A 60 patient observational evaluation of the clinical benefits and acceptance of a silicone foam dressing for formulary inclusion within 5 NHS sites in the UK

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Introduction

Managing wound exudate, delicate tissue and preventing pain and trauma at dressing change can be challenging and confusing with the plethora of dressing materials available ranging from gauze, traditional foam, silicone backed foam, hydrofibre and superabsorbent materials. Key considerations include wound exudate type, consistency and volume, the fragility of the wound bed, tissue graft and surrounding skin to prevent additional tissue trauma. In circumstances such as post skin grafting, burn injury, where friable tissue is present or when a patient experiences severe pain during dressing change or has Chronic Regional Pain Syndrome (CRPS) a silicone backed dressing is often recommended and is widely documented within the literature as being first line product choice. The evaluations reported below are part one of the NHS Trust potential formulary inclusion evaluations to explore the clinical effectiveness and patient acceptability a silicone foam dressing prior to undertaking a potential cost saving analysis.

Method

Five centres within England and Scotland independently agreed to evaluate an available silicone foam dressing range for potential formulary inclusion. The aim being to explore clinical effectiveness in terms of exudate handling ability, conformability, ease of application and removal, patient comfort rating and clinician acceptance rating.

Each centre received an evaluation initiation visit consisting of product range and data capture training. Local guidelines were followed at each site for approval to conduct potential formulary listing evaluation and informed consent was obtained from each participating patient. Adverse event reporting and patient withdrawal instructions were given.

Results

A total of 60 patients were evaluated across the 5 sites, (55%) female, (42%) male (3%) gender not stated, age range 37-100 years with an average recorded age of 68 years. A variety of wound types were recruited including trauma/complicated surgical combined (72%), pressure ulcers (10%), burn/graft/donor combined (10%) and (8%) reported as other.

A total of 206 dressing changes were recorded with an average of 3.4 changes evaluated per patient.

Exudate levels recorded as (61%) Light, (30%) Moderate and (9%) Zero exudate.

Exudate management 175 responses (135) very good, (37) good, (2) average, (1) poor and (0) very poor (83%) rated in good and very good.

Conformability to the wound 197 responses (146) very good, (40) good, (7) average, (1) poor and (3) very poor (90%) rated in good and very good.

Patient comfort a total of 194 responses (160) very good, (32) good, (1) average, (1) poor and (0) very poor compared to previously experienced dressing products (93%) rated in good and very good.

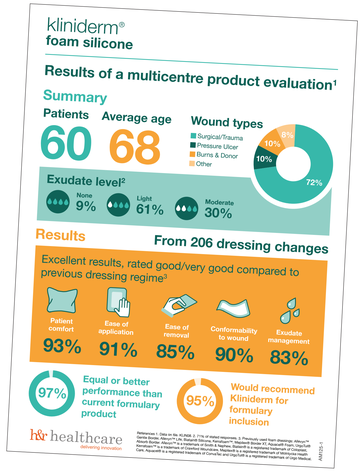
Ease of use application 194 responses (156) very good, (31) good, (6) average, (0) poor and (1) very poor (91%) rated in good and very good.

Ease of use removal 183 responses (141) very good, (35) good, (7) average, (0) poor and (0) very poor (85%) rated in good and very good.

No adverse events or patient withdrawals were reported.

97% of clinicians rated product performance equal to or better than current formulary listed or previously used product and 95% stated yes that they recommended the product for future formulary listing.

Positive patient and clinician feedback statements were recorded.



Cost effectiveness: A retrospective unit volume cost analysis to gauge potential cost benefits. One dressing size (10x10) was explored and the annual spend reduction if switched from current product to Kliniderm foam silicone offered a potential unit cost saving of £27,521[1].

Kliniderm foam silicone is a cost-effective alternative to other silicone dressings and has the potential to save up to 29% on silicone dressing spend when compared to other market leading brands[2]. This could result in significant cost savings for organisations[1].

Kliniderm foam silicone dressing has been successfully formulary listed in each evaluating centre and perspective cost savings reporting is ongoing.

Discussion/Summary

The results are positive with ease of application rated (91%) good and very good, conformability to the wound (90%) good and very good, exudate management (83%) good and very good, patient comfort (93%) good and very good and ease of removal (85%) good and very good.

Some data was not completed and are only representative of 175-197 responses in parts of the reporting of the total 206 dressing changes recorded.

