Post-market clinical evaluation of the safety and performance of ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings

KEY WORDS
- Silicone foam
- Dressings
- Evaluation
- Exudate management

This post-market evaluation assessed the performance of the ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings and gathered feedback from clinicians using both dressings to treat a variety of wounds. The primary outcomes were progression to healing through management of exudate and maintenance of a moist wound healing environment. The evaluation took place at 1 site within Poland, where 53 patients were treated according to ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings' instructions for use, and standard local practice. Data was collected at every dressing change. The results showed that both ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite Dressings had positive effects on exudate levels, periwound condition and tissue type(s) within the wound bed. The majority of wounds reduced in size during the evaluation period and twelve completely healed. Clinical and patient satisfaction was high. No adverse events were reported. The evaluation shows ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite Dressings used in clinical practice are safe, effective and acceptable for use to both practitioners and patients.

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Wound care faces many challenges, especially in the current circumstances. The incidence of wounds is growing and expected to increase further, due to the ageing population and rise in the prevalence of obesity, diabetes and lower limb arterial disease (Wounds International, 2013; Guest et al, 2017). The cost of wound care continues to escalate with estimated annual costs to the National Health Service (NHS) managing wounds and related comorbidities at £5.3 billion (Guest et al, 2017). Simultaneously, the number of nursing staff in both acute and community settings is diminishing (Queens Nursing Institute, 2019). The focus remains on providing high quality care, whilst being cost conscious. It is therefore important for healthcare professionals to be able to justify the use of wound care products and to ensure that they are used in a correct and appropriate manner.

WOUND HEALING AND MANAGEMENT

Wound healing is a complex sequence of events. Cells undergo a number of intricate biological changes to facilitate haemostasis, resist infection through the stage of inflammation, form new blood vessels, reconstruct, epithelialise and contract to close the wound in the proliferation phase, and finally form scar tissue during maturation (Bianchi et al, 2013; Han and Ceilley, 2016). The aim of wound care is to maintain progression through this process and ultimately heal the wound.

Successful wound management comprises of several factors. A full holistic assessment of the patient must be undertaken prior to evaluating the wound itself, in order to identify any underlying concerns that could impact healing. A comprehensive review of the wound should establish the site, category, dimensions, tissue type, wound symptoms and surrounding skin. The assessment should also look at skin fragility, pain and exudate levels.

EXUDATE

A moist environment will improve the rate at which a wound heals, which can be up to 2–3 times faster than a dry wound (Swezey, 2014). It is known that

a moist wound healing environment facilitates all aspects of the wound healing phases, decreasing the extent of the inflammation response, preventing the wound bed from becoming desiccated, aiding the migration of cells, preserving growth factors and assisting in enhancing wound contraction (Cook, 2011; Peate and Glencross, 2015). Exudate is a necessary and normal part of the wound healing process; however, when exudate levels increase to cause a wet wound or decrease to cause the wound to become dry, problems can occur (WUWHS, 2019). With higher levels of exudate the wound bed can become overhydrated, causing moisture to leak out onto the periwound skin (Gardiner, 2012). Once damaged, the wound can become inflamed and macerated leading to pain and discomfort, and more susceptible to the effects of irritants (Grothier, 2013; Woo et al, 2017).

Effective control of exudate is recognised as an essential requirement in wound management. Clinicians need to have an understanding of the role of exudate and how to maintain an optimal moisture balance to encourage good wound healing progression.

DRESSING SELECTION

Dressings continue to be the foundation of exudate management, helping to provide an optimum healing environment. There is currently a vast selection of products available; however, it is key for a clinician to recognise the following factors when selecting a dressing:

- Stage of wound healing
- Amount of exudate
- Adhesiveness of a dressing (ease of removal)
- Any irritation caused by the adhesive
- Absorption
- Frequency of dressing changes
- Ease of dressing use
- Amount of pain at dressing change
- Protection of the surrounding skin
- Patient preference (Flannagan, 2013; NICE, 2016).

