A clinical evaluation of 21 patients using Kliniderm foam silicone lite

KEY WORDS
- Kliniderm
- Foam silicone dressing
- Evaluation
- Wound dressing

This article describes the evaluation in clinical practice of Kliniderm foam silicone lite on 21 patients for a two-week period, with an average of four and minimum of two dressing changes. Factors evaluated included patient comfort on application, ease of application, conformability, exudate management, ability to stay in place, ease of removal, patient comfort on removal, the condition of the wound and periwound skin, and the wear time of the dressing.

BRENDA KING
Independent Nurse Consultant Tissue Viability

SIMON BARRETT
Lead Tissue Viability Specialist Nurse, Humber Teaching NHS Foundation Trust

DONNA WELCH
Lead Podiatrist, Hull University Teaching Hospitals NHS Trust

Wound healing is a dynamic and complex process, which requires an optimum environment to enable the wound to heal normally within an acceptable timeframe. An acute wound should follow a precise healing trajectory with little intervention from healthcare services required. However, a significant proportion of wounds do not follow the normal orderly sequence of wound repair, and thereby become chronic or hard-to-heal. These wounds usually require more clinical input; however, despite increased clinical input, there is still a significant number of chronic wounds in the UK, (suggested to be around 2.2 million) that fail to heal in a timely manner, costing in the region of £5 billion pounds per annum (Guest et al, 2015). Updated figures now show that this figure is rising and there were an estimated 3.8 million patients with a wound managed by the NHS in 2017/2018, of which 70% healed in the study year; 89% and 49% of acute and chronic wounds healed, respectively (Guest et al, 2020).

THE IMPORTANCE OF DRESSING SELECTION

Once systemic factors such as comorbidities and underlying pathophysiology have been appropriately addressed, it is these chronic hard-to-heal wounds that most require high-quality dressing products that can meet the challenges of local wound management. Common challenges include high levels of exudate leading to poor quality periwound skin, increased bacterial load, pain and discomfort (Persoon et al, 2004; Leonard and Vuolo, 2009). While these are concerns for the clinician managing the wound, for the patient they could mean reduced quality of life, social problems — both work and leisure-related — and the risk of social isolation (Harding et al, 2020).

Clearly, the cost of wound dressings contribute of the cost of managing the burden of chronic wounds; therefore, dressings require evidence of their clinical effectiveness in terms of optimising healing (Dissemond et al, 2020), but must also be cost-effective to reduce some of the health economic problems associated with the burden of chronic wounds.

EXUDATE MANAGEMENT

In wounds where exudate management is an issue, a dressing's ability to absorb and retain exudate is key. It is also important to understand the components of wound exudate and their role in healing (Harding et al, 2019). When considering wound exudate, it is necessary to understand the difference between exudate from an acute wound to that of a chronic wound.

Acute wound exudate contains nutrients, electrolytes, neutrophils and inflammatory mediators among other cells, and therefore provides a moist environment, which aids cell migration and movement of growth factors into the wound bed, and supports key messengers to trigger the cells required for wound repair dependent on the needs of the wound (Romanelli et al, 2010). This may include debridement of dead cells by the macrophage-releasing proteolytic enzymes to aid

autolysis, phagocytosis and removal of bacteria.

This is very different to the fluid produced by a chronic wound, which can hinder tissue repair and delay healing (Harding et al, 2019). Chronic wound fluid has been found to slow cell proliferation, interfere with growth factor availability, contain elevated levels of inflammatory mediators and activated metalloproteinase (Romanelli et al, 2010). This produces a prolonged state of inflammation, which in itself then becomes proinflammatory, so a vicious circle of inflammation develops. This prevents the wound from progressing to the next stages of wound repair. Additionally, with prolonged contact, wound exudate may damage the surrounding periwound skin.

Periwound skin damage can be painful; additionally, exudate leakage may cause quality-of-life issues for the patient (Harding et al, 2019). Therefore, it is vital that a dressing effectively absorbs and retains exudate, protecting the periwound skin and promoting a healthy wound environment.

