Clinical evaluation of the ActivHeal® Foam Contact Dressing

Key words

- Exudate
- Non-healing wounds
- Conformability
- ActivHeal Foam Contact

Chronic wounds are those wounds that have remained unhealed for more than six weeks and classified according to their underlying pathology, for example pressure ulcers, venous leg ulcers, diabetic foot ulcers and burns. Wound exudate is a key component of healing in the healthy wound. It is produced throughout the wound healing process from inflammation to epithelialisation and must be managed to maintain a moist wound environment and promote healing. This article examines how exudate can become a problem when an excessive quantity is produced, and examines ActivHeal Foam Contact, a polyurethane foam adhesive, which is designed to provide protection and absorbency for chronic and acute wounds.

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The challenge of wounds continues to be significant to clinicians and the health service in terms of managing wounds clinically, the impact on the patient experience and the cost to the NHS.

Cost-saving has become an increasing priority, within both the NHS and individual trusts. Wound management is an area where it is possible to lower the financial burden of care, as dressing selection can offer the opportunity to reduce expenditure without reducing the quality of care.

Nazarko (2005) advised that all dressings have advantages and disadvantages, and the most important aspect of caring for a wound is to choose the correct dressing for the current stage of 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[DH], 2008).

CHRONIC WOUNDS

Chronic wounds are those that have remained unhealed for more than six weeks and are classified according to their underlying pathology, for example pressure ulcers, venous leg ulcers, diabetic foot ulcers and burns (Bianchi et al, 2011).

It is estimated that 3.5 per 1,000 patients suffer from wounds (Vowden et al, 2009), with wound care accounting for 3% of the total NHS annual budget (Drew et al, 2007), therefore, the time that clinicians spend treating patients with wounds is substantial.

EXUDATE

Wound exudate is a key component of healing in the healthy wound. It is produced throughout the healing process from inflammation to epithelialisation and must be

'The management of wound exudate is a challenge and it is important to achieve and maintain an optimum moist environment'

managed to maintain a moist wound environment that promotes healing (Collins et al, 2002). Exudate is defined as a fluid produced in wounds, made up of serum, leukocytes and wound debris. The volume of exudate reduces as healing progresses. Exudate is thought to have bacterial and nutrient properties (Adderley, 2008).

Wound exudate is often misconceived as 'bad', when in fact exudate is known to assist healing by (World Union of Wound Healing Societies [WUWHS], 2007):

- Preventing the wound drying out
- Aiding the migration of tissue-repairing cells
- Providing essential nutrients for cell metabolism
- Enabling the diffusion of immune and growth factors
- Assisting separation of dead or damaged tissue (autolysis).

The management of wound exudate is a challenge and it is important to achieve and maintain an optimum moist environment (White and Cutting, 2006). In the instance of exudate escaping onto the periwound skin, maceration and wound enlargement becomes a major risk (White and Cutting, 2006).

The level of moisture required for healing has never been successfully defined, but it is important to have an awareness of the dangers of a wet wound, which cause maceration at the wound margins and can 'waterlog' the granulating tissue, causing over-granulation (Vandeputte and Hoekstra, 2006).

ASSESSMENT AND MANAGEMENT

Assessment and management of the wound is 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 help establish causation, tissue types, exudate levels and will assist in addressing patients' concerns (Timmons, 2008).

Exudate can become a problem when an excessive quantity is produced. The composition of the exudate can delay or prevent the wound-healing process. The decision of which dressing to apply will depend on the condition of the patient and the wound, but also on the reliability and cost effectiveness of the dressing regimen. Wound care dressings and nursing time are two of the greatest costs associated with chronic wounds. 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 physical and bacterial barrier to prevent leakage or extrinsic contamination (Leonard et al, 2009).

Although a 'moist' environment is the ideal, achieving the correct degree of moisture does presents a challenge to the clinician. Cutting and White (2002) have determined that the following should be considered when selecting a dressing to successfully treat wounds while minimising the potential for maceration (Cutting and White, 2002):

- Level and nature of wound exudate
- Fluid-handling capacity of the dressing
- Site and condition of the wound
- Optimal wear time for the dressing on the wound
- Specific needs of the patient
- Environmental factors
- Possible adhesive damage to periwound skin.