It is important to note that no individual dressing is suitable for use throughout the course of treatment. As the wound progresses through the healing continuum, clinicians are expected to adjust their management plan. A 'step up' and 'step down' approach is needed to ensure that the appropriate dressing is used at the appropriate time (Bajjada, 2017; WUWHS, 2019).

Including the patient and/or carer should be considered when choosing a dressing, if appropriate. Involving and recognising this participation can lead to improved concordance, a better understanding of wound progression and an opportunity for the patient to make informed decisions about their management plan (International Best Practice Statement, 2016).

SILICONE DRESSINGS

Soft silicone dressings are coated with a hydrophobic soft silicone layer that is tacky to touch. They are designed to minimise pain and adherence to the wound bed on removal and protect the surrounding skin. They conform to the wound, reduce epithelial stripping and promote comfort during wear time (Hampton, 2010; Meuleneire and Rücknagel, 2013).

Advanced Medical Solutions Ltd has enhanced its foam portfolio with the addition of ActivHeal® Silicone Foam Lite, which compliments the existing Silicone Foam range. Indicated for use on moderate to heavily exuding wounds, 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 and silicone adhesive wound contact layer. The three-layer silicone dressing (*Figure 1*) offers excellent total fluid handling capabilities, ensuring efficient management of exudate to help aid the wound healing process. The high moisture vapour transfer rate (MVTR) allows excess exudate to evaporate and, combined with the intrinsic absorption capacity of the foam, provides a high fluid capability (Advanced Medical Solutions Ltd, 2015).

The ActivHeal® Silicone Foam Lite Border and Non-Border dressings are constructed in a similar manner; however, the significant difference is the thickness of the central polyurethane pad. The Silicone Foam Lite range is 60% thinner and is designed for nil to low exuding wounds. The Lite range also has a high MVTR to permit excess exudate to evaporate and the absorption capacity of the foam to provide a suitable total fluid capability for reduced exudate levels (Advanced Medical Solutions Ltd, 2017). The reduced thickness creates

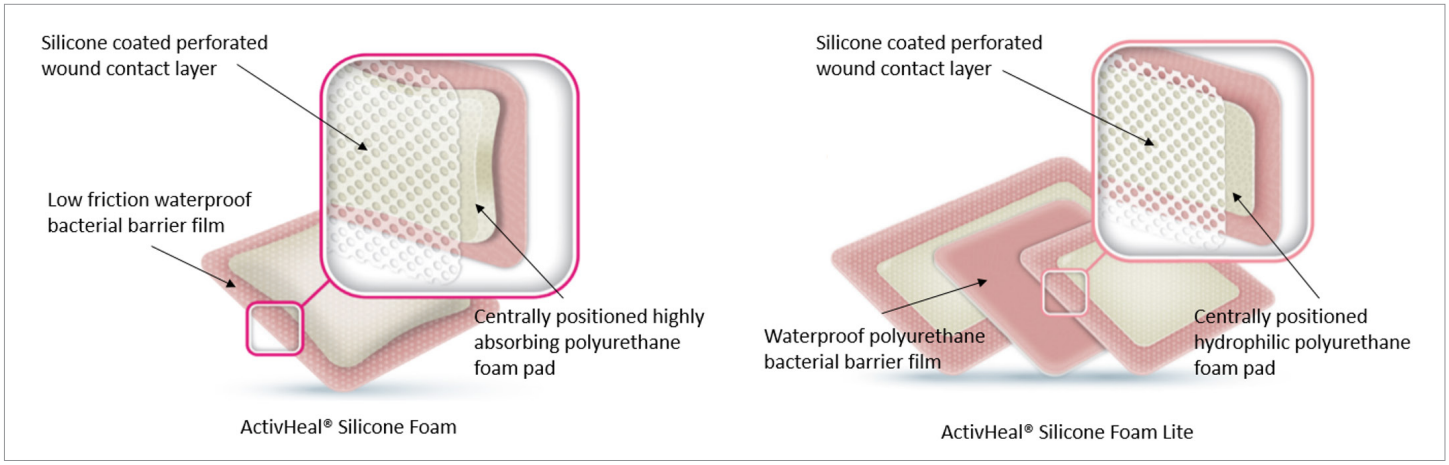

Figure 1. **ActivHeal® Silicone Foam range dressings have three layers: a waterproof polyurethane film, a central polyurethane pad and a silicone adhesive wound contact layer**

