plus Adhesive (n=6)	Allevyn Plus Sacrum (n=2)	Allevyn Non-Adhesive (n=43)	Total* (n=82)
Median % reduction in area of wound					
Baseline area (cm^2)	3.1	1.4	48.1	12.6	7.0
Final area (cm^2)	0	0	24.1	0	0
Median % reduction	100%	100%	39.1%	100%	100%

* Includes unclassified patients

Table 4
End of evaluation assessment of clinical performance for all dressings as judged by clinicians

Feature	Exceeds expectations	Satisfied	Dissatisfied	N (%)
Progress of wound	21 (26.6%)	52 (65.8%)	6 (7.6%)	79 (100%)
Condition of skin	19 (24.4%)	57 (73.1%)	2 (2.6%)	78 (100%)
Comfort	10 (12.5%)	70 (87.5%)	0 (0%)	80 (100%)
Conformability	15 (18.8%)	64 (80.0%)	1 (1.3%)	80 (100%)
Ease of application	13 (16.3%)	67 (83.8%)	0 (0%)	80 (100%)
Ease of removal	6 (7.5%)	74 (92.5%)	0 (0%)	80 (100%)
Absorbency	36 (45%)	42 (52.5%)	2 (2.5%)	80 (100%)
Durability	32 (40%)	47 (58.8%)	1 (1.3%)	80 (100%)

skin had increased to 56 (70.9%), those with inflamed skin had reduced to 7 (8.9%), maceration also reduced to 5 (6.3%) and, dry/flaky skin remained relatively unchanged at 11 (13.9%).

Ease of dressing application and removal

Overall the dressings were easy to apply (99.2%) with no difference detected between adhesive and non-adhesive which was assessed by the practicality of application as judged by the clinician. The main reported difficulty was application to pressure ulcers which occurred in three (1.8%) out of 166 dressing changes.

Dressing removal was judged to be easy in most instances (96.7% of 658 changes). Where there was difficulty, it was related to removal of Allevyn Non-Adhesive from pressure ulcers and this occurred in seven out of a total of 30 changes.

Reason for dressing change

The reason for dressing change was in most cases 'routine' (95.3%) for all Allevyn variants with very few dressings leaking (1.9%) or slipping (1.2%).

Overall acceptability

Clinicians judged the overall acceptability for 80 of the subjects. The dressings were regarded as acceptable for most subjects and wound types (77; 96.3%). Of the three subjects (3.8%) where dressings were considered unacceptable, one received Allevyn Non-Adhesive and two were unclassified. Dressing acceptability was further rated as either 'satisfied', 'dissatisfied' or, 'exceeds expectations' for a variety of performance parameters. Not all of the participants replied but the results of those who did are presented in *Table 4*.

For each parameter, the investigators (the clinicians who were changing the dressings and assessing the wounds) were asked to rate the performance of the new dressings in comparison with the previous version. The ratings were predominantly 'similar' or 'improved' with notable performance improvements in absorbency (75.3% improved) and durability (68.8% improved).

Safety data

Safety data shows very few product complaints for all four Allevyn variants. A relationship between these complaints and the dressing was established in only one case (*Table 5*). In this instance the skin became red and inflamed upon dressing removal, however, the dressing had been left in place for 11 days.

Discussion

The Allevyn range of foam wound dressings has recently undergone reformulation, taking advantage of technological developments, such as improved materials for constructing dressings — backing films with greater MVTR and new foams for improved fluid uptake. In the case of the new Allevyn the changes resulted in greater MVTR and, hence, fluid handling to improve the clinical performance. The previous Allevyn Adhesive dressing had a low fluid handling capacity in comparison with all but one of its competitor products. This was primarily due to its low MVTR.

The new Allevyn Adhesive product, performed well in fluid handling capacity testing, giving higher results than any of the other dressings tested. Increased fluid handling is achieved through greater uptake of fluid and subsequent evaporation through the backing layer.

Of the competitor samples tested, Mepilex Border (Mölnlycke, Dunstable), Biatain Foam Adhesive (Coloplast, Peterborough), Alione (Coloplast) and

Table 5
Reason for early withdrawal

	Allevyn Adhesive	Allevyn Plus Adhesive	Allevyn Plus Sacrum	Allevyn Non-Adhesive	Total*
Reason for early withdrawal					
Adverse event	1 (3.8%)	1 (16.7%)	1 (50%)	3 (7%)	7 (8.5%)
Patient lost to follow up	1 (3.8%)	0	0	3 (7%)	4 (4.9%)
Other	1 (3.8%)	0	0	0	1 (1.2%)
Total number of patients	26 (100%)	6 (100%)	2 (100%)	43 (100%)	82 (100%)

* includes one unclassified patient

Tielle (Johnson & Johnson, Hull) had high fluid handling capacities (FHC). Mepilex Border and Alione achieved this FHC through high moisture vapour transmission, which will allow them to continue to deal with fluid over longer wear times. In contrast Tielle and Biatain Foam handled most fluid through high absorbency and so their FHC may be less effective over longer wear times. Permafoam (Hartmann, Heywood), Lyofoam (Mölnlycke) Cellusorb (Urgo, Loughborough) and 3M Adhesive Foam Dressing (3M Healthcare, Loughborough) performed similarly with mid-range fluid handling capacities. Permafoam handled fluid more through absorption than moisture vapour transmission. Versiva (ConvaTec, Uxbridge), and PolyMem (Ferris, Burr Ridge, Illinois) did not perform as well in fluid handling tests probably because of their low moisture vapour transmission.

The clinical in-market evaluation was planned to measure the overall performance of the dressing range when used with a variety of wounds. The improvement in fluid handling seen in the laboratory was expected to have measurable outcomes, such as reduced risk of maceration, longer wear time, faster healing, and thereby greater cost-effectiveness. A target population of 250 subjects was planned. This report, on 82 subjects completed to date, has been prepared in order to check that clinical outcomes are in line with expectations. The interim results confirm that the revised formulation has indeed resulted in measurable improvements in clinical performance. Data from over 600 dressing changes on a wide variety of acute and chronic wounds confirms that the changes in formulation are related to tangible improvements in clinical performance. These are manifested as reduced maceration and leakage. The fluid handling of those dressings used on leg ulcers with compression is of equivalent magnitude to that on uncompressed wounds, suggesting that the revised formulation also works well under compression bandaging.

Conclusions

The new formulation of Allevyn dressings has been evaluated in the laboratory and clinically on 82 subjects with a variety of wound types, mostly chronic wounds. The laboratory performance showed improved fluid handling when compared with the previous Allevyn and the initial data is very positive from the perspective of laboratory performance translating to improved clinical performance. Used as either primary or secondary dressings, the new Allevyn performed well in all aspects of the evaluation, particularly in respect to fluid handling and durability, even when used under compression. Indeed, the clinical performance has exceeded the clinicians' expectations. Initial indications from these studies are, therefore, that the clinical performance of this new Allevyn is substantially improved compared with the previous formulation. **WUK**

Key Points

- Allevyn foam dressing has been reformulated to improve the fluid handling characteristics.
- Standard laboratory tests have confirmed improved fluid handling.
- An ongoing multinational clinical in-market evaluation has confirmed that formulation changes have translated into improved performance.
- The new formulation of the Allevyn foam dressing range has been shown to have greater absorbency. This could result in longer wear times and less maceration, even when used under compression. The clinical performance has exceeded the clinicians' expectations.

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