A limitation to this data is that it would have further benefitted from data capture on wound bed condition, peri wound skin assessment, pain score and QoL to further validate the clinical benefits and aid the cost analysis moving forward in light that (95%) of evaluators wished to take it to next stage of formulary consideration.

The evaluation product has been retrospectively contrasted and compared to (73%) foam or silicone foam dressings and (27%) hydrofibre or superabsorbent type dressings creating some variability in expectations, results and feedback. However (97%) rated as equal to or better than previously used dressing.

Conclusion

The results of these silicone foam evaluations are favourable in terms of clinical use and effectiveness but would benefit from additional work further exploring the value of silicone in reduction of pain and trauma. Clinical cost benefit pilot analysis identified significant financial savings of 29% based on dressing unit cost and has resulted in successful formulary inclusion in all evaluators Trusts.

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2. Drug Tariff (2020) Prices correct from November 2020, based on 10 x 10cm dressing

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foam silicone

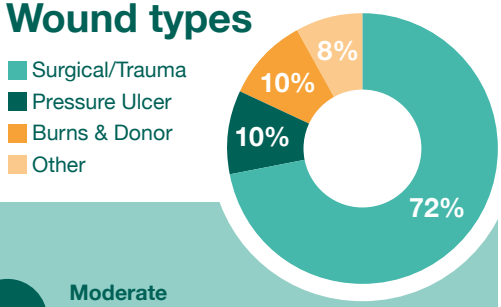
Results of a multicentre product evaluation[1]

Summary

Patients
60

Average age
68

Wound types



Exudate level[2]

None 9%

Light 61%

Moderate 30%

Results

From 206 dressing changes

Excellent results, rated good/very good compared to previous dressing regime[3]

Patient comfort	Ease of application	Ease of removal	Conformability to wound	Exudate management
93%	91%	85%	90%	83%

Equal or better performance than current formulary product

Would recommend Kliniderm for formulary inclusion

h&r healthcare
delivering innovation

References 1. Data on file. KLIN08. 2. 71% of stated responses. 3. Previously used foam dressings: Allevyn™ Gentle Border, Allevyn™ Life, Biatain® Silicone, Kerrafoam™, Mepilex® Border XT, Aquacel® Foam, UrgoTul® Absorb Border. Allevyn™ is a trademark of Smith & Nephew, Biatain® is a registered trademark of Coloplast, Kerrafoam™ is a trademark of Crawford Woundcare, Mepilex® is a registered trademark of Molnlycke Health Care, Aquacel® is a registered trademark of ConvaTec and UrgoTul® is a registered trademark of Urgo Medical.

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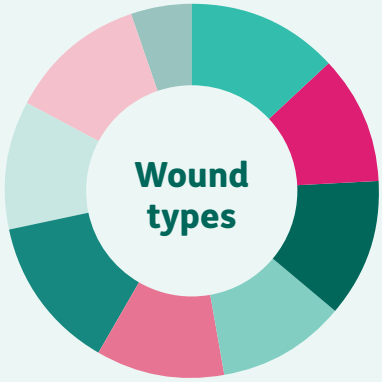
foam silicone

Results of a 469 patient Post-Market Clinical Follow-up (PMCF)[1]

This evaluation was conducted to rate **Kliniderm foam silicone** dressings performance and effectiveness in managing exudate, exudate retention and atraumatic dressing changes from **73** healthcare professionals, for **469** patients in clinical practice over a **5** month period.

469
patients



- Pressure ulcers = **66** (13%)
- Venous leg ulcers = **59** (11%)
- Diabetic foot ulcers = **50** (12%)
- Traumatic wounds = **54** (11%)
- Skin tears = **50** (11%)
- Post-operative wounds = **63** (13%)
- Donor sites = **50** (11%)
- Burns = **55** (12%)
- Other = **22** (5%)

Results

EXCEPTIONAL clinical results from a **469** patient PMCF study. Satisfaction rating:

98%
Exudate management

98%
Atraumatic dressing changes

100%
Ease of application

100%
Ease of removal

Conclusion

The results of this evalutation are favourable in terms of clinical use, clinical effectiveness, and patient satisfaction. **Kliniderm foam silicone** dressings are safe and effective for use in the management of chronic and acute wounds.

PMCF studies are vital in the ongoing medical device regulatory compliance in Europe, to identify the potential for residual risks of a CE/UKCA marked device, and to collect data and gain clarity regarding the long-term clinical performance of the product.

