A clinical in-market evaluation of ActivHeal® Foam Contact dressing

KEY WORDS
- Foam dressing
- Dressing evaluation
- In-market evaluation

Background: A clinical in-market evaluation of 10 patients was carried out to assess the performance of the ActivHeal Foam Contact dressing in clinical practice. **Aim:** The primary objective was to assess the clinical performance of the dressing in providing the optimum environment for healing. The secondary objectives were to evaluate the performance of the product in use, including ease of application and removal and patient and clinician satisfaction, and to estimate potential cost savings, including dressing cost, additional consumables and clinician time. **Methods:** This evaluation was undertaken by the Doncaster and Bassetlaw NHS Foundation Trust Wound Care Service. Patients were entered into the evaluation after the decision to treat with ActivHeal Foam Contact was made and were treated according to the product instructions and standard local practice. Data were collected at every dressing change until healing or until the treatment with the product was discontinued. **Results:** ActivHeal Foam Contact performed well with respect to fluid handling and durability, even under compression. The clinical performance of the dressing met clinicians' expectations of a foam dressing. The dressing addresses patients' needs in terms of easy application and removal, prevention of leakage and wound progression. **Conclusion:** The ActivHeal Foam Contact dressing performed well. Clinicians in the NHS are under pressure to reduce costs while delivering quality clinical outcomes, and the ActivHeal Foam Contact dressing can support this.

SUE JOHNSON
Lead Nurse,
Doncaster and Bassetlaw NHS Foundation Trust, UK

PAM SPRUCE
Clinical Director,
TVRE Consulting,
Barlaston, Staffordshire, UK

Exudate production in open wounds is essential for moist wound healing. Exudate can be defined as fluid leaking from a wound (Romanelli et al, 2010); is produced throughout the healing process and must be managed to maintain a moist wound environment that promotes healing (Collins et al, 2002). The volume of exudate reduces as healing progresses. Exudate is thought to have bacterial and nutrient properties (Adderley, 2008).

In chronic wounds, exudate appears to impede healing (Vowden and Vowden, 2004), because it:

- Slows down or even prevents cell proliferation.
- Interferes with growth factor availability.
- Contains elevated levels of inflammatory mediators and activated matrix metalloproteinases.

MANAGEMENT

The management of wound exudate is a challenge and it is important to achieve and maintain an optimum healing environment (White and Cutting, 2006). Effective exudate management can reduce time to healing, reduce exudate-related problems such as periwound skin damage and infection, improve quality of life, reduce frequency of dressing changes and clinician input, and therefore overall can improve healthcare efficiency. (Vowden and Vowden, 2004)

Thorough holistic assessment and management of the wound is the key to effective wound care. It must be remembered that dressings alone will not heal a wound. The priority should always be to optimise the patient's potential for healing through, for example, correcting identified nutritional deficiencies, maintaining good hygiene and encouraging mobilisation (Benbow, 2011). Assessment will establish causation, tissue types, exudate levels and will assist in addressing patient concerns.

"Foam dressings are important for managing chronic wounds and where exudate is problematic."

When exudate is produced in excessive quantities, problems within the wound and in the periwound skin can occur. The composition of the exudate can delay or prevent wound healing. The decision of which dressing to apply depends on the condition of the patient and the wound, but also on the reliability and cost-effectiveness of the dressing regimen.

It is essential that wound care products can promote moisture balance at the wound interface through controlled absorption and evaporation to remove excess exudate and prevent the wound drying out, while also providing a physical and bacterial barrier to prevent leakage or extrinsic contamination (Leonard et al, 2009).

Foam dressings

Foam dressings are important for managing chronic wounds and where exudate is problematic.

Advanced Medical Solutions Group (AMS) have added a new foam adhesive. The ActivHeal Foam Contact dressing is a polyurethane foam adhesive dressing which is designed to provide protection and absorbency for chronic and acute wounds.

