A clinical evaluation of 21 patients using Kliniderm silicone wound contact layer

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KEY WORDS
- Kliniderm
- Silicone contact layer
- Evaluation
- Wound dressing

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Wound management in England has recently been under the spotlight with the development of a National Wound Care Strategy Programme (NWCSP, 2019), aimed at improving wound outcomes. The trigger for this programme was the publication of the Burden of Chronic Wounds Study (Guest et al, 2015) which estimated there to be 2.2 million chronic wounds in the UK with an annual associated cost of up to £5.3 billion. Further analysis of the data revealed a potential increase in the number of chronic wounds by 11% per annum (Guest et al, 2017); recently 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 (Guest et al, 2020).

It is essential that wound care practice is both cost and clinically effective. The majority of wounds — up to 87% — are generally seen and managed in the community, and account for up to 40% of a community nurse's caseload (Dowsett et al, 2014), so to evaluate dressings in the community is an appropriate setting.

THE IMPORTANCE OF ASSESSMENT

The basis of an effective plan of care lies in an accurate holistic assessment to establish the aetiology of the wound. It is important that the cause of the wound is identified and steps are put in place to address the cause (e.g. use of compression therapy to reverse venous hypertension and treat a venous leg ulcer). The assessment should identify any patient factors that may impact on wound healing, and these must be addressed where possible.

The NWCSP supported clinicians in undertaking wound assessments with the publication of a minimum data set (MDS; Coleman et al, 2017). The MDS was developed to support implementation of the CQUIN, subject to a national quality improvement programme (NHS England, 2016). Undertaking a full wound assessment is necessary to identify treatment objectives and select the optimum wound dressing.

DRESSING SELECTION

Following holistic assessment — along with identifying and treating underlying aetiology and risk factors – the next important consideration would be the choice of a suitable wound management product. We have long known the characteristics required for an ideal dressing, which include aspects such as ease of application, conformability, patient comfort, removal without trauma, change frequency and cost-effectiveness (Dale, 1997).

Wound contact layers capable of transferring the exudate to a more absorbent secondary dressing are often overlooked in wound care in favour of one-piece, or composite, dressings. However, most

of these dressings have a maximum wear time of 7 days, whereas some silicone wound contact layers have a wear time of 14 days. Allowing the wound contact layer to remain in place for an extended period, even when the secondary dressing is changed more frequently, means that disturbance to the wound bed can be minimised and this approach may also be more cost-effective.

From a patient's perspective, pain is often a main concern (Mudge and Orsted, 2010). There are several reasons why pain may occur, one of which is procedural pain – e.g. pain relating to inappropriate dressing selection, dressing change, or wound cleansing (WUWHS, 2004). This may lead to fear of dressing change, and 'anticipatory pain', which may affect patient quality of life and their adherence to treatment (Woo, 2012), so it is essential to consider ways of minimising pain when choosing the correct dressing for the patient and their wound.

Wound contact layers provide an interface between the wound and the secondary dressing, protecting fragile healing tissue and helping to reduce pain by preventing new epithelial tissue from sticking to the dressing, while allowing exudate to pass through for absorption into a secondary dressing (Wound Source, 2021). Most wound contact layers are non-adherent; silicone wound contact layers provide some light adherence to the periwound area, but the gentle silicone loses its adhesiveness over the moist area of the wound. This provides a primary dressing that protects the wound bed, allows removal of exudate away from the wound surface into an absorbent secondary dressing, and allows pain-free atraumatic removal.

KLINIDERM SILICONE WOUND CONTACT LAYER

Kliniderm silicone wound contact layer consists of a polyurethane film coated with a soft silicone layer. Its porous structure allows exudate to pass easily into an outer absorbent dressing, such as a Kliniderm superabsorbent. The gentle silicone adhesive should minimise the risk of pain on removal and damage to the wound bed. To aid handling of the dressing, only the wound contact side of the dressing is coated with silicone, which also prevents the secondary dressing from sticking, thus allowing the secondary dressing to be changed separately. As Kliniderm silicone wound contact layer has a wear time of up to 14 days, this means that the secondary dressing if soiled can be changed without disturbing the primary dressing. Furthermore, the contact layer is transparent, allowing the wound to be monitored easily without removal.

Kliniderm silicone wound contact layer is considered suitable for most acute and chronic wound types, including skin tears, traumatic wounds, cuts, abrasions, lacerations, blisters, superficial and partial-thickness burns, surgical wounds, pressure ulcers, diabetic foot ulcers and leg ulcers. It can also be used as a wound protective layer on non-exuding wounds and on areas with fragile skin.