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Data on file. KLIN015. User survey report as part of Post Market Clinical Follow-up (PMCF) of Kliniderm foam silicone dressings, 2022.

BJN
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A soft silicone foam dressing that aids healing and comfort in oncology care

Susy Pramod

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A soft silicone foam dressing that aids healing and comfort in oncology care

Susy Pramod

ABSTRACT

Maintaining skin integrity plays a key role in the ongoing care and comfort of patients at the end of life. Unfortunately, patients receiving cancer treatments are at higher risk of altered skin integrity. Cancer treatments involve multiple modalities, all of which impair wound healing. Excess exudate can be distressing to patients, resulting in catastrophic damage to the wound bed and surrounding skin, reducing quality of life and increasing the need for specialist services. This article describes the use of the Kliniderm foam silicone range of dressings, in combination with best practice, in the treatment of wounds in the oncology setting. The case study evidence presented indicates that this range of dressings is useful in the management of radiotherapy and oncology wounds. It had a positive effect on the exudate level, wound-association pain and the peri-wound skin in these patients, aiding the management of the wound bed.

Key words: Oncology ■ Holistic wound management ■ Quality of life ■ Healing ■ Exudate ■ Soft silicone foam dressing

This is the first of a two-part series on the Kliniderm range of dressings. Both articles illustrate its use in the oncology setting: this article explores the ability of Kliniderm foam silicone to absorb exudate and promote healing; the second article demonstrates that Kliniderm foam silicone lite can prevent medical device-related pressure ulceration

Patients with cancer can experience skin damage or breakdown due to the effects of radiation, chemotherapy, malnutrition and disease progression (Payne et al 2008). Unfortunately, these patients often have several symptoms, such as lymphoedema, nausea, vomiting, fatigue, malnutrition, fungating wounds and psychological issues, that are secondary to their disease and can impair tissue repair. Coupled with the intensity of many cancer treatments, this can make wound management a challenging, long-term issue for these patients, whose lives can be severely affected (O'Regan, 2007).

Cancer can give rise to multiple skin lesions or fungating wounds (O'Regan, 2007). In addition, radiation-induced damage to the epithelium can result in skin breakdown, lower tensile strength, atypical fibroblasts and delayed healing (Anderson and Hamm, 2012). As such, radiotherapy can both impede wound healing and breach skin integrity. Chemotherapy can also cause significant wound-related problems. Administration of specific chemotherapeutic agents can result in an inflammatory reaction in tissue that has been previously irradiated (O'Regan, 2007).

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The main effects of a chemotherapeutic drug on wound healing include delayed inflammation, decreased fibrin deposition and collagen synthesis, and delayed wound contraction (Anderson and Hamm, 2012).

Patients with cancer who are experiencing nausea and vomiting can quite quickly become dehydrated and malnourished. Dehydration also adversely affects optimum wound healing by disturbing cellular metabolism and reducing circulatory blood volume. Malnourished patients are at risk of wound infection due to an impaired immune response (O'Regan, 2007).

For many oncology patients, the overall aim of wound management is to achieve wound closure, where possible. However, for a patient with a malignant wound, symptom control is more likely to be important, along with containment of exudate, or the formation of a crust or scab without exudation (World Union of Wound Healing Societies (WUWHS), 2019).

A holistic assessment is essential to determine the cause of the wound and the interventions needed to aid healing. In patients with cancer, the wound aetiology, their age and the presence of significant comorbidities can all affect the healing process, as will the wound size and depth, duration and location (Vowden, 2011). Health professionals must consider all aspects of wound care to avoid these patients further suffering. This article describes how this can be achieved, and outlines the potential role of a soft silicone foam dressing as part of this regimen of care.

Exudate and oncology wounds

Wounds in patients undergoing cancer treatment often produce moderate to high volumes of exudate.

Wound exudate contains serum, leucocytes, fibrin and wound debris, along with water, nutrients, electrolytes, inflammatory mediators, other white blood cells, protein-digesting enzymes and growth factors (WUWHS, 2019). Acute wound exudate is thought to have antibacterial and nutrient properties.

