A two-centre clinical evaluation of the new silicone foam dressing ActivHeal

KEY WORDS
- Exudate management
- Patient-centred care
- Progression to healing
- Silicone foam dressing

Aim: a clinical in market evaluation of 20 patients was carried out to assess the performance of the new ActivHeal Silicone Foam dressings in clinical practice. **Study Design:** The evaluation took place in two centres within the UK. The patients were treated according to product instructions and standard local practice. Data was collected at every dressing change until healing or the treatment of the product was discontinued. **Results:** Positive endpoints for exudate management, moist wound environment, periwound protection and patient satisfaction. By the end of the evaluation 20% (*n*=4) of the wounds had healed, 70% were improved and 10% (*n*=2) of the wounds may not have reduced in size but there had been a change in the condition of the wound bed with the removal of both necrotic and sloughy tissue. **Conclusion:** This study has shown ActivHeal Silicone Foam Border and Non-Border dressings to be an acceptable alternative to other silicone dressings in terms of patient comfort and clinician satisfaction.

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In the current economic climate there is a growing focus on the provision of high-quality, cost-effective wound care. Careful dressing selection can reduce the NHS and other organisations' expenditure without reducing the quality of care or clinical outcomes. It is therefore important for nurses to be able to justify the use of wound care products and ensure that they are used correctly and appropriately.

Changes in the skin occur as an individual ages (*Table 1*). These changes affect the integrity of the skin, making it more vulnerable to damage. Over time, skin becomes fragile, with loss of tissue thickness, skin lubrication, elasticity and strength; and a reduction in its overall protection mechanism. Chronic wounds are much more common in people aged over 65 and in the UK this group has been predicted to increase from 9.5 million in 2005 to 13 million in 2025 (Posnett and Franks, 2008). Such wounds are therefore a growing problem. Optimising the wellbeing of someone who is living with a chronic or acute wound is an essential part of patient-centred care.

WOUND MANAGEMENT

Effective wound management involves the informed selection and application of products that are matched to the patient being treated plus a clearly-defined and achievable clinical objective shared by both the clinician and patient. A full wound assessment needs to be undertaken to address the patient's needs with regards to the fragility of their skin and level of exudate. The clinicians' judgement should be based on the results of each assessment and the choice of dressing based on the clinical appearance and site of the wound (World Union of Wound Healing Societies, 2007).

Wound care products should minimise pain and damage on removal, as well as being comfortable. The repeated application and removal of adhesive dressings can cause damage to the layers of the stratum corneum, and may cause inflammation, oedematous changes, skin soreness, and have a detrimental effect on skin barrier function (Dykes et al, 2001; Langoen et al, 2009). Products that have gentle adhesion and an atraumatic contact layer reduce the likelihood of pain and trauma on removal and are more likely to have higher patient acceptability. It is important clinicians minimise periwound skin contact with exudate, protecting the area with an appropriate barrier and using atraumatic dressings where possible to avoid skin stripping as maintaining skin integrity is vital to overall patient

Table 1. Summary of the functions of skin that decline with age (Baronski, 2003; Beldon, 2006).

Physical change	Effect
Epidermis thins	Reduced blood vessels, nerve endings and collagen, leading to a decrease in sensation, temperature control, rigidity and moisture retention
Epidermis flattens	Uneven distribution of melanocytes, leading to uneven pigmentation
Tactile sensitivity and pain perception decrease	Increased danger of injury
Depletion of elastic fibres	Wrinkles
Atrophy of sebaceous glands	Dry skin
Dermal-epidermal junction flattens	Increased susceptibility to friction/shearing forces, resulting in blistering and minor injuries