FOAM DRESSINGS

The technology for foam dressings has been available since the 1950s and they have been used in wound care since the mid-1980s. Foam dressings have been one of the mainstream wound care products and continue to be important for the treatment and management of chronic wounds and where exudate is problematic.

Advanced Medical Solutions have further enhanced their foam range to introduce ActivHeal Foam Contact. The ActivHeal Foam Contact dressing is a polyurethane foam adhesive that

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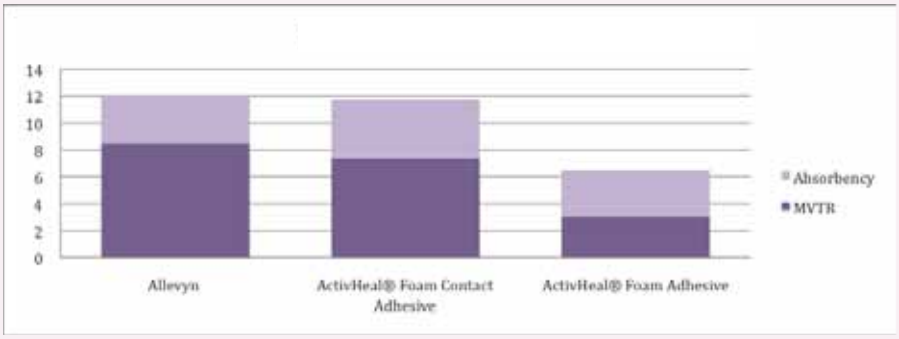

Figure 1: Total fluid-handling properties of ActivHeal Foam Contact.

is designed to provide protection and absorbency for both chronic and acute wounds.

The new 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 securely in place. Each layer of ActivHeal Foam Contact contributes to the performance of the dressing to ensure that efficient management of exudate is maintained. ActivHeal Foam Contact comprises of a polyurethane top film with a high moisture vapour transmission rate, a polyurethane foam absorbent layer and perforated wound contact layer, which is coated with an acrylic adhesive.

The wound contact layer has been specifically designed to prevent adherence of the dressing 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 into 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 final top layer of the dressing is a polyurethane film. This 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 that have a high breathable outer layer, which allows moisture to evaporate from the dressing, improve the efficacy and handling of exudate (Thomas, 1993).

In a further study, Thomas (2010) also concluded that although absorbency is important in a foam dressing, the moisture-vapour permeability plays a key role in determining its total fluid-handling capacity.

The choice of dressings should be guided by clinical effectiveness, patient choice and acceptability as well as cost (MeRec, 2008). The overall acceptability of any dressing should include not just the dressing's performance in terms of management of exudate, maintaining a moist wound healing environment and wound progression, but also acceptability to the patient and clinician as well as wear time.

AIMS OF THE CLINICAL EVALUATION

The aim of the clinical evaluation was to assess the overall clinical performance of ActivHeal Foam

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Contact dressing when used in the management of acute and chronic wounds and how it contributed to wound progression. The secondary objectives were to evaluate the performance of the product in use, including ease of application and removal, along with patient and clinician satisfaction.

The patients were included on the basis of having a wound that was suited to ActivHeal Foam Contact dressing following a full wound assessment. Patients were required to fulfil the following requirements:

- Be over 18 years old
- Either male or female
- Able to understand and consent to the evaluation
- Must have a wound that has been assessed as suitable for the ActivHeal Foam Contact dressing.

The exclusion criteria were:

- Any patient known to be non-compliant with medical treatment
- Known or suspected sensitivity to foam dressings
- Known or suspected sensitivity to adhesive dressing products
- The periwound skin is assessed as unsuitable for an adhesive dressing
- Insufficient exudate to require an adhesive foam dressing
- Patient is unable to understand and give consent to participate
- Any pregnant woman.