Exudate assessment and management are a vital part of wound care. Exudate is produced throughout the healing process, from the inflammatory phase to epithelialisation, and must be managed to maintain the moist environment that promotes and accelerates healing (Collins et al, 2002; Bullough et al, 2015). According to Swezey (2014), a moist environment can improve the healing rate by up to two or three-fold. The benefits of moist wound healing are summarised in *Box 1*.

Because it is rich in leucocytes and essential nutrients, acute wound fluid supports stimulation of fibroblast formation

and endothelial cells production (Dowsett, 2008). However, excess exudate is implicated in the damage to the wound bed, degradation of the extracellular matrix and peri-wound skin problems observed in chronic wounds (Hampton and Verral, 2013).

The aim, therefore, is to maintain a moisture balance in the wound, which can promote healing. However, this can be challenging, because exudate levels change throughout the healing process (Davies, 2012). Effective exudate control is therefore an essential requirement of wound management (Forder and Burns, 2020).

Fungating wounds are a potentially devastating complication of advanced cancer (Grocott, 2007). The high levels of exudate associated with these wounds can cause significant quality-of-life issues for patients and be extremely challenging for health professionals to manage (Verdon, 2015). Symptom control is the primary goal of their management. Holistic assessment of both the patient and wound can support this (Verdon, 2015). The management of malignant fungating wounds is complex, requiring a multidisciplinary approach (Dowsett, 2002).

Skin reactions to radiotherapy can vary from mild, such as dry skin, to slight erythema, to moist desquamation. The care of moist desquamation skin reactions is based on the principles of moist wound healing (O'Regan, 2007).

Wound assessment and management in the oncology setting

For patients at the end of life, palliative care often involves wound care (Young, 2017). As with any wound, the underlying cause needs to be identified; consideration also needs to be given to any current treatments, such as radiotherapy, that might affect the type of dressing that can be used and the dressing-change frequency. Other considerations are the wound location, which will affect both dressing application and the patient's body image, and whether necrotic tissue and excess exudate are present, as these are conducive to bacterial proliferation and will increase the risk of malodour and wound infection.

Good wound management involves a holistic approach (Davies, 2012). Dowsett and Newton (2005) argued that the concepts of wound bed preparation (WBP) and TIME (Schultz et al, 2003) must be considered in the context of holistic patient assessment, accurate diagnosis and ongoing evaluation of the outcomes of treatment interventions. Health professionals must ensure that the management plan aims to provide the best outcome for both the patient and the wound (Grothier, 2013). Effective management therefore involves managing the underlying cause of the wound, where possible, as well as product selection (Bullough et al, 2015).

In 2019, Atkin et al introduced a modified version of the TIME paradigm (TIMERS) (*Box 2*). This provides structured guidance for the management of complex, non-healing wounds, including when to consider using advanced therapies alongside standard care. Here, T is for Tissue, which focuses on the presence of devitalised or non-viable tissue, which can delay healing and/or facilitate infection. The clinical requirement is to observe for its presence and the goal is to eliminate it (Atkin et al, 2019). I is Inflammation and Infection, which pose a major challenge to healing, particularly in chronic wounds (Leaper et al, 2012). M is for managing bioburden, in particular biofilm (Wounds UK, 2017) and creating a moisture-balanced environment that promotes healing. E is for the wound Edges, which should be assessed for the need for debridement, and the use of therapies to accelerate re-Epithelialisation (Atkin, 2019). The R aims to promote tissue Regeneration and Repair, supporting wound closure (Atkin et al, 2019). The S relates to Social and patient factors, in recognition that patient engagement increases the likelihood of concordance and healing. Asking the patient about their treatment goals and what aspects of the treatment plan they are willing or able to implement will not only help ensure they receive the right information and have access to the appropriate services, but also is more likely to increase their knowledge and confidence to make informed decisions about their care (Moore, 2016).

It is also important to try to understand the wound from the patient's perspective and gain an insight into its impact on their life (Atkin et al, 2019). The patient's primary concern is not always the treatment itself, but could be a related issue. To explore the psychological impact of the wound and provide support, it is necessary to develop a relationship with the patient and their family, and gain their trust (Dowsett, 2002).