a low-profile dressing to improve patient comfort and increase conformability.

Both the ActivHeal® Silicone Foam and Silicone Foam Lite dressings are indicated when adherence to the wound bed or periwound area is a potential problem. The silicone perforated wound contact layer allows uptake of exudate, preventing excess fluid from causing maceration of the surrounding skin and reducing pain at dressing changes. The dressings can be repositioned during application or lifted during wear time for observation.

ACTIVHEAL® SILICONE FOAM AND ACTIVHEAL® SILICONE FOAM LITE DRESSING CLINICAL EVALUATION

Foam wound dressings are an effective tool in the treatment and management of chronic and acute wounds, at all stages of healing. They are designed to absorb and retain excess fluid within the dressing, providing increased wear time, whilst preventing maceration to the surrounding periwound skin.

Silicone Foam Lite is designed for situations where clinicians require a thinner dressing and fluid handling requirements are lower. Providing such a product gives the clinician a degree of flexibility when selecting a dressing at any given stage in the healing cycle (Dealey, 2012). The Silicone Lite foam dressing can absorb and retain exudate, provide an effective barrier function (White, 2007), and can be used as a primary or as a secondary dressing (Benbow, 2008). This study was designed to show that the ActivHeal® Silicone foam range can be used as the wound moves through the healing trajectory and as exudate levels reduce. The primary objective of the clinical evaluation was to confirm the clinical safety and performance of ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite in wound exudate management, wound healing progression and periwound skin conditions in a step-down approach.

METHOD

The evaluations of the ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings were undertaken at one site in Poland, to observe the clinical outcome and clinician's opinion of the dressings. The design was a clinical study, where the dressing was used alongside standard practice at the health facility. This was the preferred method to generate information on a range of patients, wound indications and to observe current practice when advanced wound dressings are used. Ethical approval was obtained. Within this design, the clinicians followed protocol to control the process and were provided with information on the dressing, with an inclusion and exclusion criteria and the maximum length of time for the study, which was 6 weeks.

Inclusion criteria for subject selection

Patients eligible for inclusion in this case evaluation were those participants who meet the following criteria:

i. Male or female, aged 18 years or above (females must not be pregnant and if of reproductive age, they should be using contraception)
ii. Subjects who are able to understand and give informed consent to take part in the evaluation
iii. No local or systemic signs of infection, including new pain or increasing pain, erythema, local

Conflict of Interest
This work was supported by an unrestricted educational grant from Advanced Medical Solutions Ltd

warmth, swelling, purulent discharge, pyrexia (in surgical wounds, typically five to seven days after surgery), delayed wound healing, abscess or malodour

iv. None to high levels of exudate (the IFU was followed for the specific dressings).

Exclusion criteria for subject selection

Patients who were to be excluded from participating in this evaluation were:

i. Patients who decline the invitation to take part
ii. Patients who are known to be non-compliant with medical treatment
iii. Patients who are known to be sensitive to any of the dressing components
iv. Broken/damaged or prone to blistering periwound skin
v. Presence of a clinically infected wound as determined by the presence of three or more of the following clinical signs: periwound erythema, pain between dressing changes, malodourous wound, abundant exudate, oedema, abscess, cellulitis, purulent discharge, discolouration, friable granulation tissue which bleeds easily
vi. Patients who have a current illness or condition which may interfere with wound healing in the last 30 days, which may interfere with wound healing (carcinoma, connective tissue disease, autoimmune disease, or alcohol/drug abuse)
vii. Life expectancy of less than 6 months.