The assessment of ActivHeal Foam Contact was conducted in the form of evaluations 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 gathered 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. Both the patient and clinicians were asked to give their opinion on how the dressing performed.

The evaluation parameters/considerations applied were:

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

RESULTS

The results gained from the dressing assessment of the ActivHeal Foam Contact dressing were collated and analysed.

Six patients' wounds were evaluated, including the following wound types:

- Exuding postoperative abdominal wound

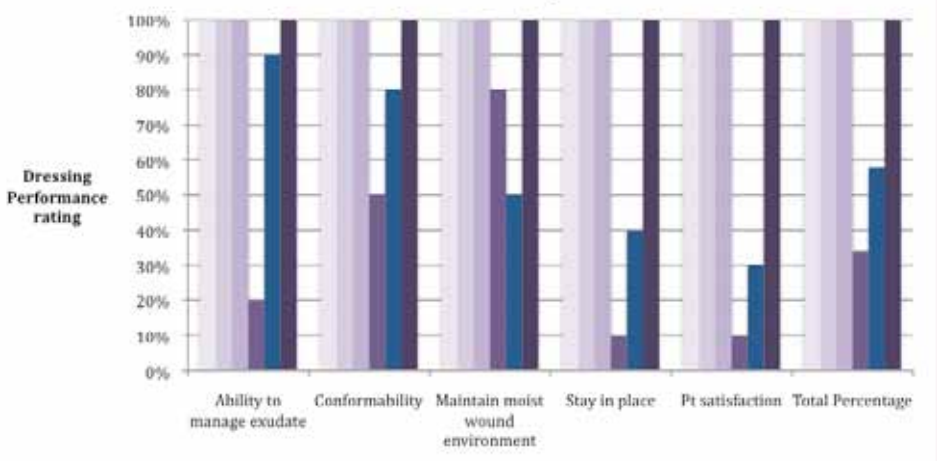

Figure 2: Overall assessment of dressing performance.

- Diabetic foot ulcer
- Stump wound
- Dehisced surgical wound to groin
- Pinilodial sinus
- Venous leg ulcer.

The patients' progress was monitored, with photos and assessments taken at each dressing change to illustrate how the wounds had progressed, but also to assess both the clinical and patient feedback in regards to the dressing.

The six patients were all male and the exudate levels were assessed as moderate. The dressings were changed at three and seven-day intervals. In most cases the ActivHeal Foam Contact dressing was used as a primary dressing, however, on occasions it was used as a secondary dressing. The data was analysed and is shown in *Figure 2*.

Exudate

A key function of foam dressings is their ability to manage exudate and reduce the risk of maceration; four of the patients assessed gave a dressing performance rating of 100% in regards to exudate management. It was also noted that the condition of the surrounding skin had fewer problems with issues such as maceration and redness.

The number of dressing changes was the same with the ActivHeal Foam Contact as there would have been with the previous dressing (Allevyn®; Smith and Nephew). One patient, whose wound was a pilonidal sinus being dressed at home, felt that the dressing did not manage exudate. However, it was felt that, due to the nature of the wound, it may have required an increase in dressing changes until exudate levels subsided.

Conformability

Conformability is an important factor to consider when evaluating a dressing as it can improve patient comfort and have a positive impact on the patient experience. Four of the patients assessed gave a dressing performance rating of 100% in regards to conformability. The ActivHeal Foam Contact achieved this as it was noted that the foam pad and adhesive contoured well to the wound and the surrounding skin — also the patient felt comfortable wearing the dressing.

Moist environment

A moist environment is needed to enhance the autolytic process and acts as a transport medium for essential growth factors during epithelialisation (Cutting and Tong, 2003). If the wound becomes too dry this will slow epithelial migration, but if the wound is too wet, the exudate may damage the periwound skin and cause maceration.

The clinicians felt that the ActivHeal Foam Contact dressings overall performance in regards to maintaining a moist environment was 100% in four of the patients and 80% in another patient. Overall the clinicians were satisfied with the dressings' ability to maintain the right environment as the wounds showed progression of healing and wounds reducing in size.