The three-layer adhesive dressing has been designed to improve the total fluid handling properties of the dressing while providing a full adhesive coverage across the dressing, ensuring it stays in place. Each layer of the ActivHeal Foam Contact dressing contributes to the performance of the dressing to ensure that efficient management of exudate is maintained. The dressing comprises of a polyurethane top film with a high moisture vapour transmission rate, a polyurethane foam absorbent layer and a perforated wound contact layer which is coated with an acrylic adhesive.

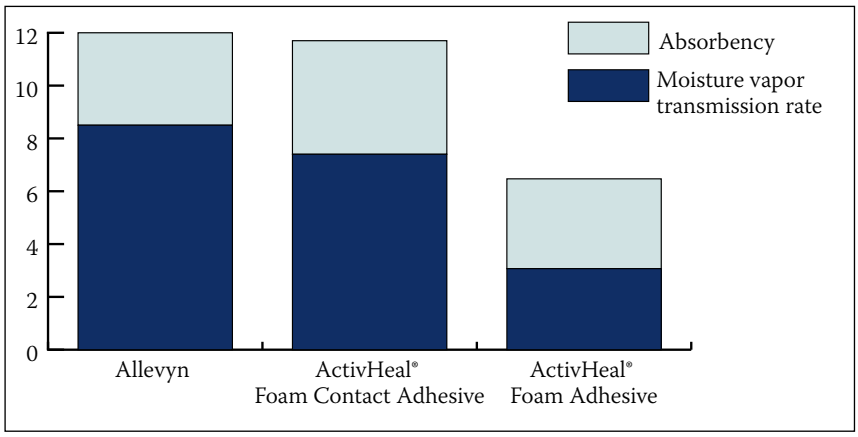


Figure 1. Total fluid handling properties.

The wound contact layer has been designed to prevent adherence to the wound bed by preventing the growth of granulation tissue into the dressing. The contact layer is coated with an acrylic adhesive to aid a secure fit, however, when it comes in contact with moisture it is inactivated to ensure that it will not adhere to the wound.

Improved adhesion to the periwound skin will help with longer wear time and translate into less skin damage and wound bed trauma, particularly through dressing removal and rucking during wear.

The core of the dressing is a layer of absorbent polyurethane foam which is ergonomically shaped to improve conformability to the wound area. The wound exudate is rapidly and vertically absorbed into the hydrophilic foam. The top layer of the dressing is a polyurethane film which provides an effective barrier function and is waterproof, while allowing the transpiration of exudate. The high moisture vapour transmission rate allows excess exudate to evaporate and, combined with the intrinsic absorption capacity of the foam, provides an excellent total fluid handling capability (AMS, data on file, 2012; *Figure 1*). Dressings which have a high breathable outer layer that allow moisture to evaporate from the dressing improve the efficacy and handling of exudate (Thomas, 1993).

EVALUATION

The objective of the evaluation was to assess the clinical performance of ActivHeal Foam Contact in providing an optimum environment for healing in the management of acute and chronic wounds. This was evaluated by observing wound progression over a 4-week period. The secondary objectives were to evaluate the performance of the product in use, including ease of application and removal and patient and clinician satisfaction, and to estimate potential cost savings, including dressing cost, additional consumables and clinician time.

Ethical approval was not required, as the dressing was evaluated within the standard care delivered. Local guidance for product evaluations was followed. Data were collected on the clinicians' standard use of the product without any changes to treatment protocol. The evaluation was conducted

Table 1. The patients and wound types assessed in the evaluation.

Patient	Age (years)	Wound type	Duration (weeks)
1	45	Surgical digital amputation site	8
2	58	Surgical – abdominal wound	8
3	33	Venous leg ulcer	Not known
4	78	Surgical – dehisced fem pop bypass wound in groin	6
5	44	Surgical – groin wound	3
6	72	Neuro-ischaemic diabetic foot ulcer	16
7	24	Pilonidal sinus	25
8	64	Ulcer – Medial malleolus	16
9	63	Trauma (stump wound)	6
10	59	Complex surgical – leaking umbilicus	Not known

in accordance with basic ethical principles such as informed consent and consent for photography. Patients were identified by a number and their age in order to maintain confidentiality. Patients had to fulfil the following requirements:

- Over 18 years old
- Understand and can consent to the evaluation
- Have a wound assessed as suitable for the ActivHeal Foam Contact dressing

Exclusion criteria:

- Known to be non-compliant with treatment
- Known or suspected sensitivity to foam dressings
- Known or suspected sensitivity to adhesive dressing products
- Periwound skin assessed as unsuitable for an adhesive dressing
- Insufficient exudate to require an adhesive foam dressing
- Unable to understand and give consent.
- Pregnancy.