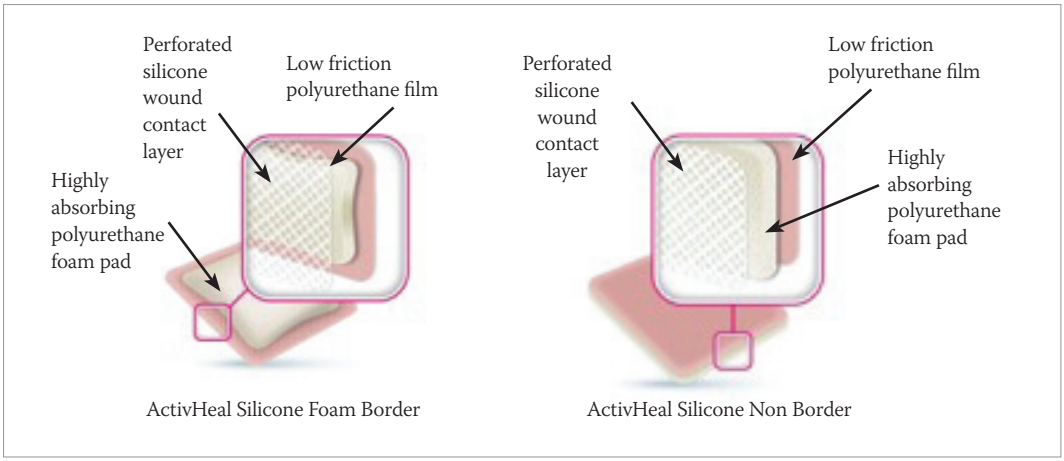

Figure 1. ActivHeal Silicone dressings have three layers: a waterproof polyurethane film, a central absorbent polyurethane pad and a silicone adhesive wound contact layer

health and quality of life, particularly in the elderly (White et al, 2012). The decision as to which adhesive type to use should be based on the patient. Silicone dressings may be used on wounds with compromised skin, e.g. vulnerable or fragile patient skin.

SILICONE DRESSINGS

Soft silicones have been developed to minimise pain, be atraumatic at dressing changes, protect the surrounding skin and promote comfort during wear time (Hampton, 2010). Silicone-based dressings are allergy free, conform to the wound, prevent epithelial stripping on removal and prevent pain at dressing change (White, 2005; Meuleneire et al, 2013). Advanced Medical Solutions has enhanced its foam portfolio with the ActivHeal Silicone Foam range. The ActivHeal Silicone Foam Border and Non-Border dressings are constructed from a low-friction waterproof polyurethane film, with a highly absorbing polyurethane central pad with a silicone adhesive wound contact layer. The three-layer silicone dressing (*Figure 1*) has been developed to give excellent total fluid handling capabilities, ensuring efficient management of exudate is maintained and aiding the wound healing process. The high moisture vapour transfer rate allows excess exudate to evaporate and, combined with the intrinsic absorption capacity of the foam, provides high fluid capability (Advanced Medical Solutions, data on file, 2015). ActivHeal Foam Silicone Border and Non-Border are indicated when adherence to the wound bed or periwound area is a potential problem. The perforated silicone-coated wound-contact layer minimises pain during dressing changes, allows uptake of exudate and prevents excess fluid causing maceration of the surrounding skin.

EVALUATION STUDY DESIGN

The ActivHeal Silicone Foam Border and Non-Border dressings were evaluated on patients recruited from two centres in large acute hospitals through the wound care services. The dressings were observed within standard practice. No other changes were made to the wound care pathway. The aim was to assess the overall clinical performance of the ActivHeal dressings when used in the management of acute and chronic wounds and how they contribute to wound progression. The patients were not randomised to treatment and no additional interventions were made to standard care; therefore ethical approval was not required. Organisational consent was obtained from Research and Development as well as patient consent.

As adhesive foams can be used as both a primary and secondary dressing, the evaluation included the use of the ActivHeal Silicone Foam Border and Non Border alongside other prescribed dressings. Wound size, wound bed status, exudate levels, periwound skin condition and wound pain were the outcomes measured. The following were evaluated to assess dressing performance: ease of use, conformability to the wound, patient comfort during removal and wear, clinician satisfaction in regards to ease of application and removal, and its ability to stay in place.