Clinicians were provided with copies of the guidelines along with case report forms and patient consent forms. The appropriate patients were enrolled in the evaluation once they had provided informed consent. Patients were not randomised, and no additional interventions were made to standard care.

The ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite were applied to wounds requiring advanced wound dressings, following full wound assessment. These included wounds where the clinician had identified requirement for removal of devitalised tissue and provision of a moist wound healing environment.

The primary intention of the evaluation was to assess the ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings in their ability to promote healing through the management of wound exudate, wound healing progression and maintenance of periwound skin condition in the following wounds: leg ulcers, diabetic ulcers, pressure ulcers, postoperative surgical wounds, superficial and partial thickness burns, and trauma wounds (including skin tears, lacerations and abrasions). Wound size, wound bed status, exudate levels, periwound condition and safety of the device were assessed. Dressing performance was also assessed i.e. ease of use, conformability to the wound, patient comfort during wear and removal, clinician satisfaction, ability to stay in place and overall product satisfaction.

RESULTS

The ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings were evaluated on 53 patients. The wounds treated had exudate levels ranging from moderate to high for ActivHeal® Silicone Foam, and nil to low for the ActivHeal® Silicone Foam Lite. The wounds contained necrotic, sloughy and/or granulating tissue. The distribution of wound types for the whole study can be seen in *Figure 2.*

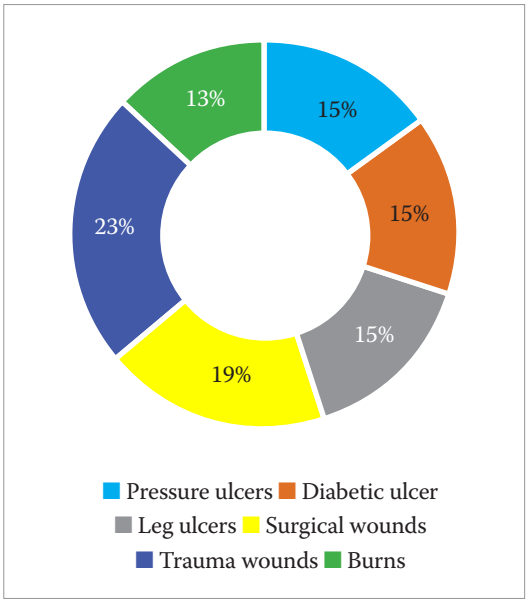

Figure 2. **Distribution of wound types in the study**

CLINICAL EFFICACY

ActivHeal® Silicone Foam dressing

Figure 3 shows the status of the wounds at the end of the clinical evaluation of the ActivHeal® Silicone Foam dressing, prior to stepping down to the

