

# An evaluation of Allevyn™ Adhesive and Non-Adhesive foam dressings

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## Abstract

**Aims:** A clinical in-market evaluation on 197 patients was carried out to assess the performance of the improved range of Allevyn hydrocellular foam dressings in clinical practice. The aim was to provide an insight into the uses and performance of the products in a clinical setting and on multiple indications. **Methods:** This evaluation took place in 13 centres across five European countries. Patients were entered into the evaluation after the decision to treat with the evaluation products was made. Patients were treated according to the product instructions and standard local practice. Data was collected at every dressing change until healing or until treatment with the evaluation products was discontinued. **Results:** Dressings were classed as satisfactory in terms of absorbency at 93% of dressing changes and were classed as acceptable for the indication treated for 96% of patients. For 92% of patients clinicians rated the dressings as satisfactory or exceeding expectations with regard to progress of the wound, and for 96% of patients regarding dressing durability. For 66% of patients clinicians stated that the evaluation dressings were improved in terms of absorbency in comparison with the previous range. **Conclusions:** The results of this study show that the improvements made to this foam dressing have translated into real clinical outcomes across a number of parameters, particularly in terms of clinician satisfaction. **Conflict of interest:** This study was carried out by Smith & Nephew as part of an in-market evaluation.

## KEY WORDS

Allevyn™ foam dressing  
Exudate  
Maceration  
Evaluation

Exudate is produced throughout the wound healing process from inflammation to epithelialisation. During the Renaissance period wound exudate was described as 'nature's balsam' and it was thought that it should

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not be interfered with (Haeger; 1989), and by the middle of the twentieth century Gilge (1948) demonstrated that maintaining a moist wound environment increased healing rates in venous leg ulcers. Winter's work (1962) further supported the advantages of moist wound healing.

The negative effects of chronic wound exudate have been described in many studies (Grinnell and Zhu, 1994, 1996; Rogers et al, 1995; Falanga, 2000), as have the detrimental effects of excessive exudate on wound healing. It is therefore essential that modern wound care products can promote moisture balance at the wound interface through controlled absorption and evaporation to remove excess exudate and to prevent the wound drying out, while also providing a physical and bacterial barrier to prevent leakage or extrinsic contamination.

Many wound care products designed to manage exudate are available in the UK today and they aim to maintain a moist wound environment that can assist healing. In 1994 there were 40 dressings that performed this function available through the NHS, but with more than

50 dressings entering the market each year; this increasing number of products has made it more difficult for clinicians to become proficient in the use of each and every product.

Smith & Nephew (Hull) have recently reformulated an existing product by improving the way it handles exudate. Allevyn™ products are hydrocellular foam dressings designed for use on moderate to highly exuding wounds. The dressings absorb, retain and transpire to achieve the optimal balance of fluid. This process helps to promote faster healing by maintaining an optimal wound healing environment and reduces the risk of maceration by not allowing the wound to become too wet. In 2006, the fluid handling capacity of the dressings was improved to 182g/100cm<sup>2</sup>/24 hours (Allevyn Adhesive) by the addition of a surfactant to the foam to increase the rate of fluid uptake and by the top film being improved to make it more 'breathable'. The top film increases its permeability in the presence of excess fluid but then reverts back to its previous permeability once the excess fluid has been removed. This allows enough moisture to be retained within the dressing to prevent it drying out.

### Clinical in-market evaluation

Clinical data on the performance of products is often collected via clinical trials however these are restricted to a very specific set of patients. The objective of this evaluation was to generate data on the performance of the recently reformulated Allevyn Adhesive, Allevyn Non-Adhesive, Sacrum, Plus Adhesive and Plus Sacrum dressings in a clinical setting on all indications, therefore addressing the needs of the general population and clinicians.

Ethics approval was not sought because the study was a non-comparative post-market evaluation of products which were used within their approved indication. Data was collected on the clinicians' standard use of the product, without any changes to treatment protocol. However, as the study involved human participants it was conducted in accordance with basic ethical principles such as informed consent and respect for the confidentiality of participants. No patient identifiers were used.