All wound types suitable to be dressed with the Kliniderm silicone wound contact layer were considered for inclusion in the evaluation.

AIMS OF THE EVALUATION

The aims of the evaluation of Kliniderm silicone wound contact layer were to consider:

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

Therefore, considering some of 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. It was also considered a suitable dressing for use on the different wound aetiologies included in the evaluation.

Before gaining consent for the evaluation, all patients had a full wound assessment following the National Wound Care Strategy Programme minimum data set for wound assessment, to ensure suitability for inclusion (Coleman et al, 2017).

Box 1. Inclusion and exclusion criteria

Inclusion criteria

- Wound suitable for inclusion as per product indication
- Over 18 years of age
- Signed informed consent

Exclusion criteria

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

Box 2. Evaluation criteria

1. Patient comfort on application
2. Ease of application
3. Conformability
4. Fluid transfer to secondary dressing
5. Ability to stay in place
6. Ease of removal
7. Patient comfort on removal
8. Wound condition
9. Periwound condition
10. Wear time

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, supplying 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 refused to take 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, which were completed at each dressing change. 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 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 primary care. The evaluation included different wound aetiologies *(Figure 1)*, including 11 (52%) leg ulcers of venous, or mixed venous and arterial disease (all were in full or reduced compression therapy as appropriate to treat the venous hypertension); three (14%) diabetic foot ulcers (DFUs); and six (29%) trauma wounds, which included one to the elbow, one to the foot and four to the leg. There was also one (5%) malignant wound included in the evaluation. Six male and 15 female patients took part in the evaluation, with an average age of 83; although the age range was 49–102, nearly 50% of patients were aged 90 years and above.

The wound duration category recorded five (24%) in the 0–4 week range and four (19%) in each of the other ranges. All but one of the eight patients in the ranges 6-months–1-year and 1-year plus were patients with leg ulcers, wounds known for their risks