Fixation

For dressings to remain cost-effective, it is important that they stay in place. In four of the patients the ActivHeal Foam Contact dressing was rated as 100% for staying in place. Of those four patients, two of the wounds dressed were in groin areas, which are difficult to dress. Both patients were happy with the performance of the dressing and were happy as the dressing remained waterproof so that they were able to wash and shower. The patients also reported a lack of pain on dressing removal.

At the end of each patient evaluation the clinicians were asked to rate the overall acceptability of the ActivHeal Foam Contact dressing. In four of the cases the clinicians rated the overall performance of the dressing as 100%. This shows that the ActivHeal Foam Contact dressing is acceptable for its intended use and translates into positive clinical outcomes for the patient. The clinicians felt that ActivHeal Foam Contact was similar to Allevyn foam dressings in terms of absorbency, fluid-handling, wound progress and durability.

CASE STUDY ONE

Mr L was a 58-year-old man with a history of Chrohn's disease. He was

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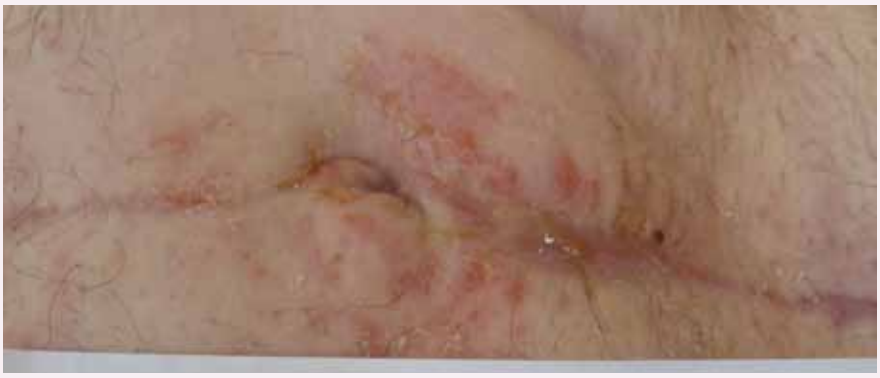

Figure 3: Case study 1 — wound at initial assessment.

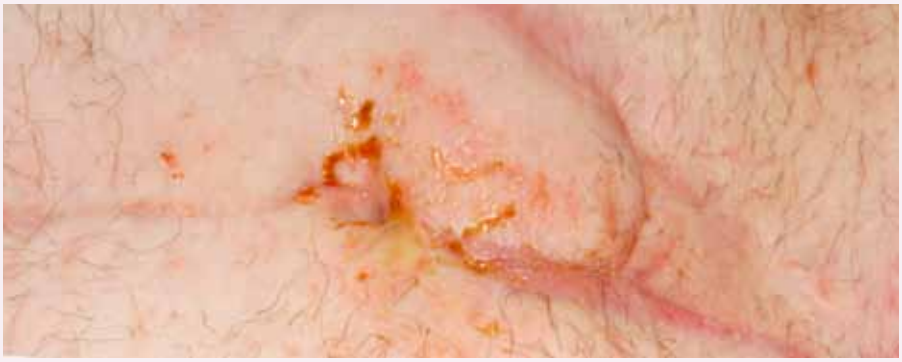

Figure 4: Case study 1 — wound at second dressing change.

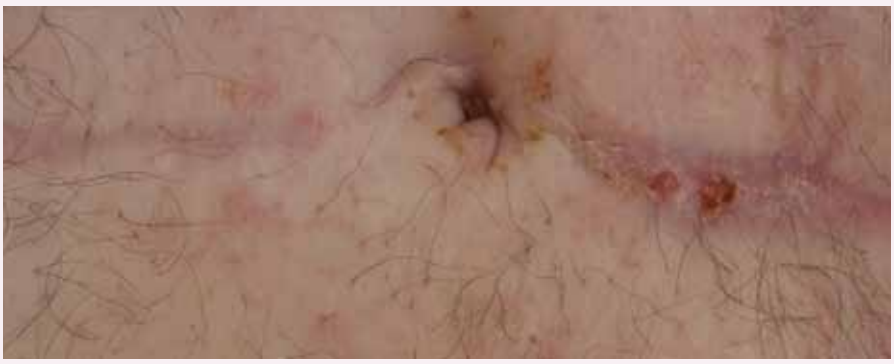

Figure 5: Case study 1 — the wound at third visit.