KLINIDERM FOAM SILICONE LITE

Foams have been used in wound management for many years, with some of the earlier sheets of foam used as skin substitutes and then flat foam dressings and cavity fillers. Since then, foam dressings have become more sophisticated, with improved design to ensure they have the necessary characteristics required for an ideal wound dressing that creates an environment conducive to healing.

These dressings are often a combination of hydrophobic and hydrophilic foam – this means that the hydrophobic properties of outer layer protect the wound from liquid and bacteria but allow gaseous exchange and water vapour, with the exudate wicked through to the hydrophilic core of the dressing, away from the wound (Dhivya et al, 2015). Adhesive (with borders) and non-adhesive dressings (requiring secondary fixation) are available.

The Kliniderm foam silicone lite is a lighter version of the Kliniderm foam silicone, which has been evaluated elsewhere (Rafter et al, 2016; Drewery, 2015; Stephens, 2020). The 'light' version is primarily designed for wounds with low/moderate levels of exudate. It is also suitable for use on oncology-related wounds and to prevent and manage device-related pressure ulcers (Pramod, 2021). It is a soft conformable foam dressing, designed to manage wound fluid and create the correct wound environment to support wound repair. It has a semipermeable outer membrane and is available with a silicone border, or as a non-bordered dressing. The bordered formulation is shower-proof, whereas the non-bordered is not; however, the non-bordered can be cut to size, to fit the shape of the wound if required.

Kliniderm foam silicone lite is indicated for pressure ulcers, diabetic foot ulcers (DFU), leg ulcers, postoperative wounds, skin abrasions, superficial and partial-thickness burns, donor sites and traumatic wounds; the bordered version has low-profile edges so that the dressings stay in place. All patients included in the evaluation had wound types suitable for the dressings' indications.

AIMS OF THE EVALUATION

The aims of the evaluation of Kliniderm foam silicone lite were to consider:

- Patient comfort both at application and at dressing removal
- Ease of application and removal of the dressing
- The conformability of the dressing to the wound
- The ability of the dressing to manage exudate
- The ability of the dressing to stay in place and the wear time of the dressing
- The condition of the wound and periwound skin.

Therefore, addressing some of the challenges faced when managing chronic wounds and considering the attributes of an ideal dressing. Patient demographic data were also collected, along with wound type and size, and the clinician's perspective on the performance of the dressing.

METHOD

The evaluation was undertaken in the community in Hull and East Riding. Ethical approval was not required, as this was an evaluation of a wound dressing that was already available on the Drug Tariff so could be prescribed. It was also considered a suitable dressing for use on the different wound aetiologies included in the evaluation.

Prior to gaining consent for the evaluation, all patients had a full wound assessment following the National Wound Care Strategy Programme (NWCSP) minimum data set (MDS) for wound

Box 1. Inclusion and exclusion criteria

Inclusion criteria

- Wound suitable for inclusion as per product indication
- Over 18 years of age
- Ability to give signed informed consent

Exclusion criteria

- Not willing or unable to give consent
- Known allergy or sensitivity to the dressing products
- Under 18 and unable to consent

Box 2. Evaluation criteria

1. Patient comfort on application
2. Ease of application
3. Conformability
4. Ability to manage exudate
5. Ability to stay in place
6. Ease of removal
7. Patient comfort on removal
8. Wound condition
9. Peri wound condition
10. Wear time

assessment (Coleman et al, 2017) to ensure suitability for inclusion.

Patients meeting the criteria *(Box 1)* were approached for their consent to be involved in the evaluation. A verbal explanation was provided to the patient; this supplied detail of the product to be evaluated, the rationale for the evaluation and their role within the evaluation. They also had the opportunity to look at and feel the dressing and were reassured that, if they refused to consent to be involved in the evaluation, it would not affect their treatment in any way and a suitable alternative dressing would be provided.

Twenty-one patients were approached and invited to take part in the evaluation. There were no patients approached who did not consent to taking part. The evaluation was not intended to measure outcomes in terms of wound healing, as the evaluation was aiming to assess the factors listed previously, but would report on the appearance of the wound and periwound skin after treatment. The evaluation was for a minimum of two weeks, with an average of four dressing changes, but with a minimum of two dressing changes.