Figure 1. Wound types included in the evaluation

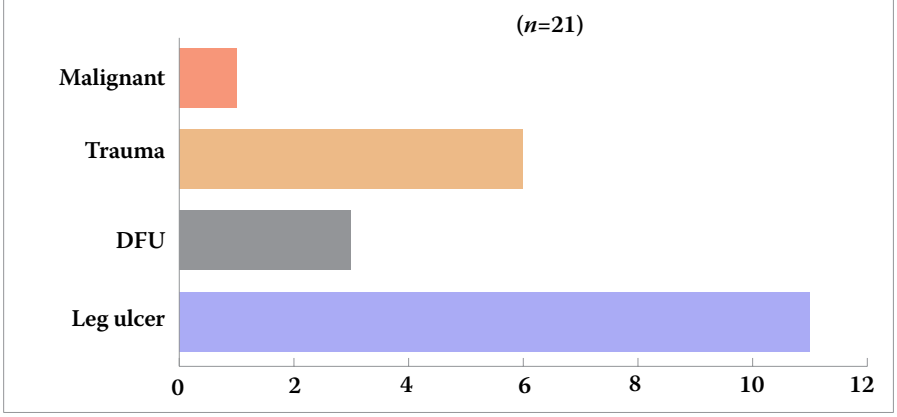


Figure 2. Wound duration

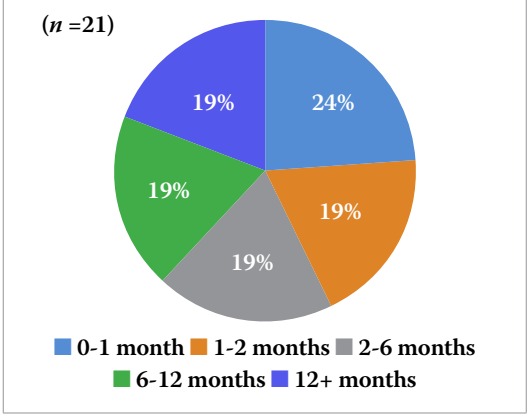


Figure 3. Wound and periwound condition

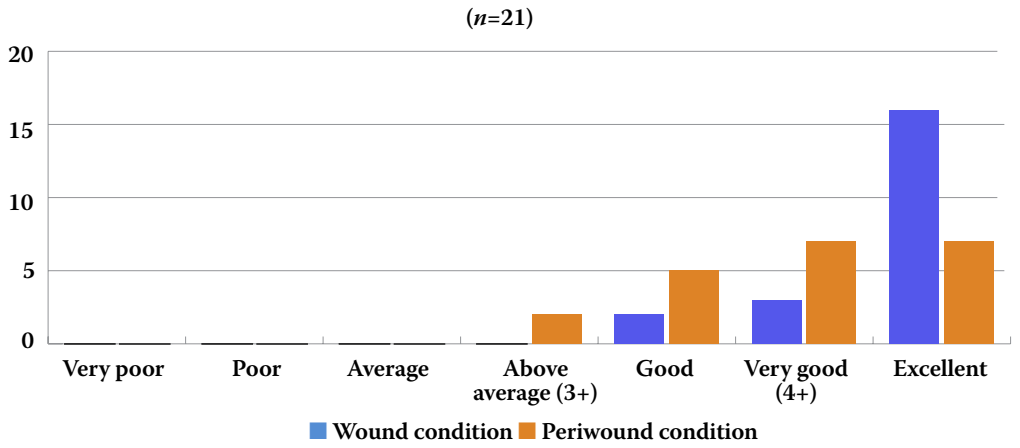
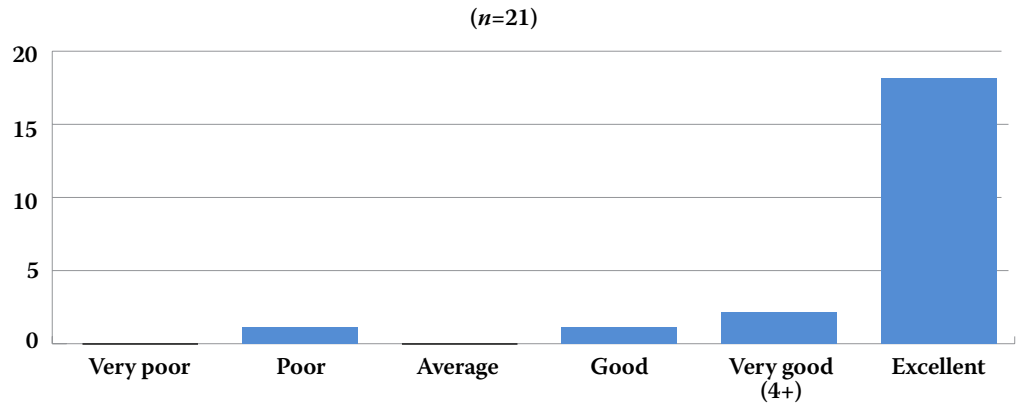


Figure 4. Comfort on removal



of chronicity; the other wound in this range was a DFU *(Figure 2)*.

In terms of wound size, 12 of the wounds were recorded as <10cm^2 and the remaining nine were recorded as 10–25cm^2. There were no wounds greater than 25cm^2 and there were no cavity wounds included in the evaluation.

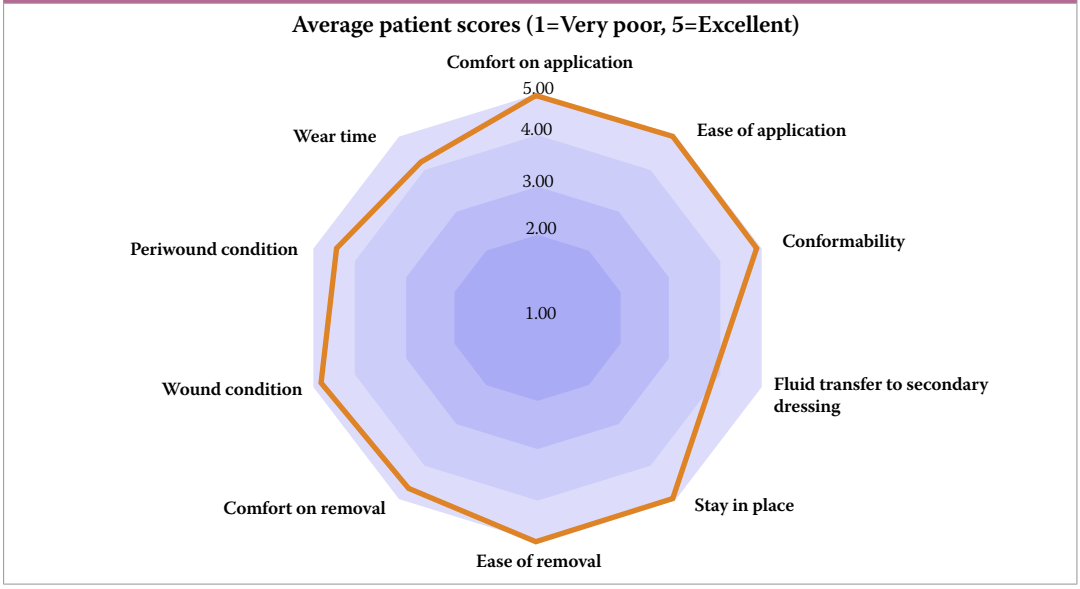
Exudate levels were recorded as either light (16 = 81%) or moderate (4 = 19%); no wounds were reported as being dry or having heavy levels of exudate. Data were not completed in this category for one patient.