Box 1. Benefits of a moist healing environment

- Facilitates all aspects of the wound healing phases
- Decreases the extent of the inflammatory response
- Prevents the wound bed from becoming desiccated
- Aids cell migration
- Preserves growth factors

Sources: Cook, 2011; Peate and Glencross, 2015

Box 2. Elements of the TIMERS framework

T	Tissue deficient or non-viable
I	Infection or inflammation
M	Moisture imbalance: too much or too little
E	Edge of wound: undermining or non-advancing
R	Repair of tissue and regeneration
S	Social factors that impact healing

Source: Atkin et al, 2019

Concordance and adherence

Patient choice and involving patients in clinical decision-making are central to the national agenda to improve the patient experience, concordance and thus care outcomes (Department of Health, 2010; Stanton et al, 2016). Concordance places greater emphasis on factors that may not be directly associated with the condition, but might affect a patient's choice of whether or not to follow a treatment plan (Moffatt, 2004). Non-concordance is highly prevalent in oncology settings and is associated with moderate to severe patient distress and with poor quality of life (Chadwani, 2017). The health professional must ensure that their

objectives for the treatment plan are the same as those of the patient; otherwise, a disempowered patient and non-adherence to treatment are the likely outcomes (Weiss and Britten, 2003).

Involving patients in their care is likely to improve their understanding of how their wound might progress towards healing and give them an opportunity to make informed decisions about their management plan (Moore, 2016). The availability of easy-to-understand, accurate information on cancer prognosis, treatment (including its benefits and harms), palliative care, psychosocial support and likelihood of treatment response can improve patient-centred communication and shared decision-making (Chan et al, 2012). This is likely to improve adherence to treatment (Chadwani, 2017).

Dressing selection

Dressing selection should aim to:

- Promote a moist healing environment
- Address any issues within the wound bed and at the wound edges and peri-wound skin
- Identify the least costly dressing that will meet the wound requirements (Jeffcoate et al, 2009).

Foam dressings are generally made from polyurethane that has been heat treated to provide a smooth contact surface. They provide thermal insulation, do not shed fibres or particles, and are gas permeable (Thomas, 2010). They are generally soft, pliable (for conformability) and low adherent. An important function is their ability to absorb exudate and maintain a moist environment (Hedger, 2014).

Soft silicone foam dressings were developed to minimise the problems of pain and trauma at dressing change and to protect the peri-wound skin (Lawton and Langoen, 2009). These dressings are a family of solid silicones, which are 'soft and tacky' (Drewery, 2015). Ideally, a wound dressing should have sufficient tack to stay securely in place for the duration of wear, but able to be removed without skin stripping or trauma to the wound bed (Rippon et al, 2008).

Soft silicone foam dressings adhere gently to the surrounding skin, and are designed to minimise trauma on removal and not leave an adhesive residue on the skin (Meuleneire and Rücknagel, 2013). Several clinical studies have shown that they minimise pain on removal in a range of wound types and patient groups, including paediatric patients (Morris et al, 2009) and patients with burns (Edwards, 2011), heel ulcers (Hampton, 2010) and radiation-induced skin reactions (MacBride et al, 2008). In addition, Timmons et al (2009) found that their use improved patients' quality of life by reducing pain on removal, lessening anxiety and accelerating the healing process. This encouraged the author to evaluate the Kliniderm foam silicone range of dressings in the oncology setting.

Case study 1

A 20-year-old woman with a history of dermoid tumour on her upper left back was treated with chemotherapy and scheduled for proton beam therapy, which is an advanced form of external radiotherapy that uses high-energy proton beams instead of photon X-ray beams or electrons (Cancer.Net, 2018). Her skin integrity was poor due to the enlargement of the tumour, as well as because of the effects of systemic chemotherapy. She presented with multiple areas of skin breakdown at the tumour site. The pain from the weight of the tumour was such that she was using a sling to support her arm.