The evaluation was for a maximum of 6 weeks. The dressing was discontinued if the wound healed or at a patient's request, and could be changed to implement a different treatment. Patients were included if they were over 18 years of age and assessed as being suitable to receive a silicone foam dressing. Patients were excluded if they could not give informed consent or had suspected allergies to any of the dressing components.

Each patient's age, sex, wound type, comorbidities and past medical history was recorded. Wound duration, wound bed status, exudate level, periwound skin condition, pain and previous treatment(s) were recorded at the start of the evaluation. Wound assessments were performed at the start and at every dressing change to evaluate the status of the wound, highlight any elements that may delay healing and determine whether treatment objectives had been met (Ousey and Atkin, 2013). The reason for the dressing change, comfort, ease of dressing application and removal were noted, as were any additional products used. At the end of the evaluation, clinicians were asked whether they were 'very satisfied', 'satisfied' or 'not satisfied' with regards to exudate management, maintenance of a moist environment, wound progression, ease of use, conformability, patient satisfaction and overall assessment of the dressing. Data were recorded in a standardised form by the clinician, using simple analysis.

RESULTS

ActivHeal Silicone Foam dressing was used on 20 patients recruited from two centres in large acute hospitals through the wound care services. From among these, 8 patients (40%) were male and 12 patients (60%) were female. The patients' ages ranged from 45 to 102 years, with a mean age of 73.5, and co morbidities were presented in 85% (*n*=17) of the patients.

The most common wound type was pressure ulcer (30%), moisture lesion (5%), skin tears (20%), acute/trauma wounds (15%) and surgical wounds, diabetic ulcers and venous leg ulcers all at 10%. *(Figure 2)*.

The dressing was applied according to the manufacturer's instructions, on a range of wound types in both acute and chronic states. *Figure 2* shows the types of wounds by aetiology and highlights whether ActivHeal Silicone Foam Border and Non-Border dressings were used as a primary or secondary dressing.

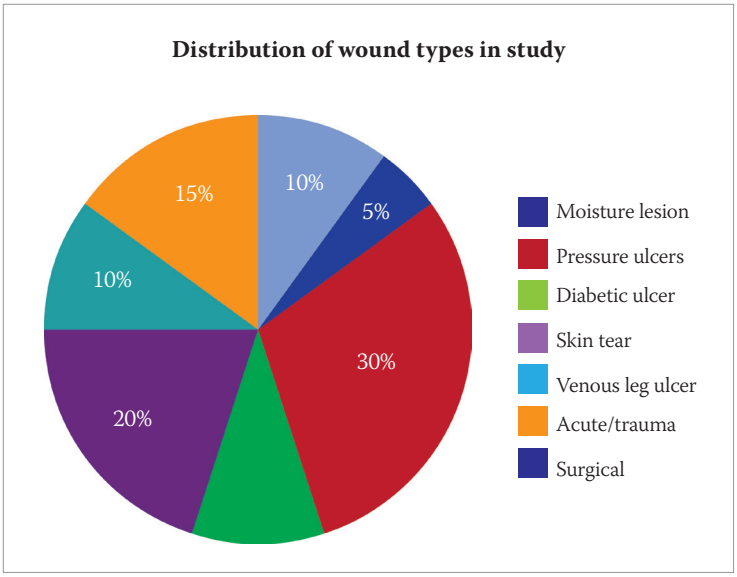

Figure 2. Distribution of wound types in study

Table 2. List of wounds by aetiology			
Type of wound		**Primary (*n*=8)**	**Secondary (*n*=12)**
Surgical wounds	x		2
Acute wounds	x		2
Trauma wound	x		1
Skin tear	x	4	
Pressure ulcer	Category 2	2	
	Category 3	1	2
	Category 4		1
Diabetic ulcer	Neuropathic		1
	Neuroischaemic		1
Leg ulcer	Venous	1	1
Moisture lesion			1