Overall, Kliniderm silicone wound contact layer scored highly across all the parameters evaluated. For comfort on application, ease of application, conformability, ability to stay in place, ease of removal, and condition of the wound and periwound *(Figure 3)*, the majority recorded the highest score of 5 (excellent) with a score of 4 for the remaining patients. In the category of fluid transfer, a range of scores from 3.5 to 5 were recorded. In the category of patient comfort on removal, the majority of scores were between 4 and 5, with one patient scoring the dressing at 2 (poor'; *Figure 4*). For the periwound area and wear time, a range of mainly 4 and above was recorded, apart from one recording of 3 in each of these categories. For more information on the overall average scores, see *Figure 5*.

DISCUSSION

Kliniderm silicone wound contact layer was found to meet many of the characteristics of an 'ideal' dressing — particularly in terms of comfort on application, ease of removal and patient comfort during the wear time of the dressing, which are all

Figure 5. Average patient scores



important from a patient perspective. From the clinician's perspective, these are also important; the ease of application and conformability may also help to avoid waste.

In three patients, fluid transfer to the secondary dressing was rated in the average range. Two of these were recorded as only having light levels of exudate, and for the same patients the periwound and wound condition was rated as 4 or 5 (good or excellent).

The one patient who scored a 2 (poor) for dressing comfort was someone with a trauma wound, so some of the pain may have been related to the injury, and the type of discomfort was not recorded as part of this evaluation.

CONCLUSIONS

In managing wounds where the focus is on reducing the risk of trauma and pain at dressing change, and also disturbing the wound dressing as infrequently as possible, a silicone wound contact layer would appear to be a suitable choice. Kliniderm silicone wound contact layer was demonstrated to be a suitable dressing for the majority of wounds included in this evaluation. The dressing was rated above average on all parameters, and the performance of the dressing was also rated highly by the clinicians undertaking the evaluations. WUK

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Evaluation of Kliniderm Silicone Wound Contact Layer on patient with T-Cell lymphoma being treated with total skin electron beam therapy.

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Introduction

74 year old female, known T-Cell Lymphoma. She had been treated with total skin electron beam therapy resulting in erythrodermic and cracked peeling skin predominantly affecting the inner arms the back of her legs and trunk. She had been an inpatient due to her ongoing treatment but was readmitted due to the radiotherapy reactions to the medical assessment unit and referral was made to tissue viability and palliative care for assessment of wounds.

1st Assessment

Patient had extensive radiotherapy reactions to inner arms, back of legs and trunk. She was in severe pain and required sedation before assessment and dressing of wounds could begin. We were concerned due to the overall condition of her skin and required a non adherent flexible dressing that would prevent further trauma. Due to the nature of the wounds and the risk of infection Flamazine was used under the primary dressing, the dressing chosen was Kliniderm Silicone Contact Layer to ensure dressings would not adhere to raw areas and any exudate could pass through to prevent any maceration and potential deterioration to extremely friable skin, burns gauze was used as secondary dressing. Dressing changes were initially needed daily.

2nd Assessment

4 days later we reassessed wound which had been changed daily by ward staff following our care plan, the skin was improving and patient no longer required sedation. Wounds to the back of her legs and inner arms had reduced in size by approximately 50% and epithelisation was evident, improvement in the wound bed was also seen on the trunk. Patient did not experience any pain whilst wearing the dressing and they were easily removed causing no further discomfort for the patient. Dressing changes reduced to alternate days.

3rd Assessment

A further 2 dressing changes (4 days later) patient was reassessed. Reduction by approximately 80% seen on trunk and inner arms and backs of legs had healed. Patient very happy with dressing and felt no discomfort during dressing changes. Continued with alternate days due to areas being dressed and difficulty keeping dressings in situ.

4th assessment

At 6th dressing change (3 days later) patient was reassessed by tissue viability. Patient's wounds had fully healed.

Conclusion

Kliniderm Silicone Contact Layer was used as primary dressing for a total of 11 days. The dressing did not cause any trauma or adhere to any fragile skin, was found comfortable to wear by patient and was very easily removed on dressing change. The number of dressing changes were able to be reduced within the first 4 days, they were then kept at alternate days due to the position of the wounds and the limitations of keeping any dressings in situ on these areas. Kliniderm Silicone Contact Layer did not cause any maceration and handled the transfer of exudate well.