197 patients were recruited from the adult (over 18 years) populations routinely seen by the clinicians involved in the evaluation across 27 centres in the UK, Ireland, Spain, France and Italy. The centres consisted of public and private hospitals and non-hospital-based wound clinics and home care services. No inclusion or exclusion criteria were specified. The patients recruited were suitable for treatment with the product in accordance with the indications and contraindications in the standard patient insert leaflet in the country that the products were being used in and the decision to treat the patient with Allevyn dressings was made before the patient was considered for inclusion in the evaluation. The patients were treated according to the product's instructions for use and by the individual centre's protocols throughout the evaluation.

The evaluation was in the form of a collection of case studies documented using a standard data collection form provided by Smith & Nephew which allowed the data gathered to be pooled and summarised to provide an understanding into the uses and performance of the products in a clinical

**Table 1**

**Number of patients receiving each Allevyn variant**

	Number of patients assigned to dressing						Total
	Surgical wound	Traumatic wound	Pressure ulcer	Diabetic foot ulcer	Venous leg ulcer	Other/unclassified	
Allevyn Adhesive	20	8	32	5	7	12	84
Allevyn Plus Adhesive	3	0	2	0	1	0	6
Allevyn Sacrum	0	0	3	0	0	0	3
Allevyn Plus Sacrum	2	0	3	0	0	0	5
Allevyn Non-Adhesive	2	17	7	16	21	21	84
Unclassified	3	4	7	0	0	1	15
<b>Total (All dressings)</b>	<b>30</b>	<b>29</b>	<b>54</b>	<b>21</b>	<b>29</b>	<b>34</b>	<b>197</b>

setting and on multiple indications. No additional procedures were administered because of the patient's participation in this evaluation other than completion of the data collection form and photography of the wound. No additional restrictions were placed on the patient or on their concomitant medication/therapies as a result of taking part in the evaluation.

The following information was recorded at the initial assessment:

- ▶▶ Patient age, gender and relevant medical history
- ▶▶ Treatment setting
- ▶▶ Wound location and duration.

Wounds were categorised as either:

- ▶▶ Malignant wounds
- ▶▶ Surgical wounds
- ▶▶ Traumatic wounds
- ▶▶ Pressure ulcers (grade 2–4 using the EPUAP Classification [1999] guidelines)
- ▶▶ Diabetic foot ulcers
- ▶▶ Venous leg ulcers
- ▶▶ Mixed aetiology leg ulcers
- ▶▶ Arterial leg ulcers
- ▶▶ Donor sites
- ▶▶ Graft sites
- ▶▶ Burn
- ▶▶ Other:

The following data was collected at the initial assessment and at every dressing change for a minimum duration of four weeks and continued, where possible, to healing or 12 weeks:

- ▶▶ Date
- ▶▶ Wound type, size, depth
- ▶▶ Wound bed tissue types, exudate level and presence of clinical signs of infection
- ▶▶ Additional products used including secondary dressings
- ▶▶ Pain experienced from the wound
- ▶▶ Reason for dressing change
- ▶▶ Dressing choice
- ▶▶ Difficulty of dressing application and removal
- ▶▶ Clinician's satisfaction with dressing absorbency.

At the end of the evaluation the following data was collected:

- ▶▶ Date and reason for the discontinuation of treatment
- ▶▶ Assessment of clinician satisfaction with the dressing against various performance characteristics and in terms of overall acceptability.

Any complaints about the product were recorded throughout the evaluation.

### Results

#### Patient demographics

From October 2006 to November 2007, 197 patients were recruited into the evaluation. Overall, the median age of patients was 72 years, ranging from 25–99 years with a slightly greater percentage of women (56%) than men (44%) in the study. The majority of patients were treated in hospital (35%), at home (25%) or in wound clinics (27%) with the remaining 13% being treated

in nursing homes, GP surgeries and podiatry clinics.

**Dressing applications and wound types**

The number of patients receiving each Allevyn variant is summarised in *Table 1*. The majority of patients received either Allevyn Adhesive (n=84) or Allevyn Non-Adhesive (n=84) dressings. A number of patients received more than one Allevyn variant so the predominant variant was documented as the treatment received. Fifteen were unclassified as no predominant Allevyn variant was used throughout the evaluation.

Of those wounds predominantly receiving Allevyn Adhesive dressings, there were 32 (38%) pressure ulcers and 20 (24%) surgical wounds. Of those wounds predominantly receiving Allevyn Non-Adhesive dressings, there were 21 (25%) venous leg ulcers, 17 (20%) traumatic wounds and 16 (19%) diabetic foot ulcers.