All clinicians involved in the evaluation were provided with information about the dressing, how it should be used and what to assess for, and were provided with evaluation sheets for data capture. Instructions were also provided on how to complete the evaluation sheet, which did not contain any patient identifiable information and thus maintained patient confidentiality.

The data captured included the patient's gender, age, wound aetiology, level of exudate, wound size and wound duration. Exudate was recorded as dry, light, moderate or heavy. Wound sizes were recorded within the ranges of <10cm^2, 10–25cm^2 and >25cm^2. Wound duration was recorded in the ranges of 0–4 weeks, 4–8 weeks, 2–6 months, 6 months–1 year, and 1 year plus.

Data were also recorded that would address the aims of evaluation. There were 10 factors considered independently (Box 2) to address the aims of the evaluation. These were all scored on a 1–5-point Likert scale where 1 equals very poor, 2 equals poor, 3 equals average, 4 equals good and 5 equals excellent. Lastly, two questions were posed asking the clinicians to rate their personal opinion of the performance of the evaluation dressing.

RESULTS

All patients were seen in the community. Eleven male (52%) and nine female (48%) patients took part in the evaluation (data on gender missing from one patient), with an average age of 72 (range 18–94). There was only one female in the DFU group and a younger average age of 62 (range 35–83) in the patients with DFUs.

The different wound aetiologies included four (19%) leg ulcers of venous, or mixed venous and arterial disease; all patients were in full or reduced compression therapy as appropriate to treat the venous hypertension; ten (48%) DFUs, six (29%) trauma wounds and 1 (5%) malignant wound were included in the evaluation *(Figure 1)*.

The wound durations recorded were seven (33%) in the 0–4 week range, four (19%) in the 4–8 week range, six (29%) in the 2–6 month range, one (5%) in the 6-month–1-year range and three (14%) in the >1-year range *(Figure 2)*. The three wounds with the