METHOD

The dressing assessment was conducted through ongoing evaluation and data collection. The wounds were measured and photographed prior to the start of the process and at a minimum of weekly intervals. This enabled the data to be collated to provide clinical evidence relating to the performance of the ActivHeal Foam Contact dressing in clinical practice, progression of the wound and the achievement of patient outcomes.

Table 2. Wound outcome

Patient	Primary dressing	Secondary dressing	Initial wound size	Duration (weeks)	Frequency dressing change per week	Outcome
1	ActivHeal Foam Contact	None	5 cm × 3 cm	4	2	Healed
2	Acticoat® Flex (2 weeks)	ActivHeal Foam Contact	1 cm × 1 cm, 3 cm deep	4	2	Healed
3	ActivHeal Foam Contact	None	2 cm × 1.5 cm, 0.5 cm deep	4	2	2 cm × 1.5 cm, minimal depth, improving
4	Acticoat Flex	ActivHeal Foam Contact	N/A – seroma	4	2	Healed
5	Acticoat Flex	ActivHeal Foam Contact	2 cm × 0.5 cm, 0.5 cm deep	2	1	Healed
6	Acticoat Flex	ActivHeal Foam Contact	0.6 cm × 0.3 cm, 0.5 cm deep	4	2	Healed
7	Acticoat Absorbent	ActivHeal Foam Contact	6 cm × 1.5 cm, 2 cm deep	1	4	6 cm × 1.5 cm, 2 cm deep, some irritation
8	Acticoat Flex	ActivHeal Foam Contact	4 cm × 2 cm	4	2	4 cm × 2 cm, some irritation
9	Calgitrol® Ag	ActivHeal Foam Contact	0.4 cm × 0.1 cm	3	2	Healed
10	ActivHeal Foam Contact	None	N/A – seroma	2	2	Healed

Both patients and clinicians were asked to give their opinion on how the dressing performed.

The evaluation parameters/considerations were:

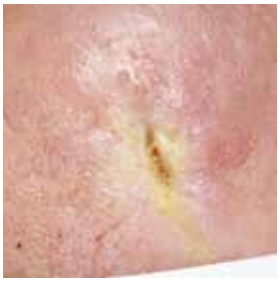
- Ability to manage exudate.
- Conformability.
- Maintaining a moist wound environment.
- Ease of use.
- Assessment of wound bed/wound progression.
- Dressings wear time.
- Ease of application and removal.
- Patient comfort and experience.
- Clinician satisfaction.

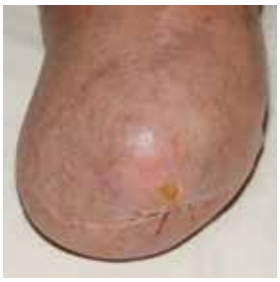
Documentation

Information on the patient and product in use was recorded as follows:

- Patient specific information (study number, age, sex, co-morbidities, pain).
- Wound specific information (wound aetiology, size, depth, type of tissue in the wound bed, exudate level, duration of wound prior to the evaluation and previous care).
- Product information (ease of use, dressing change data, ease of application and removal, progression of the wound, dressing wear time, patient comfort).
- Final assessment (reason for discontinuation of treatment, clinician satisfaction with product).

Case study 1.





Mr T was a 63-year-old-man who had undergone a below-knee amputation some years ago. He was referred to the wound care clinic with a small wound to his stump that had failed to heal following trauma. At initial assessment, the wound exhibited 100% sloughy tissue, some signs of periwound maceration, and exudate levels were moderate (*top*). The priority was exudate management. The dressing previously used was Allevyn Adhesive and Intrasite® Gel (both Smith & Nephew Healthcare), changed three times a week.