**Product performance**

The following product performance parameters were recorded by the clinicians at each recorded dressing change.

**Absorbency and exudate management**

Clinicians were asked (yes or no) whether they were satisfied with the absorbency of the dressings after each dressing removal and 93% of the evaluation dressings were classed as satisfactory. There was a high percentage of satisfaction with absorbency for all wound types over the course of the study; surgical wounds (92%), traumatic wounds (97%), pressure ulcers (94%), malignant wounds (86%), venous leg ulcers (86%), mixed leg ulcers (89%), burns (100%), arterial leg ulcers (98%) and other (98%). Overall, when the level of exudate was recorded as moderate or heavy at the previous assessment the satisfaction with the dressing in terms of absorbency was 96% and 72% respectively.

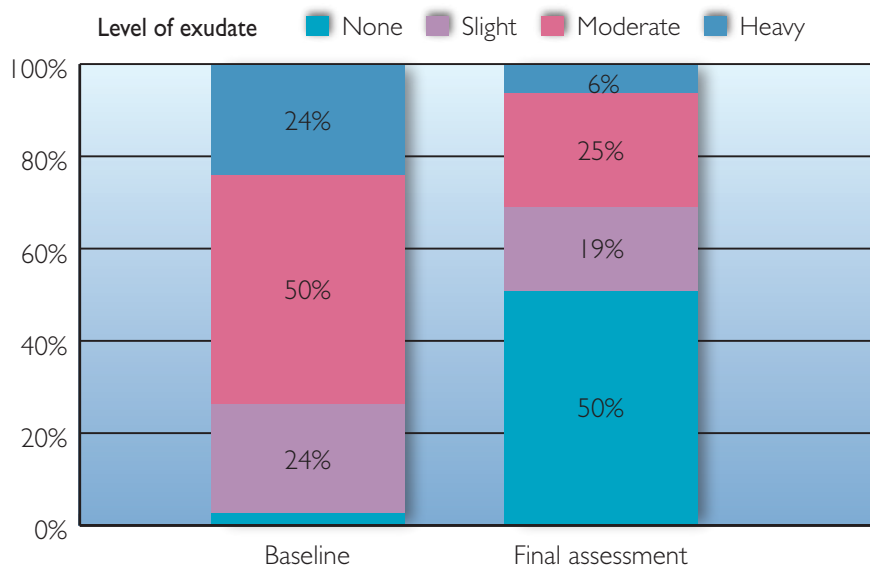
The percentage of dressing changes where the clinician was satisfied with absorbency was observed to be greater where Allevyn had been applied as the primary dressing at the previous assessment (97%) than where Allevyn had been used as the secondary dressing (90%).

**Table 2**

**Clinician satisfaction with dressing absorbency by exudate levels at the previous recorded assessment**

	Allevyn Adhesive	Allevyn Sacrum	Allevyn Non-Adhesive	Allevyn Plus Variants	Unclassified	Total
Percentage absorbency satisfaction (total number of dressings)						
No exudate	100% (55)	100% (2)	100% (32)	50% (4)	-	98% (93)
Slight exudate	99% (256)	100% (13)	100% (207)	100% (13)	97% (35)	99% (524)
Moderate exudate	97% (295)	100% (28)	96% (320)	83% (35)	97% (114)	96% (790)
Heavy exudate	82% (73)	100% (22)	72% (108)	33% (36)	74% (39)	72% (278)
Overall*	96% (684)	100% (67)	93% (675)	65% (86)	92% (190)	93% (1702)

\*This includes dressings that did not have the level of exudate recorded at the previous recorded assessment



**Figure 1. Level of wound exudate at the baseline and final assessment**

*Table 2* shows clinician satisfaction with dressing absorbency by the level of exudate at the previous recorded assessment.

There was a large reduction in the level of exudate from the reference wound from baseline to the final assessment over all wound types (*Figure 1*).

**Wound size**

Clinicians documented wound size by the length, width or area of the wound. During the study, 43% of wounds healed. Median

percentage reductions in wound area and depth of 95% and 100% respectively were observed after a median of 41.5 days (range 3–237 days). This performance was consistent across most indications (*Table 3*).