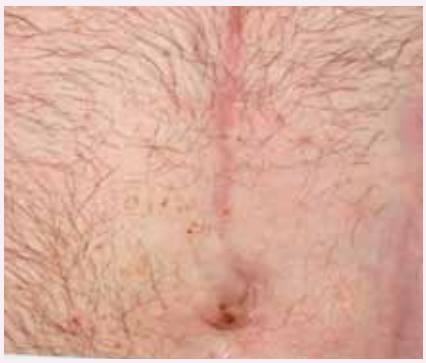

Figure 6: Case study 1 — wound at final dressing change.

taking medication for rheumatoid arthritis as well as a statin. Mr L was referred to the wound care clinic following surgery to the umbilical area eight weeks previously.

At initial assessment the wound exhibited 100% granulation tissue and normal periwound skin, although there was a high level of exudate (*Figure 3*). Following a wound assessment, the priority for the wound was exudate management. The dressing previously used was Allevyn Adhesive but Mr L had experienced sensitisation to it, therefore, it was decided to try the new ActivHeal Foam Contact for exudate management. A 15cm x 15cm dressing was applied, which was easy to apply and conformed well to the wound.

The dressing was changed every three days and as the patient was being treated as an outpatient this was done by the patient's wife. On return to the wound care clinic after three weeks, the wound was reassessed and no reaction to the adhesive was observed (*Figure 4*).

The dressing was still easy to remove and the patient found the dressing

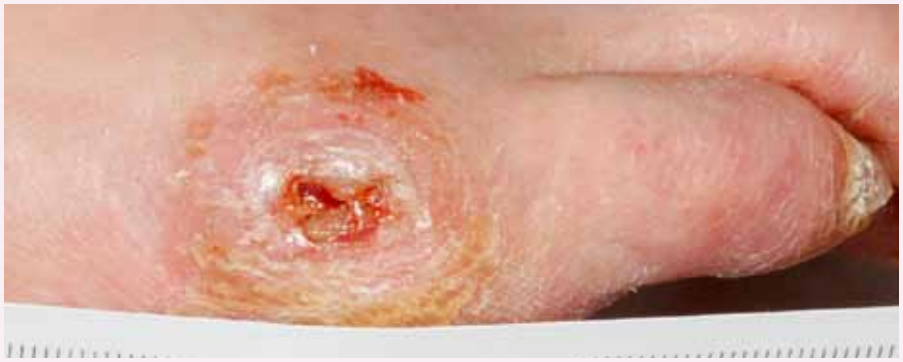

Figure 7: Case study 2 — the wound at initial presentation.

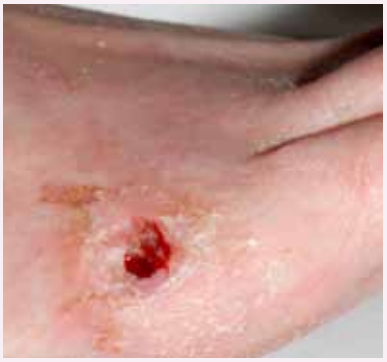

Figure 8: Case study 2 — The wound at the second clinic visit.