PRIMARY DRESSING

ActivHeal Silicone Foam Border and Non-Border dressings were used as a primary dressing on 40% of the wounds treated (*n*=8), and improvement was observed in all patients. No wounds increased or deteriorated in size, and there were positive changes in wound dimensions observed in all patients, showing wound progression. Based on the data the mean wound length and width were calculated to be 2.35 cm x 2.48 cm at the start of the evaluation and 1.4 cm x 1.5 cm at the end of the evaluation. The wound bed status was also observed to improve in all patients. Changes in wound size during treatment is an indicator of subsequent response to treatment and ultimately healing (Vowden, 2011). Initially, only 63% (*n*=5) of patients with the dressing used as a primary dressing was recorded as having 100% granulation present at the start of the evaluation which changed to 25% (*n*=2) of the wounds being healed and the other 75% (*n*=6) containing both granulating and epithelial tissue at the end of the evaluation.

A trend towards lower exudate levels was seen, with more patients ending the assessment period either healed or with low levels of exudate when compared to the start of the evaluation. At the start of the evaluation 75% (*n*=6) patients had moderate levels of exudate, 12.5% (*n*=1) with low levels and 12.5% (*n*=1) with high levels of exudate. At the end of the evaluation 25% (*n*=2) had no exudate as the wound was healed, 37.5% (*n*=3) had low levels, 25% (*n*=2) had moderate levels and 12.5% (*n*=1) had high levels of exudate.

SECONDARY DRESSING

ActivHeal Silicone Foam was used as a secondary dressing on 60% of the wounds treated (*n*=12), and improvement was observed in all patients. It was used in conjunction with other products including:

- A hydrogel (16.6%, *n*=2), to assist in the debridement of necrotic tissue
- A fibrous gelling alginate dressing (16.6%, *n*=2), used for absorbency of exudate and desloughing of the wound bed
- An alginate dressing (25%, *n*=3), used either as a rope or felt dressing, and to assist with absorbency, aid autolysis and deslough the wound bed
- An antimicrobial dressing (41.6%, *n*=5), to reduce the bioburden in the wound bed.

No wounds increased or deteriorated in size, and there were positive changes in wound dimensions observed in all patients, showing wound progression. Based on the data, the mean wound length and width were calculated to be 4.43 cm x 7.04 cm at the start of the evaluation and 3.15 cm x 2.19 cm at the end of the evaluation. The wound bed status was also observed to improve in all patients. Initially, only 25% (*n*=3) of patients with the dressing used as a secondary dressing were recorded as having 100% granulation present at the start of the evaluation. At the the end of the evaluation, this had changed to 16.6% (*n*=2) of the wounds being healed; 16.6% (*n*=2) contained granulating tissue; 41.6% (*n*=5) contained both granulating and epithelial tissue, and 16.6% (*n*=2) contained, slough, granulating and epithelial tissue.

A trend towards lower exudate levels was seen, with more patients ending the assessment period either healed or with low levels of exudate when compared to the start of the evaluation. At the start of the evaluation 33.3% (*n*=4) patients had moderate levels of exudate, 33.3% (*n*=4) with low levels and 33.3% (*n*=4) with high levels of exudate. At the end of the evaluation, 16.6% (*n*=2) had no exudate as the wound was healed, 66.6% (*n*=8) had low levels and 16.6% (*n*=2) had moderate levels, no patient had high levels of exudate.