**Signs of infection**

The percentage of patients with clinical signs of infection reduced from 29% at baseline to 8% at the final assessment. The presence of clinical signs of infection in patients post baseline was lower when the evaluation dressing was applied as the primary dressing (26%)

**Table 3**

Wound healing

Indication	Percentage of patients healed	Median percentage reduction	
		Area	Depth
Surgical wound	50% (n=30)	100%	100%
Traumatic wound	72% (n=29)	100%	100%
Pressure ulcer	43% (n=54)	88%	100%
Diabetic foot ulcer	33% (n=21)	93%	90%
Venous leg ulcer	38% (n=29)	97%	100%
Overall	43% (n=197)	95%	100%

**Ease of application and removal**

Clinicians were asked at each dressing change whether the dressings were difficult to apply and whether they were difficult to remove (yes or no). Dressings were reported as being difficult to apply in only 1% of all applications and as difficult to remove at 3% of all removals.

**Pain on removal**

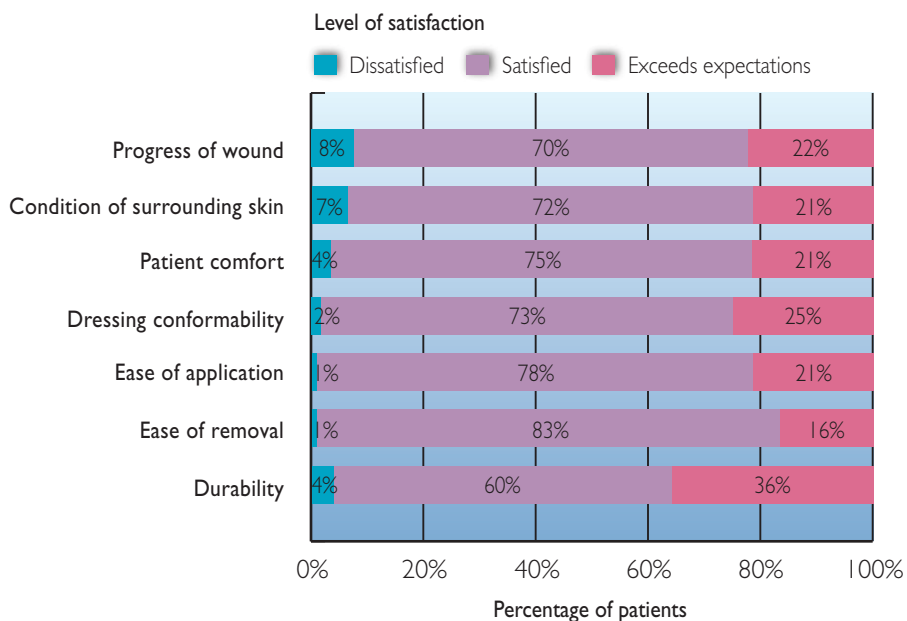
For 67% of all dressing removals patients reported no pain at dressing removal. Slight pain was reported at 26% of dressing removals and moderate or severe pain at 6% of removals.

**Reason for dressing change**

Overall, 90% of dressings were removed as part of routine treatment with 10% removed for other reasons. Of these, 6% were removed due to leakage and 1% removed due to dressing slippage. The remaining 3% were removed for 'other' reasons (including removal by the patient and damage to the dressing).

**Overall acceptability**

At the end of the evaluation clinicians were asked to rate the overall acceptability of the dressings and to rate their experience with the dressings as 'dissatisfied', 'satisfied' or 'exceeds expectations' for a number of performance parameters (Figure 2). Additionally, clinicians were asked to rate the performance of the new formulation products in comparison with the previous formulation for each performance parameter (Figure 3). This comparison was made based on the clinicians' previous experience with Allevyn dressings.



**Figure 2. Clinician satisfaction with the evaluation dressing.**

rather than a secondary dressing (44%) at the baseline assessment.

**Appearance of the wound**

Clinicians were asked to estimate the percentage of tissue types present in the wound at each assessment. The median percentage of devitalised tissue was observed to reduce from baseline to final assessment for each Allevyn dressing. The overall median reduction in devitalised tissue was 20%.

**Condition of surrounding skin**

From baseline to the final assessment, the number of patients with healthy skin surrounding the wound increased from

35% to 66%. There was a reduction in the number of patients with inflamed (39% to 14%), macerated (19% to 8%) and dry and flaky (13% to 11%) skin surrounding the wound from baseline to the final assessment.