ActivHeal Foam Contact dressing was chosen for exudate management. The patient remained active using a prosthetic limb under which he wore a Juzo® stocking to cover the stump. The sacral-shaped ActivHeal Foam Contact dressing was used over the wound for enhanced conformability.

The dressing was changed every 3 days by the patient. On his second visit to the clinic, the wound was reassessed. The dressing had remained in place and was comfortable and conformable which had enabled him to continue to wear his prosthetic limb. The dressing had effectively managed the exudate levels as there were no signs of maceration. The patient experienced no pain when the dressing was *in situ* or when it was removed. The wound had started to granulate.

At the third visit, the dressing changed to twice a week and exudate levels had started to reduce. The exudate management remained excellent as the wound had continued to reduce in size and the periwound area remained intact, demonstrating that the ActivHeal Foam Contact dressing provided the right environment for wound healing. The dressing continued to be comfortable and remained in place even under stress when the patient used his prosthetic limb.

At the final review (*bottom*), the ease of removal was good and the dressing had stayed in place with good conformability, exudate handling and patient comfort. The wound had 100% epithelial tissue and no exudate and the ActivHeal Foam Contact dressing was discontinued. The ActivHeal Foam Contact dressing demonstrated effective management of exudate and created the right environment for healing and wound progression.

RESULTS

Ten patients were recruited through the Complex Wound Clinic at Doncaster and Bassetlaw Hospitals NHS Foundation Trust (*Table 1*). The patients were all male, and aged from 24 to 78 years (mean age 54 years). Four people had pre-existing medical conditions which could compromise wound healing, including three people with diabetes.

None of the patients had an infection which required antibiotic therapy, although six were assessed as requiring topical dressings to reduce the bioburden in the wound. Silver was the antimicrobial agent of choice and a range of these products was used under the evaluation dressing. No patients developed wound infections during the evaluation.

Four patients complained of mild wound pain at the start of the evaluation and two complained of mild pain associated with skin irritation around the wound. All the patients were assessed as having moderate to high levels of exudate.

Wound outcomes

The overall aim of the study was to evaluate the effectiveness of the ActivHeal Foam Contact dressing as a polyurethane foam dressing when used in standard practice where an adhesive foam dressing would be used. In wound management there is widespread use of foams as a primary dressing to protect the wound, provide a moist wound environment and manage exudate. They are also used as a secondary dressing to maintain the moisture balance in the wound and facilitate the effectiveness of the primary product.

ActivHeal Foam Contact dressing performed well in the majority of wounds as both a primary and secondary product (*Table 2*).

- Seven patients healed when the treatment regimen was changed to include ActivHeal Foam Contact dressing.
- Two patients continued to improve, although the periwound skin became irritated in one of these. The other patient was lost to follow up, but at the last assessment his ulcer was progressing well.
- In one patient the wound did not progress.
- Two patients who were known to have skin sensitivity to Allevyn Adhesive (Smith & Nephew Healthcare) were treated with ActivHeal Foam contact dressing with no adverse effects.

Dressing performance

In total 42 assessments were undertaken over the 10 patients. On application:

- The dressing was easy to apply and conformed well in 100% of assessments (*n*=42).
- Only one clinician was required to apply the product in 100% assessments (*n*=42).
- The dressing performed well under compression therapy, which was used in 20% of patients (*n*=2).
- It also stayed in place when applied onto a stump wound under a prosthetic limb.