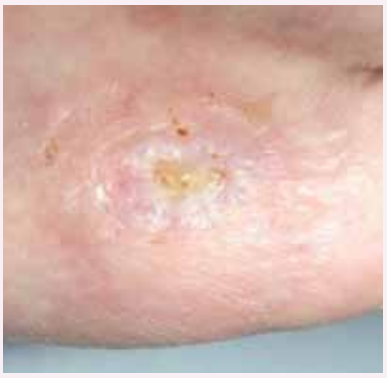

Figure 9: Case study 2 — the wound at final assessment.

comfortable to wear and could wash with the dressing in situ. The dressing had stayed in place and managed the exudate effectively as there were no signs of maceration. The exudate levels remained moderate. The patient experienced no pain when the dressing was in situ. However, an increase in colonisation was noted and, therefore, a small silver-coated low adherent dressing was applied to the wound and the ActivHeal Foam Contact was applied as a secondary dressing. The ActivHeal Foam Contact dressing continued to be easy to apply and conformed well to the wound.

At the third visit, two weeks later, the wound continued to show granulating tissue, and the exudate levels had reduced (*Figure 5*). The condition of the periwound remained normal. Application and removal remained easy and there was no pain. The dressing continued to demonstrate an excellent ability to conform to the wound.

Exudate management remained excellent as the wound had continued to reduce in size and the periwound remained intact, demonstrating that the ActivHeal Foam Contact dressing provided the right environment for wound healing. The dressing continued to be comfortable for the patient. A further ActivHeal Foam Contact was applied as the primary dressing. At the final review, the ease of removal was good and the dressing had stayed in place for seven days along with good conformability, exudate handling and patient comfort (*Figure 6*). The wound was noted to have 100% epithelial tissue and no exudate. The use of the ActivHeal Foam Contact dressing was discontinued.

CASE STUDY TWO

Mr S was a 72-year-old man with a previous history of ischaemic heart disease, chronic obstructive pulmonary disease (COPD) and type 2 diabetes. Mr S was also a heavy smoker with a history of alcohol abuse. He was referred to the clinic with a neuro-ischaemic diabetic foot ulcer to the lateral side of the right foot of 16 weeks' duration. On assessment, the wound was moderately exuding and presented with 100% sloughy tissue (*Figure 7*).

The priority was to manage the exudate effectively and ensure the periwound skin remained intact. A silver-coated low adherent dressing was also applied at this time to reduce bacteria load, along with ActivHeal Foam Contact as a secondary dressing.

The wound was reviewed on Mr S's return to the wound care clinic three weeks later. The dressing had been changed every three days in the community by a nurse. The dressing was easy to remove and the patient found the dressing comfortable to wear and was able to wash with it in situ.

The dressing stayed in place even in this difficult-to-dress area and, as there were no signs of maceration, the dressing seemed to be managing the exudate effectively. The wound was reassessed and there was 100%

granulation tissue and the exudate levels remained moderate (*Figure 8*).

The patient was not experiencing any pain when the dressing was in situ. The ActivHeal Foam Contact dressing continued to be easy to apply and was conforming well to the wound.

Mr S was brought back to clinic two weeks later and the wound was reassessed. The ActivHeal Foam Contact remained in place and continued to be comfortable to wear for the patient. The patient indicated that there was no pain upon removal of the dressing. A review of the wound showed 100% epithelial tissue, no exudate and a periwound area that remained normal.

With particular regard to this patient's wound, the clinician noticed that the ActivHeal Foam Contact dressing was conformable to the contours of the body and that there were no issues with dressing slippage. It also stayed in place well, with the patient able to wear a normal shoe (*Figure 9*).

DISCUSSION

In both case studies featured here, the main challenge was to manage exudate effectively and demonstrate wound progression. The ActivHeal Foam Contact dressing demonstrated effective management of exudate, and created the right environment for healing and wound progression.

The dressing provided good clinical outcomes while allowing easy dressing usage and not causing pain and trauma to the patient on removal.

After final review of the patients in this study, the clinicians' recorded the following benefits of the ActivHeal Foam Contact dressing:

- The dressing was easy to remove and apply
- The dressing conformed well to the wounds
- It remained in place for the duration of wear time
- The wound had healed during the treatment time
- The periwound area remained intact
- The patients were able to shower and carry on with normal activities of daily living
- There was no sensitisation to the adhesive
- The patients were very pleased with the outcome
- The clinicians were also pleased with the clinical outcome

The outcome of the case studies and clinical evaluations supports usage of the new ActivHeal Foam Contact dressing and has demonstrated that the product has the required attributes of foam dressings for use on a range of chronic wounds.