**Wound pain during wear**

At 44% of dressing changes patients reported some wound pain (slight, moderate or severe) during wear: Overall, of the 81% of patients that had some pain (slight, moderate or severe) at the baseline assessment, only 18% of patients reported some wound pain (slight, moderate or severe) during wear at the final assessment.

For 96% of patients, the clinician reported the evaluation product as acceptable for the indication that was treated.

For a very high percentage of patients, the clinician was either satisfied with the evaluation dressing or it exceeded their expectations in terms of the wound condition and dressing performance (Figure 2). In comparison with the previous formulations the clinician also rated the evaluation product as either similar or improved for nearly all patients (Figure 3), with notable improvements in absorbency. For 66% of patients clinicians stated that

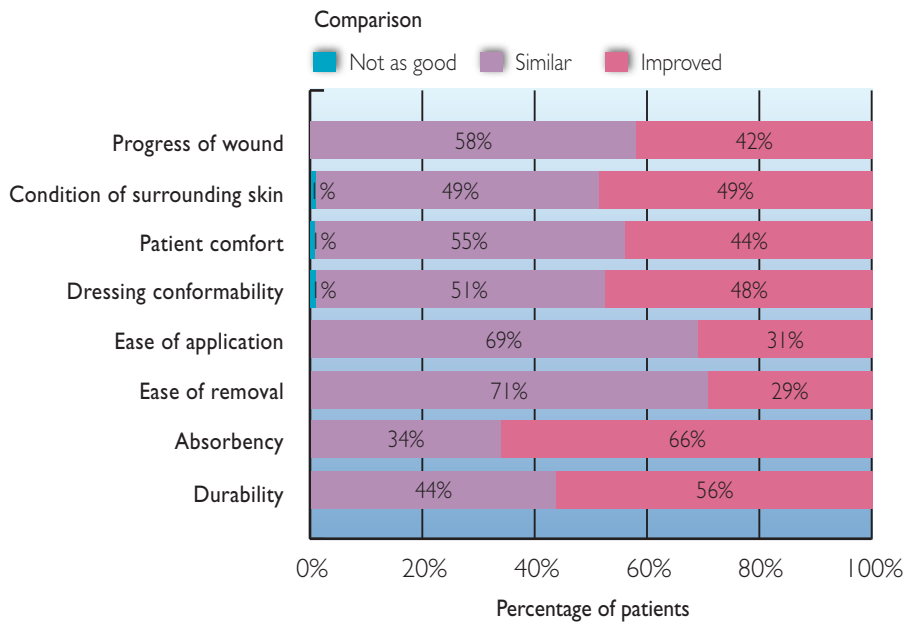


Figure 3. Clinician comparisons with previous formulation products.

they thought the revised formulation was improved in terms of absorbency and 56% stated that they thought it was improved in terms of durability.

**Safety**

There were seven complaints about the products, including itching, irritation and development of infection, four of which were thought to be related to the dressing (all four cases involved Allevyn Adhesive). One complaint of maceration of the skin surrounding the wound was received, however the clinician was unconvinced that this was caused by the Allevyn Adhesive dressing in use as the condition of the wound did not improve after treatment with the Allevyn dressing was discontinued.

The study consisted of 197 patients with 2,022 recorded Allevyn dressing applications over a median duration of 41.5 days (range 3–237 days). This equates to a low level of product complaints in terms of exposure and suggests no concerns with the safety of the evaluation products.

**Discussion**

The Allevyn range has recently undergone reformulation to improve its exudate management. The new Allevyn products have been designed to provide a faster rate of fluid uptake and to reduce the risk of maceration and the

potential for fluid leakage and odour, which is often embarrassing for patients. In vitro testing by Smith & Nephew has demonstrated that the Moisture Vapour Transmission Rate (g/m<sup>2</sup>/24 hours) of reformulated Allevyn Adhesive is 1152 compared with 434 for the previous formulation. This ensures that excess wound fluid is transpired away more quickly, increasing the fluid handling capacity of the dressing and promoting a longer wear time. A longer wear time in turn reduces the cost of nursing time (Russell, 2002) and the inconvenience to patients of multiple dressing changes. The improved fluid handling capacity of this range of dressings can offer patients reassurance and confidence and may help reduce the detrimental effects of stress and anxiety that are often associated with chronic wounds.