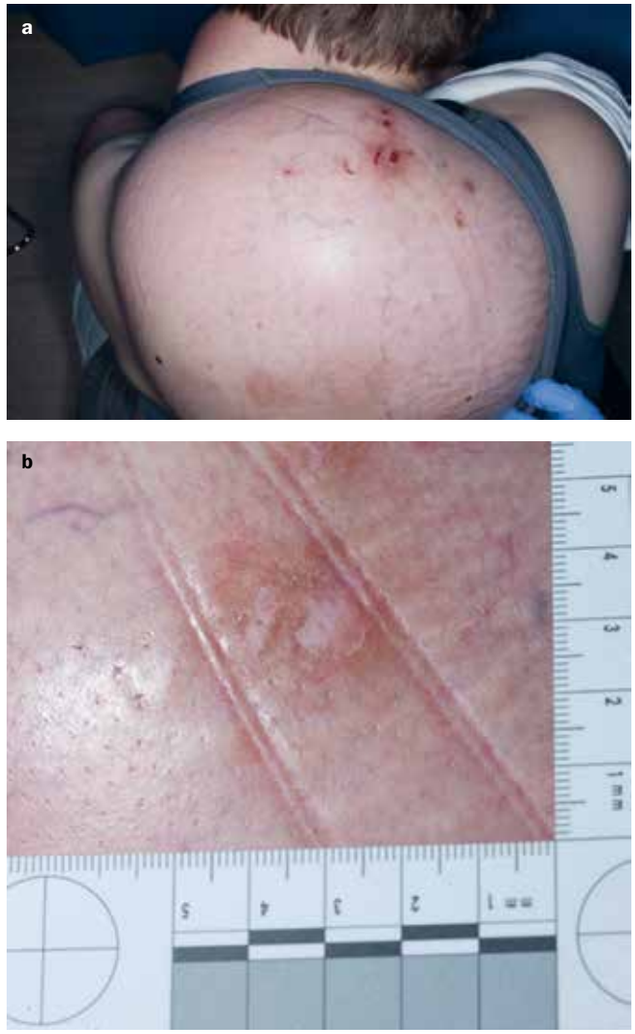

Figure 1. Case study 1: simple, non-advanced wound dressings had been applied previously, but these were ineffective

It was not possible to measure the wound because the skin breakdown was scattered around the upper back, making it difficult to map. The exudate level was low and the wound bed was granulating. The patient had previously tried different types of simple, non-advanced wound dressings, but these were ineffective, with each one being used for one day only (*Figure 1a* and *Figure 1b*).

The patient consented to try Kliniderm foam silicone in the hope that it would prevent the discomfort experienced when the wound rubbed against the sling. Due to the patient's fragile skin, Kliniderm foam silicone lite was used to absorb exudate and promote a moist environment, as well as to provide some pressure relief from the sling rubbing against the tumour.

A 50 x 20 cm dressing was selected, which covered the entire tumour. The patient reported that the dressing was very comfortable, and continued to wear the sling. The soft

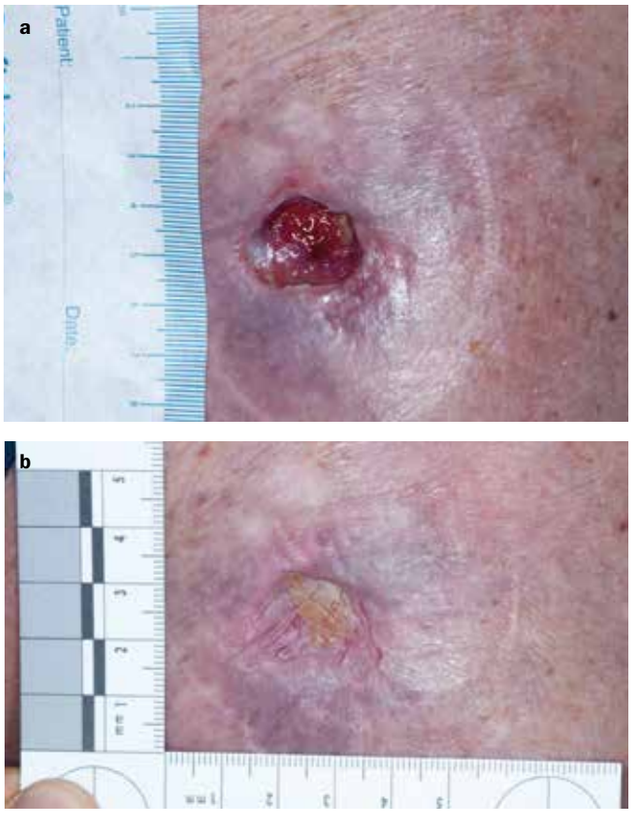

Figure 2. Case study 2: a chronic wound developed on the patient's right hip following radiotherapy. The wound at presentation (a); the wound healed after 4 weeks of treatment with the soft silicone foam dressing (b)

silicone foam dressing was changed twice a week. No other dressing products were used. The wound healed, with full epithelialisation, in 3 weeks, despite the patient receiving multimodal treatments and proton beam therapy.