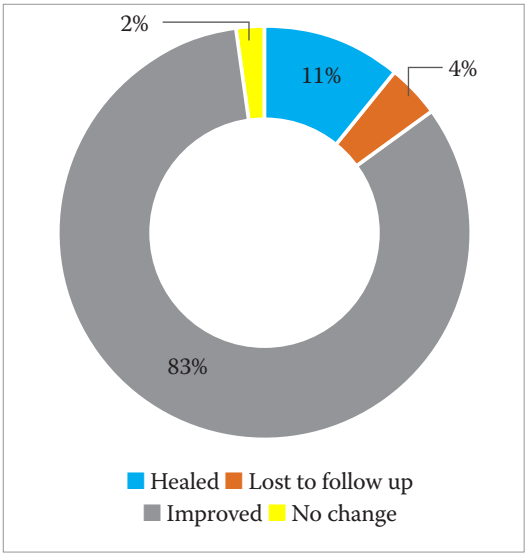

Figure 3. Wound progression ActivHeal® Silicone Foam

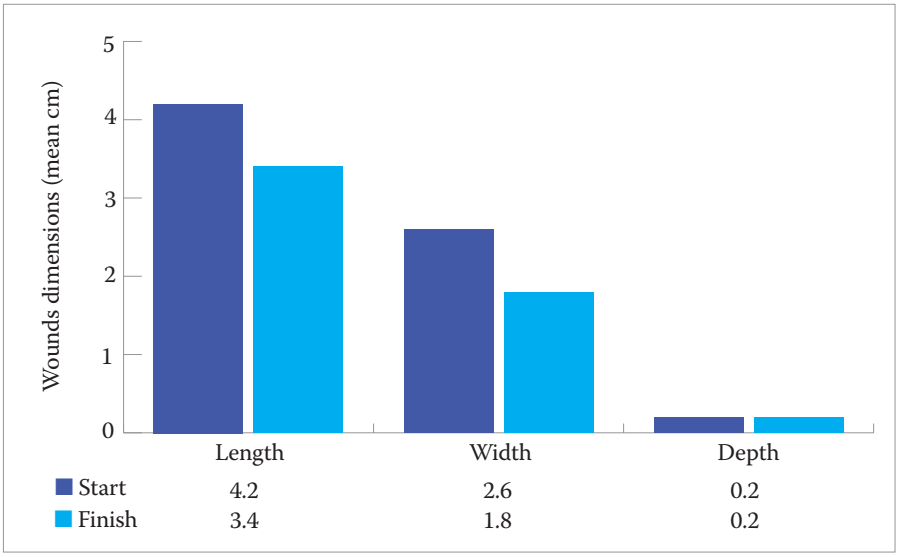

Figure 4. Wound dimensions ActivHeal® Silicone Foam

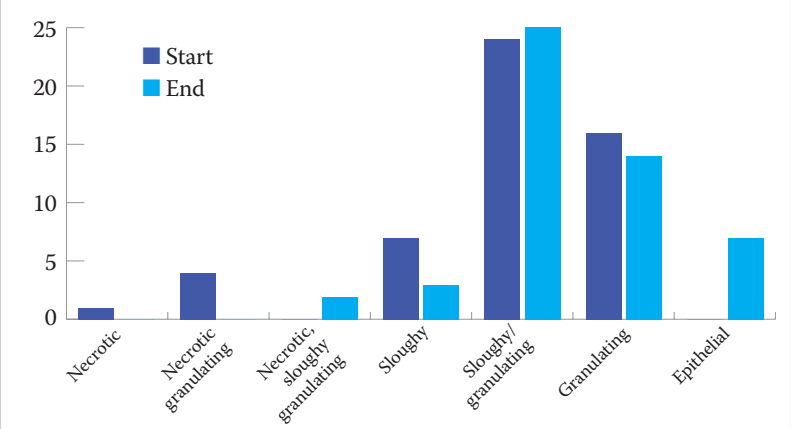

Figure 5. Tissue types - ActivHeal® Silicone Foam

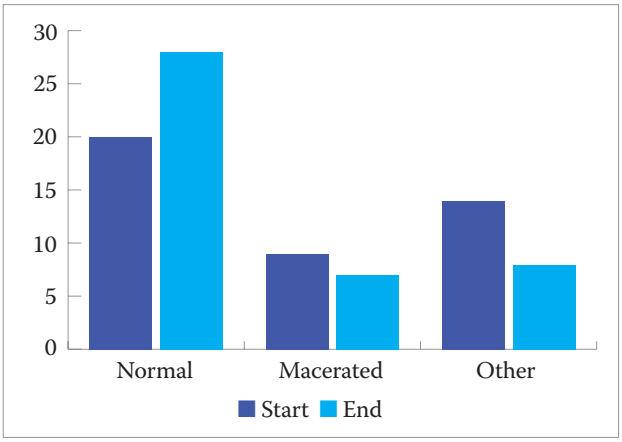

Figure 6. Periwound progression ActivHeal® Silicone Foam

ActivHeal® Silicone Foam Lite dressing. Reductions in wound dimensions were observed. Initially at baseline, the mean wound length, width and depth were 4.2cm and 2.6cm and 0.2cm, respectively; at the end of the evaluation the mean length, width and depth were 3.4cm, 1.8cm and 0.2cm. (*Figure 4*) At the end of the evaluation period for this dressing, 83% (*n*=44) of the wounds improved and had progressed significantly towards healing. An improvement in tissue type and wound aetiology was reported, with a reduction in the percentage of devitalised tissue (*Figure 5*). Six wounds healed, 1 wound remained unchanged and 2 were lost to follow-up. Lower levels of exudate were seen in the majority of wounds assessed. Figure 6 shows a reduction in observed levels of exudate and an improvement in periwound skin during the evaluation period. This demonstrates that the dressing effectively absorbed and retained exudate, preventing and reducing maceration.

ACTIVHEAL® SILICONE FOAM LITE

The number of total patients decreased to 44, due to 6 patients' wounds healing with ActivHeal® Silicone Foam use, and 2 patients being lost to follow-up. *Figure 7* shows the status of the wounds at the end of the clinical evaluation of the ActivHeal® Silicone Foam Lite dressing. Reductions in wound dimensions were observed. Initially at baseline, the mean wound length, width and depth were 3.4cm, 1.9cm and 0.2cm, respectively; at the end of the evaluation the mean length, width and depth were 2.7cm, 1.37cm and 0.1cm (*Figure 8*). At the end of