While biological elements of care are clearly important, psychological and social factors are highly influential as wound care is inherently a subjective experience. Restrictions on patients' daily life can profoundly affect their ability to adhere to treatment, therefore holistic assessment should include a discussion with the patient to determine their expectations of outcomes of the chosen dressing. It is important to consider the opinions of the patient and whether they find the dressing acceptable, as this should enhance compliance (Miller and Collier, 1996).

The changes made to the evaluation products were intended to improve exudate management. Overall, 93% of dressing changes were classed as satisfactory in terms of absorbency, with 97% classed as satisfactory when the evaluation product was applied as the primary dressing at the previous assessment. This suggests that the dressings successfully managed exudate which could result in a better quality of life for the patient and potentially allow an increased dressing wear time. In addition in 93% of patients, clinicians said that they were satisfied with the dressing performance with regards to the condition of the surrounding skin or that it exceeded their expectations. Clinicians were asked to compare the new and previous formulation Allevyn products based on their previous experience with the dressing. For 99% of patients clinicians stated that the new formulation products were improved or similar to the previous formulation in terms of the condition of surrounding skin. This could be a result of the improved exudate handling properties of the evaluation products. In addition clinicians said that they were satisfied with Allevyn or that it exceeded expectations in terms of ease of application and removal in 99% of patients. This demonstrated that in addition to providing beneficial wound healing and patient outcomes, the dressings were easy for clinicians to use.

**Conclusions**

The data from this study provides positive evidence regarding the use of the evaluation products on a number of wound types in different treatment settings. Overall, it shows that the evaluation products are acceptable for their intended use and that the changes made to the product have successfully translated into improved clinical outcomes. This is demonstrated by the fact that all clinicians reported that the products were similar or improved in comparison with previous Allevyn in terms of absorbency handling, wound progress and durability.

By understanding the complexities of exudate management and its related quality of life issues and building a

therapeutic relationship with the patient it is possible to reduce the impact of chronic wounds, even when healing is not the goal.

It can be concluded that the improvements made to the products have translated into positive clinical outcomes and that these evaluation products are suitable for use in a number of indications. **WUK**

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#### Case report

The following is a case report from the study by Sylvia Leonard, Tissue Viability Clinical Nurse Specialist, Luton and Dunstable Hospital NHS Foundation Trust. The patient was a 62-year-old woman with insulin-controlled diabetes who had Charcot changes to the left foot identified in 2006. A mid-foot osteotomy was carried out to remove a medial bony prominence caused by the dislocation of the navicular and medial cuneiform joint, which was restricting her ability to wear appropriate orthotic devices and limiting her mobility. She also had a past medical history which included cardiomegaly, hypertension, chronic anaemia, retinopathy, and peripheral neuropathy.

Within one week of the surgery the patient was readmitted as the wound had dehisced and required repeated debridements. The wound was left to heal by secondary intention. Microbiological and haematological investigation yielded little as to the cause of wound dehiscence, therefore the consultant put the cause down to the Charcot process and a deficiency in the microvascular circulation.

The patient was referred to the tissue viability nurse at the request of the consultant, two weeks after the initial procedure, for advice on the most appropriate management. On examination the patient presented with an 11cm long, 6cm wide and 3.5cm deep malodorous wound to the medial aspect of the left foot. The bed was covered in sloughy, fibrous tissue, producing large amounts of serous exudate, and the peri-wound skin was macerated. The patient was very embarrassed about the smell from the wound and was anxious about the soiling of bed linen and slippers with saturated, sodden dressings.

#### Wound management

The suggested management for this wound was divided into three phases: larvae therapy, topical negative pressure therapy (TNPT) and moist

wound healing with an absorbent foam dressing in conjunction with first an antimicrobial and then a hydrofibre. Larvae therapy was used to debride the wound, reduce the bioburden and odour. Only one treatment was required as the wound bed was slough-free within five days. TNPT at 125mmHg on continuous flow was then chosen as the most appropriate treatment option to manage the still heavily exuding wound. The patient was finally discharged with TNPT after a 20-day stay in hospital, with instructions for district nurses to change the dressing every two days (including weekends).