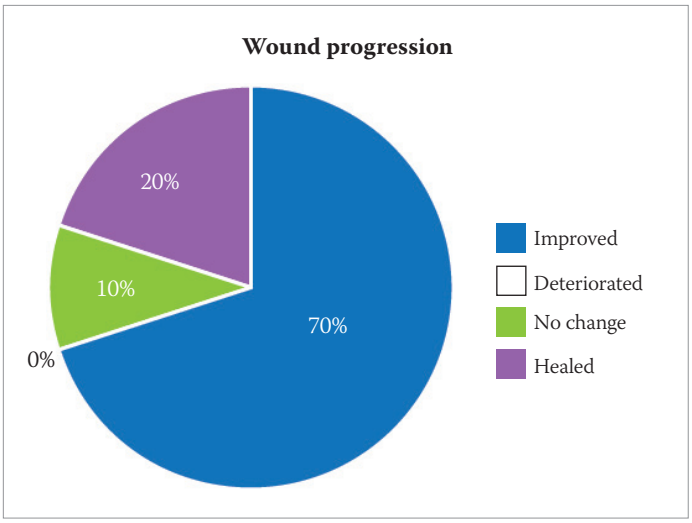

Figure 3. Wound progression

OVERALL RESULTS

The periwound skin did not deteriorate with over 70% (*n*=14) of the patients periwound skin improving, 10% (*n*=2) showing no change of which they were classed as having a normal periwound skin at the start of the evaluation, and 20% (*n*=4) of the wounds were healed at the end of the evaluation. These results showed that the ActivHeal Silicone Foam Border and Non-Border dressings successfully and effectively managed exudate, with a reduction in levels of exudate and no occurrences of maceration during the use of the dressings.

The results (*Figure 3*) also demonstrated a wide range of notable outcomes and wound progression. This was demonstrated through wound size reduction and the promotion of granulating and epithelial tissue. By the end of the evaluation 20% (*n*=4) of the wounds had healed, 70% were improved and 10% (*n*=2) of the wounds may not have reduced in size but there had been a change in the condition of the wound bed with the removal of both necrotic and sloughy tissue.

At the end of the evaluation, clinicians were asked to rate the overall acceptability of the dressings. Clinicians were 'very satisfied' and 'satisfied' with ActivHeal Silicone Foam dressing for all performance characteristics assessed (*Figure 4*). In

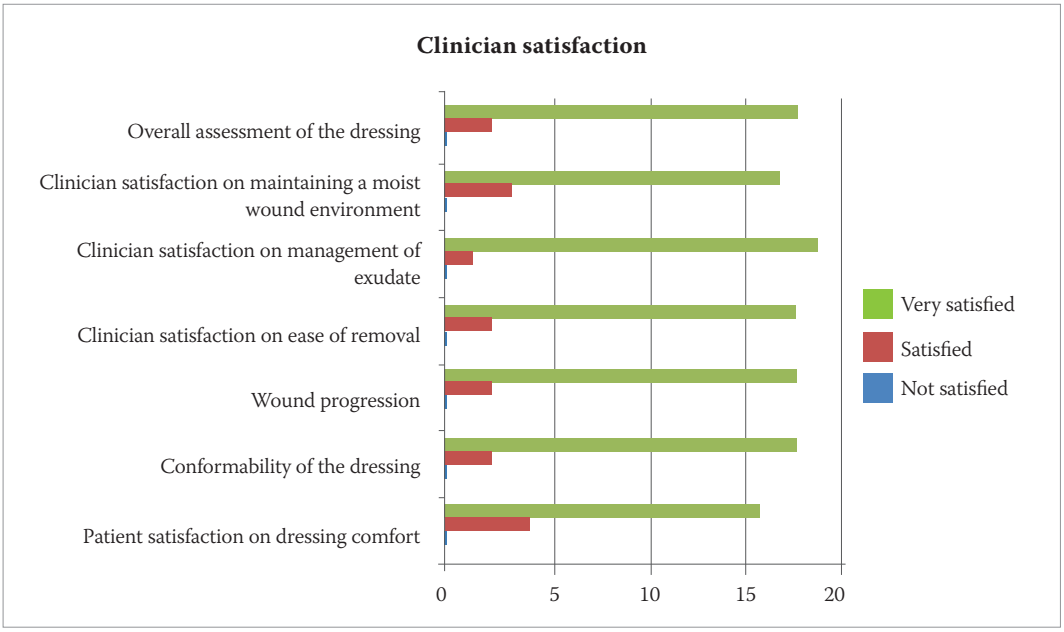

Figure 4. Clinician satisfaction of ActivHeal Silicone Foam performance characteristics

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regards to patient satisfaction to dressing comfort, 80% (*n*=16) were 'very satisfied' and 20% (*n*=4) were 'satisfied' with the use of the dressing.