Figure 1. Wound types included in the evaluation

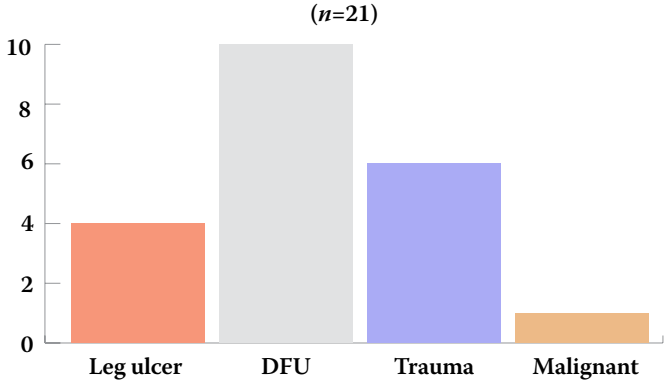


Figure 2. Wound durations

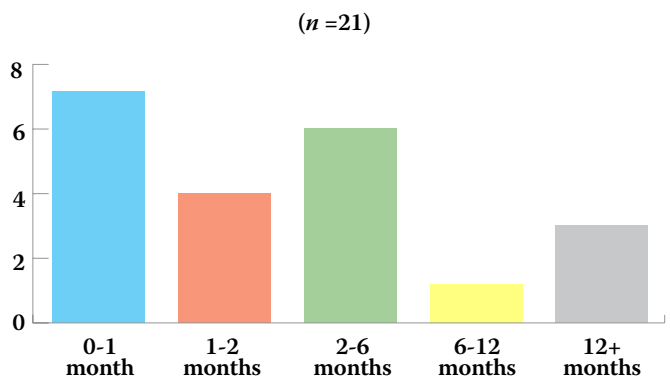


Figure 3. Wound sizes

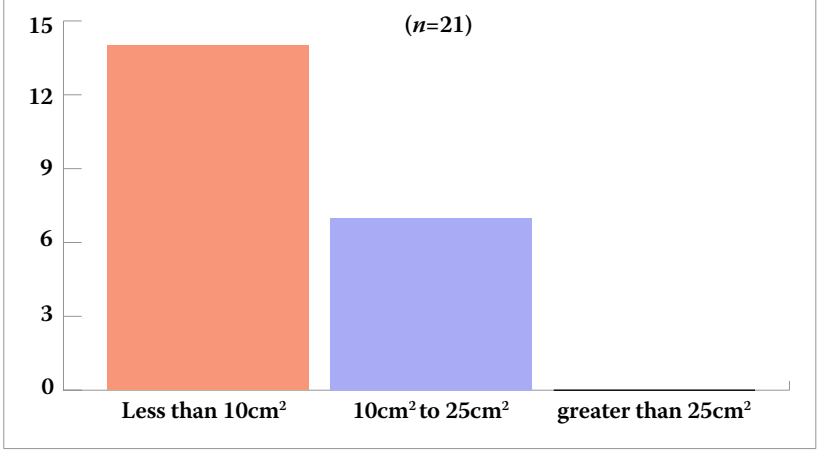
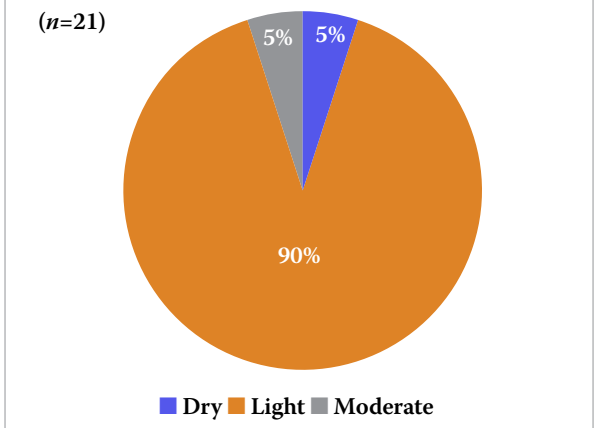


Figure 4. Exudate levels



Box 3. Potential cost savings

Kliniderm dressings could offer potential cost savings. Previous studies (Drewery, 2015; Barrett, 2015) on the Kliniderm range (Kliniderm foam silicone and Kliniderm superabsorbent dressings) found that introducing Kliniderm could result in overall cost savings. Clinicians rated the dressings highly and cost savings were made when the dressings were added to the formulary.

Table 1.

Parameters	Average score
Comfort on application	4.7
Ease of application	4.7
Conformability	4.6
Exudate management	4.4
Stay in place	4.2
Ease of removal	4.6
Comfort on removal	4.4
Wound condition	4.7
Periwound condition	4.3
Wear time	4.3

longest wound duration included one leg ulcer and two DFUs.

The majority of the wounds in the evaluation – 14 (67%) – were less than 10cm². The remaining seven (33%) were in the range of 10–25cm² *(Figure 3)*. There were no wounds greater than 25cm² included in the evaluation. All wound depths were recorded as between 2mm and 4mm. There were no cavity wounds included in the evaluation.

Apart from one (trauma wound) that was recorded as being dry, and one (malignant wound) recorded as having moderate exudate levels, the remaining 19 wounds were recorded as having only light levels of exudate *(Figure 4)*.

In the categories of ease of application and conformability, Kliniderm foam silicone lite was rated with an overall average score of 4.7 out of 5. For exudate management, there was an overall rating of 4.4. Comfort on application had an overall average of 4.7. Wound condition was also rated overall at 4.7 *(Figure 5)*. In the other categories, the overall average rating for each was between 4.3 and 4.7 (listed in *Table 1* and *Table 2*; illustrated in *Figure 6*).

The majority of wounds were treated with a bordered Kliniderm foam silicone lite (18 = 86%) and three (14%) with the non-bordered version.

DISCUSSION

Kliniderm foam silicone lite was evaluated against some of the characteristics necessary for the 'ideal' wound dressing. These included some of the key performance indicators considered necessary to reduce pain and discomfort for the patient around ease of use, pain-free application and removal and comfort during wear time, which overall were rated 'good' in the evaluation. Exudate management and maintenance of a healthy wound bed and periwound area, which were again rated 'good' in the evaluation.

The majority of wounds in the evaluation had only light levels of exudate; however, the dressing was still rated as 'good' in the category of exudate management. As this is a light version of the Kliniderm foam silicone dressing, this would probably be the dressing of choice for low/moderately exuding wounds.