CONCLUSION

ActivHeal Foam Contact addresses patients' needs in terms of easy application and removal, minimal dressing changes, prevention of leakage and wound progression.

The ActivHeal Foam Contact dressing performed well in the evaluation in respect to fluid handling and durability, even when used under compression. The clinical performance of the dressing met the clinicians' expectations of a foam dressing.

Choosing the appropriate dressing to manage a wound is essential, with clinicians ensuring that their choice is the best available, whilst 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 patients with chronic wounds, and foam dressings are one of the best treatments available (Thomas, 1993).

Clinicians should have the appropriate skills and training to ensure that they understand the importance of wound assessment. An accurate assessment combined with knowledge of dressings will help with appropriate dressing selection, which will promote the optimum environment for healing to occur. WUK

Table 2
Results of all the case studies in the series

Case study 1	Case study 2	Case study 3	Case study 4	Case study 5	Case study 6
58-year-old man, Surgery to umbilical area	*44-year-old male, Wound to left groin post op*	*72-year-old male Ulcer to lateral side right foot*	*24-yearold male Pilonidal sinus*	*64-year-old male Ulcer to left medial malleoli*	*63-year-old male Exuding left stump*
Initial assessment Exudate high 100% granulation Dressing easy to apply, conformed well	*Initial assessment Exudate moderate 100% granulation Dressing easy to apply, conformed well*	*Initial assessment Exudate moderate 100% slough Dressing easy to apply, conformed well*	*Initial assessment Exudate high 100% granulation, Periwound maceration Dressing easy to apply, conformed well*	*Initial assessment Exudate moderate 100% slough Periwound inflamed Used under compression Dressing easy to apply, conformed well*	*Initial assessment Exudate moderate 100% slough Periwound macerated Dressing easy to apply, conformed well with prosthesis*
Second assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear Wound reducing in size	*Second assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear No signs of maceration*	*Second assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear No signs of maceration 100% granulation*	*Second assessment Dressing had not stayed in place Had been reapplied by carer Dressing discontinued at patient request*	*Second assessment Dressing easy to remove Managed exudate well Stayed in place, Comfortable to wear No maceration Wound reduced in size — 20% slough; 30% granulation; 50% epithelial*	*Second assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear Wound reducing in size — 100% granulation Periwound skin normal*
Third assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear Wound reducing in size	*Third assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear Wound healed*	*Third assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear Wound healed*		*Third assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear Patient found adhesive irritating —has sensitivities to adhesives. Dressing discontinued*	*Third assessment Dressing easy to remove Managed exudate well Stayed in place Comfortable to wear Wound reducing in size*
Fourth Assessment Dressing easy to remove Exudate level reduced Stayed in place Comfortable to wear Wound healed					*Fourth assessment Dressing easy to remove Handled exudate well Wound deteriorated Re-referred back for vascular investigation*
Overall performance Feedback from clinician on exudate management: conformability, maintaining moist environment, staying in place — all excellent Patient satisfaction — excellent	*Overall performance Feedback from clinician on exudate management: conformability, maintaining moist environment, staying in place — all excellent Patient satisfaction — excellent*	*Overall performance Feedback from clinician on exudate management: conformability, maintaining moist environment, staying in place — all excellent Patient satisfaction — excellent*	*Overall performance Feedback from clinician on exudate management: conformability, maintaining moist environment, staying in place — all satisfactory Patient satisfaction — poor*	*Overall performance Feedback from clinician on exudate management: conformability — very satisfactory; maintaining moist environment and staying in place — satisfactory Patient satisfaction — poor*	*Overall performance Feedback from clinician on exudate management: conformability, maintaining moist environment, staying in place — excellent Patient satisfaction — excellent*