In the areas assessed, the clinicians noted satisfaction in regards to all of the parameters. The majority being rated as 'very satisfied'. ActivHeal Silicone Foam dressing performed well in respect to exudate management, maintaining a moist wound environment and wound progression which substantiates the essential requirements of a foam dressing when treating patients with wounds (Thomas, 1993).

Foam dressings have evolved dramatically to include a silicone adhesive to assist in minimising pain and trauma to the wound bed and skin surrounding the wound. Patients' tolerance of dressings and ease of removal for the dressing is an important attribute and a key aspect for an adhesive dressing. With this in mind and in terms of acceptability, clinician satisfaction was high with regards to the ease of removal as 90% (*n*=18) were very satisfied and 10% (*n*=2) were satisfied. Reducing the potential mechanisms for pain can help promote patient comfort and improve clinical outcomes (Richardson and Upton, 2010). In regards to patient satisfaction to dressing comfort 80% (*n*=16) were very satisfied and 20% (*n*=4) were satisfied with the use of the dressing, and in the long term assists in the management of the friable, vulnerable traumatic damaged tissue and achievement of satisfactory clinical outcomes for both the patient and the clinician.

DISCUSSION

A common goal for both acute and chronic wounds is the management of excess exudate, periwound skin protection and healing alongside the promotion and maintenance of patient comfort and quality of life. Reducing the potential mechanisms for pain can help promote patient comfort and improve clinical outcomes (Richardson and Upton, 2010). It is important clinicians are aware of key factors that may exacerbate the vulnerability of skin, take precautions to protect the periwound area and use a dressing that does not cause trauma on removal. Evidence shows that silicone adhesive dressings remove less stratum corneum from the wound when compared to either a hydrocolloid or polyurethane foam (Matsumura et al, 2014). Timmons et al (2009) found that silicone dressings improved patients' quality of life by reducing pain on removal and anxiety. Patients' tolerance of dressings and ease of removal are important attributes for an adhesive dressing. Clinician satisfaction was high with regards to ease of removal, which was assessed on every patient at the end of the evaluation, with 90% (*n*=18) 'very satisfied' and 10% (*n*=2) 'satisfied'. Patient satisfaction was high with regards to dressing comfort that was assessed on every patient at the end of the evaluation, with 80% (*n*=16) 'very satisfied' and 20% (*n*=4) 'satisfied'. This study has shown ActivHeal Silicone Foam to be an acceptable alternative to other silicone dressings in terms of patient comfort and clinician satisfaction.

Excessive amounts of exudate can cause the periwound skin to become macerated and even break down (White and Cutting, 2003). There was a reduction in observed levels of exudate and no occurrences of maceration with the use of ActivHeal Silicone Foam dressing. This dressing therefore performed well with respect to exudate management. It also maintained a moist wound environment and assisted wound progression; essential requirements of a foam dressing when treating patients with wounds (Thomas, 1993).

CONSIDERATIONS

This evaluation included just 20 patients. Larger studies are therefore needed to further explore whether the findings are related to the cohort or are applicable to all patients with wounds. Exudate levels are hard to assess and quantify. They can be subjective and dependent on the judgement of the clinician assessing the wound (World Union of Wound Healing Societies, 2007).

CONCLUSION

This 20 patient-evaluation demonstrates that ActivHeal Silicone Foam dressings are effective in the management of both acute and chronic wounds as either a primary or secondary dressing. It demonstrates positive endpoints for exudate management, moist wound environment and periwound protection. Clinicians are under pressure to deliver good quality outcomes and the results from this evaluation demonstrate that ActivHeal Silicone Foam dressings could be considered a satisfactory alternative silicone foam. WUK