In general, the clinicians found the product easy to handle in terms of application, removal and conformability. As well as providing benefits to both patient and clinician, its ease of use may help to avoid wastage.

Table 2. Percentage of respondents rating the dressing good/excellent

	Comfort on application	Ease of application	Conform-ability	Exudate manage-ment	Stay in place	Ease of removal	Comfort on removal	Wound condition	Periwound condition	Wear time
% good to excellent	**95%**	**100%**	**100%**	**83%**	**76%**	**100%**	**90%**	**95%**	**81%**	**86%**

Figure 5. Wound condition

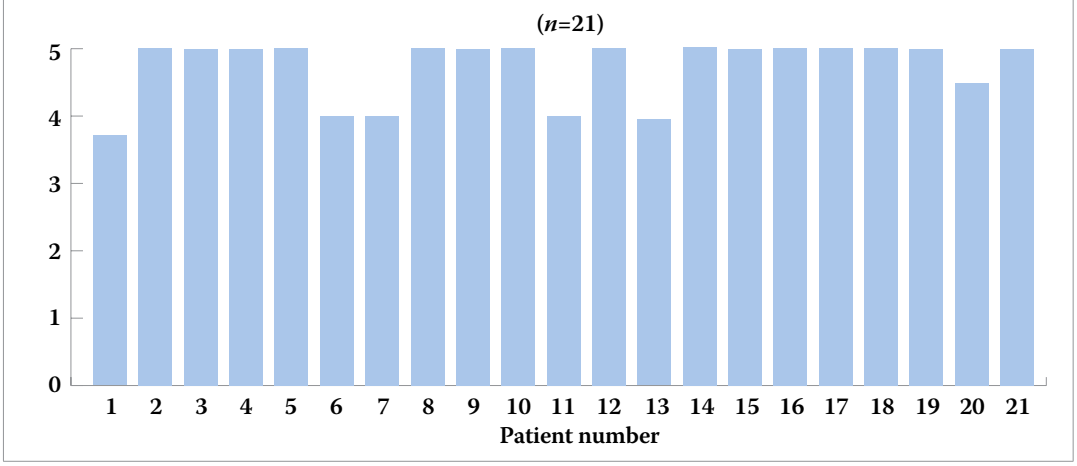
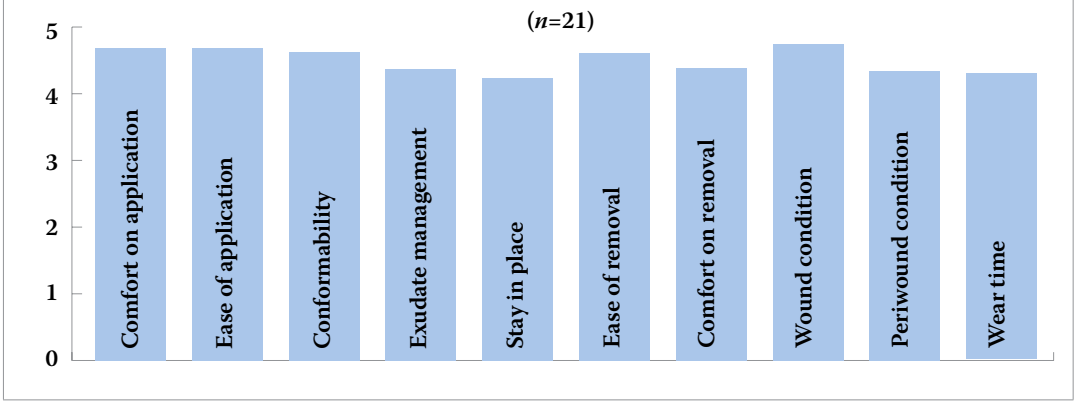


Figure 6. Evaluation criteria



CONCLUSIONS

This evaluation has demonstrated Kliniderm foam silicone lite to be a suitable dressing for the majority of wounds involved. The dressing was rated good or above on all 10 parameters, and the majority of clinicians' opinions were positive. WUK

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