The consultant requested that the patient attended twice weekly at the outpatients clinic after discharge, so that the wound could be monitored. A wound swab taken the day of discharge was positive, indicating *Pseudomonas aeruginosa*. The wound was producing a purulent discharge and was again malodorous. The patient's blood sugars were stable as were her vital signs. An antimicrobial wound contact layer was used in conjunction with the TNPT to combat the infection and the consultant prescribed a course of antibiotics as he was concerned about the patient developing osteomyelitis. The infection did little to slow the progress of the wound, and within three weeks the wound had filled with granulation tissue measuring 10cm x 5.2cm (Figure 4).

After this period the wound was reassessed by the TVN. Although the exudate remained purulent the level had reduced significantly, there was no wound odour and the peri-wound skin appeared healthy. It was agreed to discontinue the TNPT and change to an absorbent foam dressing to manage the exudate, provide an optimum wound environment and maintain the integrity of the peri-wound skin. Allevyn Adhesive was then chosen as a secondary dressing and the patient was recruited into the study. The antimicrobial was continued as the primary dressing owing to the purulent nature of the exudate. Once



**Figure 4.** The wound on 28th March, after topical negative pressure therapy was discontinued, at the start of the study.

the exudate became less viscous and wound swabs showed no significant bacterial growth it was decided to discontinue the antimicrobial primary dressing and change to a hydrofibre with Allevyn Adhesive remaining as a secondary dressing and conducting dressing changes every 48 hours (Figure 5).

The exudate proved to be problematic despite the evidence of healing and reduction in wound size. In response the TVN changed the secondary dressing to Allevyn Plus Adhesive four weeks later. With the exception of 1 cm<sup>2</sup> area the wound had completely epithelialised. As before the exudate levels were disproportionate to the size of the wound and the area rapidly became overgranulated. At this time the hydrofibre was discontinued and Allevyn Plus Adhesive was chosen as the primary dressing. The integrity of the peri-wound skin was maintained throughout this period despite the frequency of dressing changes. The patient was very pleased with the progress of the wound remarking on how the removal of Allevyn Adhesive had been the easiest compared with all the dressings used in the management of her wound. She also found it the most comfortable to wear. If redressed in a timely manner the dressing handled the exudate and she could wear her slippers with confidence. The patient's only reservation was that the district nurses needed to reduce the number of visits as the wound healed and this increased her anxiety over infection and



**Figure 5.** The wound after antimicrobial treatment was stopped, illustrating the reduction in wound size and oedema achieved over 3.5 weeks.

the possibility of the wound breaking down again. Reassurances were given by the TVN and district nurses that she could contact them at any time.

Over the next six months the wound remained static, with a small area of overgranulation (Figure 6) despite various attempts at using pressure relief, a steroid cream and silver nitrate by the consultant. Exudate levels had improved and as they decreased the primary dressing was stepped down to Allevyn Adhesive. The overgranulation was in fact a sinus tract which, when explored 15 months later, led to the discovery of a suture anchor (a soluble suture which was used to close the fascia) used during the patient's original operation. This was removed along with any remaining stitch material and the patient's postoperative recovery was uneventful and the wound healed without problem.

In this study the clinician rated the new Allevyn products as acceptable for this indication and in terms of the progress of the wound, condition of surrounding skin, patient comfort, dressing conformability, ease of application and removal, absorbency and durability the clinician said that the dressings exceeded expectations and were improved in comparison to previous formulation Allevyn.

### Conclusion

This case presentation has demonstrated the effective and



**Figure 6.** The wound two weeks later showing a reduction in wound size but with one area that is not healing. The wound was producing copious amounts of exudate.

appropriate use of the new Allevyn products as part of the wound exudate management process in promoting wound healing in a manner which met the needs of both the patient and the clinicians. The patient was very anxious initially, due to past experiences with other dressings but stated that she was impressed with the Allevyn Adhesive. This improvement in quality of life is a real positive outcome for this patient. **WUK**

### Key Points

- ▶▶ Allevyn foam dressings have been reformulated to improve their fluid handling properties.
- ▶▶ A multinational evaluation has been valuable in confirming that the improvements to the products have translated into positive clinical outcomes.
- ▶▶ The evaluation demonstrated that Allevyn dressings are suitable for use on a number of indications and in multiple treatment settings.
- ▶▶ The dressings satisfied or exceeded the clinicians' expectations with regard to wound progress in 92% of patients.