Table 3. Comparative costs

ActivHeal Foam Contact dressing sizes (cm)	ActivHeal Foam Contact dressing prices (£)	Allevyn Adhesive sizes (cm)	Allevyn Adhesive prices (£)
7.5 × 7.5	1.29	7.5 × 7.5	1.43
10 × 10	1.89	10 × 10	2.10
12.5 × 12.5	2.18	12.5 × 12.5	2.57
10 × 20	2.70		
15 × 15	4.16	17.5 × 17.5	5.07
20 × 20	6.05	20 × 20	7.38
Sacral	3.20	Sacral	3.87/5.57

On removal:

- The dressing was easy to remove and comfortable on removal in 100% of assessments (*n*=42).
- ActivHeal Foam Contact dressing was also reported to be comfortable to wear in 92.8% of assessments (*n*=39). Two patients reported skin sensitivity around the wound.
- The dressing stayed in place on nine patients (95.8% assessments, *n*=41). One patient reported problems with the dressing not staying in place on his pilonidal sinus.
- The dressing was considered to have managed

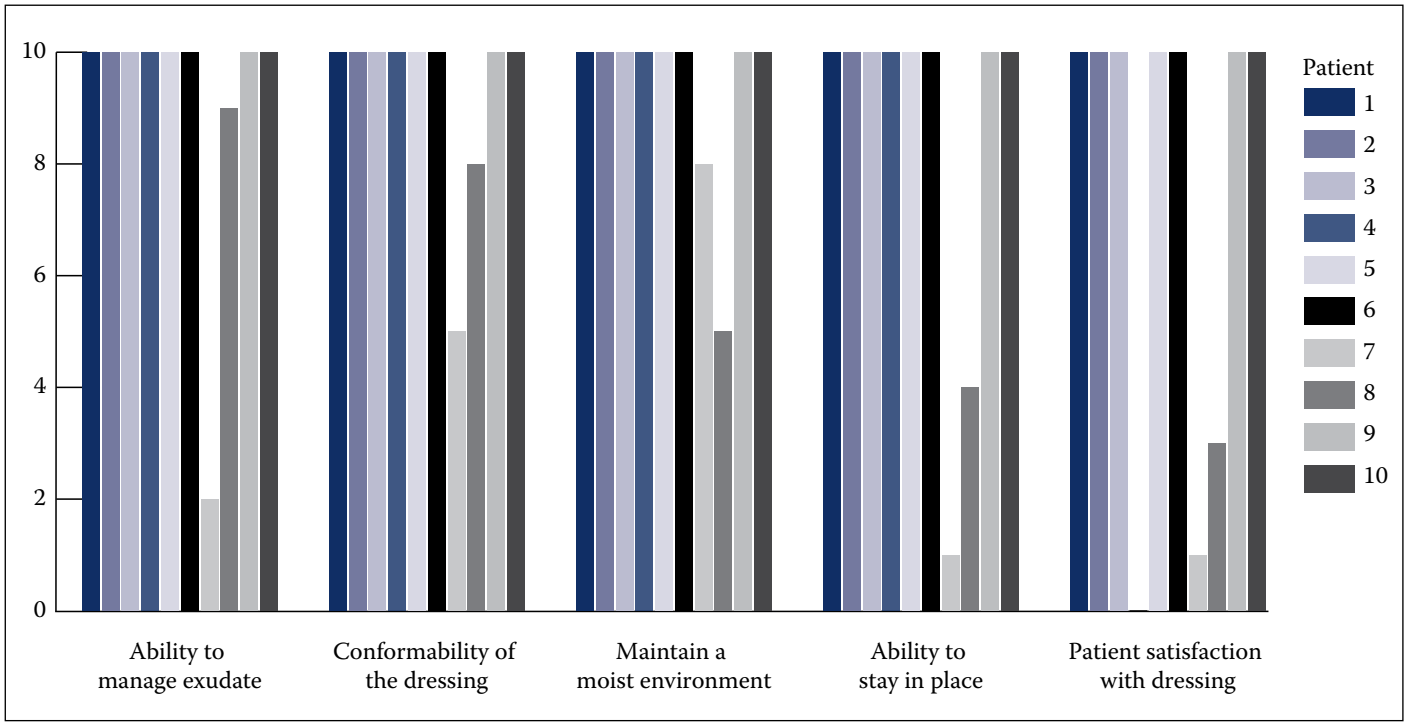
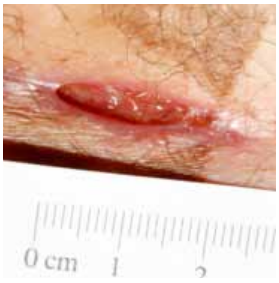


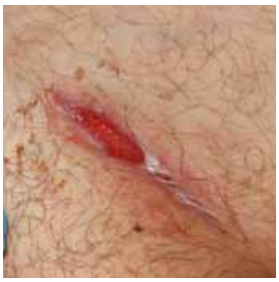
Figure 2. Patient satisfaction

Case study 2.