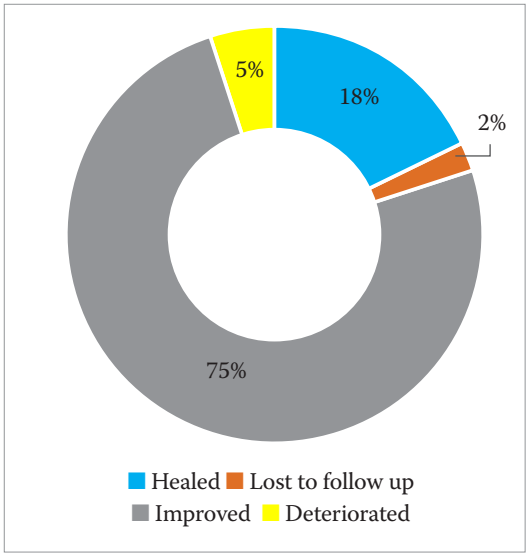

Figure 7. Wound progression ActivHeal® Silicone Foam Lite

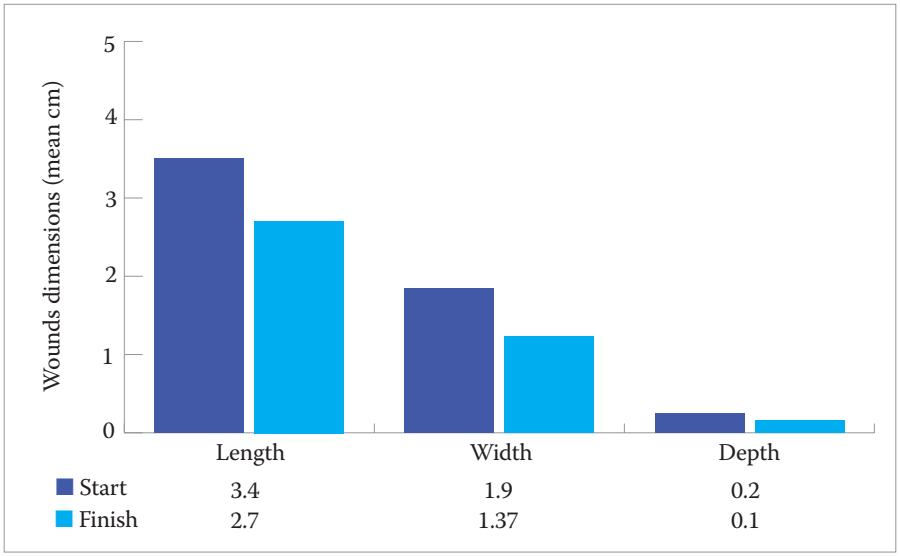

Figure 8. Wound dimension ActivHeal® Silicone Foam Lite

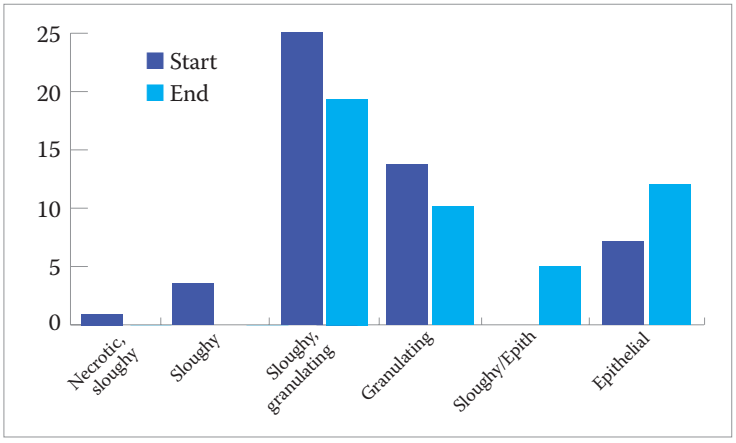

Figure 9. Tissue type ActivHeal® Silicone Foam Lite

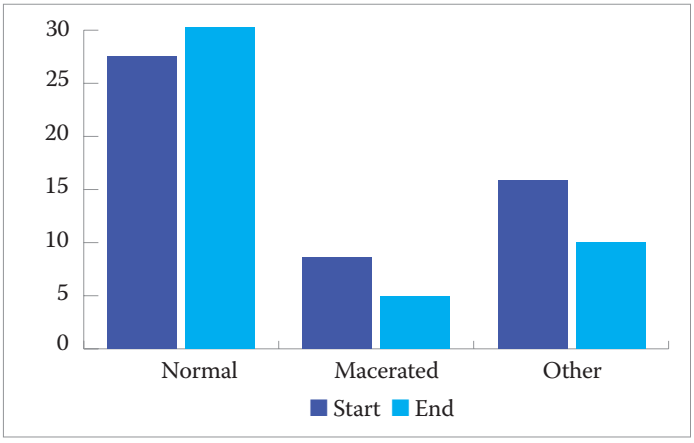

Figure 10. Periwound progression ActivHeal® Silicone Foam Lite

the evaluation period for this dressing, 75% (n=33) of the wounds improved or progressed significantly towards healing and treatment was stepped down further to a different wound care product. The tissue types and wound aetiology showed improvement with a reduction in the percentage of devitalised tissue (*Figure 9*).

Figure 10 shows a reduction in observed levels of exudate and an improvement in periwound skin during the evaluation period. This demonstrates that the dressing effectively absorbed and retained exudate, preventing and reducing maceration. A further 8 wounds healed, 2 wounds deteriorated, and 1 patient remained lost to follow-up.

It is important to note that the decision was made to step down to ActivHeal® Silicone Foam Lite dressing in the two wounds which deteriorated when exudate levels remained moderate to high, which may have impacted healing. Despite this, overall, lower levels of exudate were seen in the majority of wounds assessed.

USER OPINION

ActivHeal® Silicone Foam Dressing

Table 1 gives levels of satisfaction with various characteristics of the ActivHeal® Silicone Foam Dressing. The majority of clinicians were satisfied or very satisfied with the product characteristics. Overall satisfaction levels were high.