Mr L was a 44-year-old man. He was referred to clinic with a dehisced surgical wound to his left groin which had been present for 3 weeks (*top*). On assessment the wound was exuding moderate levels of exudate and presented with 100% granulating tissue. The wound measured 2 cm × 0.5 cm. The priority of the wound was to manage exudate effectively and ensure the periwound skin remained intact. The challenge also for this wound was to ensure that the dressing remained in place in this difficult area. The wound had been previously dressed with Acticoat® foam (Smith & Nephew Healthcare).



The wound was reviewed on Mr L's return to clinic 2 weeks later. The dressing was easy to remove and Mr L had found the dressing comfortable to wear and was able to wash with it *in situ*. The dressing stayed in place in this difficult to dress area and there were no signs of maceration. The dressing managed the exudate effectively.



The wound was reassessed 2 weeks later. The ActivHeal Foam Contact dressing remained in place and continued to be comfortable to wear. The wound had healed with 100% epithelial tissue (*bottom*) and Mr L was discharged from the clinic.

the exudate effectively on nine patients (95.8% assessments, *n*=41) The negative response was from the person with pilonidal sinus.

- Patients were able to wash/bathe/shower in 100% of dressing changes, although they were advised not to immerse the dressing or soak in the bath.
- No additional fixation was used at any dressing change throughout the evaluation period.

Overall experience

At the end of the evaluation, the clinician and patient were asked to rate their overall opinion of the dressing performance using a visual analogue score where 1=poor and 10=excellent (*Figure 2*).

Overall the dressing appeared to perform well. Only two patients were unhappy with the dressing performance. It should also be noted that where patient 8 gave lower scores at the end of the evaluation, he was satisfied with the conformability, ability to stay in place and comfort of the dressing until he started to develop periwound skin irritation near the conclusion of the evaluation. This may have influenced his overall opinion.

ActivHeal Foam Contact dressing performed well in respect to fluid handling and durability even under compression. The clinical performance of the dressing met the clinicians' expectations of a foam dressing. The dressing addresses patients' needs in terms of easy application and removal, prevention of leakage and wound progression.

Potential cost savings

The study undertaken with ActivHeal Foam Contact dressing suggests that there is a potential for cost savings (*Table 3*). It was impossible to calculate other than to identify that:

- The frequency of dressing change was the same as with the foam dressing previously used.
- No further adhesive products were required for extra security.
- The unit price per dressing for ActivHeal Foam Contact is less than other similar products on the Drug Tariff (*Table 3*).

DISCUSSION

Adhesive foam dressings are used widely in wound management to absorb exudate, and act as either a primary or secondary dressing. The aim of the clinical in-market evaluation was to observe the performance of the ActivHeal Foam Contact dressing when used in standard practice on wounds assessed as requiring an adhesive foam product. The value of this methodological approach is that it reflects clinical practice and demonstrates the clinical challenges that clinicians face when managing wounds. While the data are not as robust as that collected through a more structured study, this does demonstrate on an individual patient basis how clinicians often have to regularly change treatment regimens to manage the complexity of wound healing. It also demonstrates how patients can participate in their own care by using a dressing which is easy to apply, reducing the cost of nursing care.

ActivHeal Foam Contact dressing performed well over a wide range of wounds. These wounds were not particularly complex or excessive in size, but were those which required a foam dressing which would be comfortable, easy to use so that the patients could self care, and could manage exudate safely and effectively. It conformed well to the wound and provided patient comfort and security. The high level of

patient acceptability is demonstrated in the final evaluation data.