Table 1. ActivHeal® Silicone Foam				
Levels of satisfaction with various characteristics of the ActivHeal® Silicone Foam Dressing	**Not Satisfied**	**Satisfied**	**Very Satisfied**	**Lost to Follow up**
Managing Exudate	0%	26%	70%	4%
Maintaining Moist Environment	2%	32%	60%	6%
Wound Progression	9%	25%	60%	6%
Ease of Use	0%	25%	68%	7%
Atraumatic removal and prevents ingress of granulation tissue	0%	21%	72%	7%
Conformability of the dressing	2%	19%	74%	5%
Dressing Contours to anatomical sites	2%	21%	72%	5%
Patient satisfaction/comfort	2%	25%	66%	7%
Overall assessment of the dressing	2%	36%	58%	4%

Table 2. ActivHeal® Silicone Foam Lite				
Levels of satisfaction with various characteristics of the ActivHeal® Silicone Foam Lite Dressing	**Not Satisfied**	**Satisfied**	**Very Satisfied**	**Lost to follow up**
Managing Exudate	9%	37%	52%	2%
Maintaining Moist Environment	4%	33%	61%	2%
Wound progression	9%	26%	63%	2%
Ease of use	0%	22%	76%	2%
Atraumatic removal and prevents ingress of granulation tissue	0%	20%	78%	2%
Conformability of the dressing	2%	20%	76%	2%
Dressing contours to anatomical sites	0%	24%	74%	2%
Patient Satisfaction / Comfort	4%	24%	70%	2%
Overall assessment of the dressing	2%	28%	68%	2%

ActivHeal® Silicone Foam Lite

Table 2 gives levels of satisfaction with various characteristics of the ActivHeal® Silicone Foam Lite Dressing. The majority of clinicians were satisfied or very satisfied with the product characteristics (as previously highlighted, the dressing had been used off label on wounds with a higher level of exudate than is indicated for the dressing). Overall satisfaction levels were high.

SAFETY

No safety or adverse events were reported that were device related during the post market study. This suggests that for this particular evaluation there are no concerns with the safety of the ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite Dressing.

DISCUSSION

The results of this clinical evaluation provide good evidence that the ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings can lead to positive healing outcomes for patients with chronic wounds. The dressings were used to treat a variety of wounds including leg ulcers, diabetic ulcers, pressure ulcers, post-operative surgical wounds, superficial and partial thickness burns and trauma wounds (including skin tears, laceration and abrasions).

ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings successfully absorbed and retained exudate, helping to prevent maceration and improve the condition of the periwound skin. It has been widely reported in

the literature that when the skin surrounding a wound is compromised, it can increase patient discomfort (WUWHS, 2019). Uncontrolled exudate can macerate the periwound skin or even cause a breakdown (Adderley, 2008; Stephen-Haynes, 2011; Gardiner, 2012; WUWHS, 2019). The evaluation demonstrates that ActivHeal® Silicone Foam and ActivHeal® Silicone Foam Lite dressings achieved high levels of comfort and satisfaction. Wound size and depth also improved over the study period. Both dressings were well tolerated by patients and clinician satisfaction with regard to treatment was high overall.

Furthermore, the majority of dressing changes were performed following a routine wound assessment as part of standard of care, rather than because of clinical need, such as failure of the dressing to stay in place, leakage or strikethrough. The dressings also performed well on removal, which may have contributed to the high level of patient satisfaction. These factors added to acceptability for use in clinical practice and suggest that use of these dressings throughout the healing process may enhance patient comfort.

CONSIDERATIONS

This evaluation included 53 patients. A larger study is planned 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 judgment of the clinician assessing the wound (WUWHS, 2019).

CONCLUSION

Selecting the right product – not just the first time, but every time – creating an optimal wound healing environment and managing wound exudate, is paramount. As the wound moves through the wound healing process and as exudate levels reduce, it is important for clinicians to incorporate a step-down approach.

This clinical evaluation found that both ActivHeal® Silicone Foam dressing and ActivHeal® Silicone Foam Lite dressing are effective in the management of both acute and chronic wounds and they are safe, effective and more than acceptable to practitioners and patients providing an alternative to other silicone foam dressings. WUK

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