Overall ActivHeal Foam Contact dressing provided a suitable environment to facilitate wound healing, and to manage exudate safely and effectively. It also performed well when used as a secondary dressing where a primary product was required to address other problems in the wound bed (such as increased bacterial load and removal of devitalised tissue), securing the product in place while providing exudate management. A high proportion of patients in the evaluation were assessed as having an increase in wound bioburden, and as a result required antimicrobial primary dressings (silver). There were no problems observed, and the dressing performance was not impaired. The dressing provided safe and secure adhesion so that there was no leakage of exudate, and a minimal risk of periwound skin damage associated with adhesive dressings.

It should be noted that while the exclusion criteria suggested that ActivHeal Foam Contact dressing should not be used where there was a known or suspected sensitivity to adhesive foam dressings, the clinicians made the clinical decision to evaluate on two patients who had known sensitivities to Allevyn Adhesive. At the point of application the periwound skin in these people was healthy, and as a result no problems were detected. The patients benefited from this decision as their wounds healed.

While it was not possible to undertake a meaningful budget impact analysis on the seven patients who healed, due to variation in dressing regimens, there is a possibility for cost savings because of the unit price of the dressing, the comparative frequency of dressing changes with a market leading comparator, and the low risk of complications when used appropriately.

Further studies may be useful to determine the full clinical and cost benefits of this dressing.

CONCLUSION

Choosing the appropriate dressing to manage a wound is essential, with clinicians ensuring that their choice is the best available, while providing cost effectiveness. Clinicians working in the NHS are under pressure to reduce costs while delivering good quality clinical outcomes, and the ActivHeal Foam Contact dressing can deliver this.

The role of foam dressings in the treatment of chronic wounds is well established. The provision of a moist wound healing environment and good exudate handling properties are essential when treating chronic wounds, and foam dressings are one of the best treatments available (Thomas, 1993).

Accurate assessment combined with knowledge of dressings will help with appropriate dressing selection, which will promote the optimum environment for healing. By selecting dressings that are appropriate for the type and condition of the wound, clinicians will improve patient outcomes and the patient experience, ensure patient safety and provide effective interventions, while also keeping in line with recommendations to keep quality at the heart of every clinical contact (Department of Health, 2008).

It is essential that 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 bacterial barrier to prevent leakage or extrinsic contamination (Leonard et al, 2009). The ActivHeal Foam Contact dressing performed well in the evaluation in respect to fluid handling and managing exudate and addresses both patient and clinician expectations of a foam dressing. WUK

"By selecting dressings that are appropriate for the type and condition of the wound, clinicians will improve patient outcomes."

REFERENCES

Adderley U (2008) Wound exudate: What it is and how to manage it? *Wound Essentials* 3: 8–13

Advanced Medical Solutions Group (2012) Data on File. AR037/12

Benbow M (2011) Dressing awkward wounds. *Journal of Community Nursing* 25 (6) 16–22

Collins F, Hampton S, White R (2002) *A–Z Dictionary of Wound Care*. Quay Books, London

Department of Health (2008) *NHS 2010–2015: From Good to Great. Preventative, People centred, Productive*. DH, London

Leonard S, McClusky P, Long S et al (2009) An evaluation of Allevyn adhesive foam dressing. *Wounds UK* 5(1): 17–28

Romanelli M, Vowden K, Weir D (2010) Exudate management made easy. *Wounds International* 1(2)

Thomas S (1993) Foam dressings: a guide to the properties and uses of the main foam dressings available in the UK. *Journal of Wound Care* 2(3): 153–6

Vowden K, Vowden P (2004) The role of exudate in the healing process: understanding exudate management. In: White RJ, editor. *Trends in Wound Care: Volume III*. Quay Books, London

White R, Cutting KF (2006) Modern exudate management : a review of treatments. Available at: bit.ly/H3hmle (accessed 25.02.2013)

ACKNOWLEDGEMENT

This article was supported by Advanced Medical Solutions.