Case study 2

A 64-year-old man developed a chronic wound on his right hip from radiotherapy for a biopsy-confirmed basal cell carcinoma. He has a history of Hodgkin's lymphoma and cutaneous T-cell lymphoma. Before his referral, the wound had been treated with an antimicrobial dressing, followed by an alginate (for desloughing) and a secondary foam dressing for 4 weeks. By the time the patient presented at the clinic, the wound was 2 months old and was deep (because the large, thickened tumour had broken down) and sloughy.

The patient found it extremely painful when the wound area was touched (self-reported pain score: 9/10), making it difficult to cleanse and dress. The wound measured 2 x 1.8 cm (length x width) (*Figure 2a*) and was producing a moderate volume of exudate, but there was evidence of granulation tissue.

Kliniderm foam silicone border was applied to provide a moist environment and absorb the exudate. No other dressings were used. The dressing was changed twice weekly.

The wound healed within 4 weeks *(Figure 2b)*. The patient reported that the peri-wound pain reduced with each week. The dressing was easy to apply and remove without causing any trauma. It conformed to the wound, avoided epithelial stripping and was comfortable during wear (Hampton, 2010; Meuleneire and Rücknagel, 2013). The patient commented that he was able to change the dressing by himself. It managed the exudate well, which improved his quality of life.

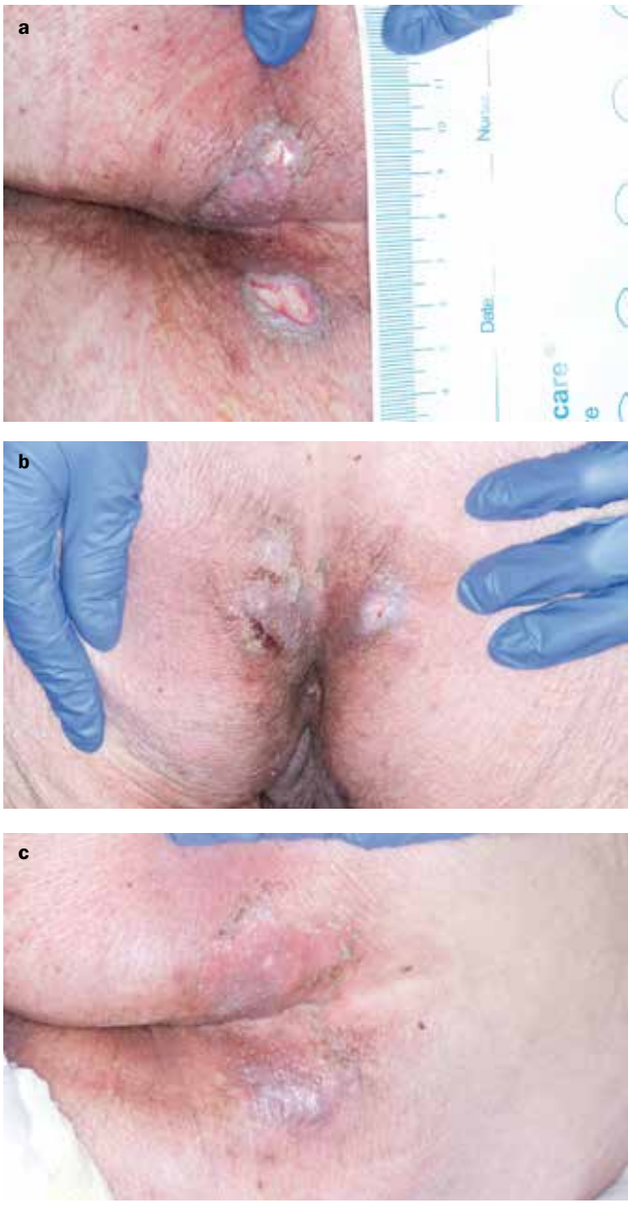

Figure 3. Case study 3: the pressure ulcers at presentation in a patient with metastatic endometrial cancer (a); the ulcers after 1 week, when the honey dressing was discontinued (b); healing occurred after 3 weeks of treatment with the soft silicone foam dressing (c)

Case study 3

A 68-year-old woman was admitted with neutropenic sepsis of unclear source, anaemia and acute kidney injury. She has a diagnosis of stage 4 endometrial cancer with metastases to the liver. She was undergoing weekly chemotherapy, taking oral steroids, and had oedema and ascites. Subsequently, her skin condition was very poor (*Figure 3* and *Figure 4*).

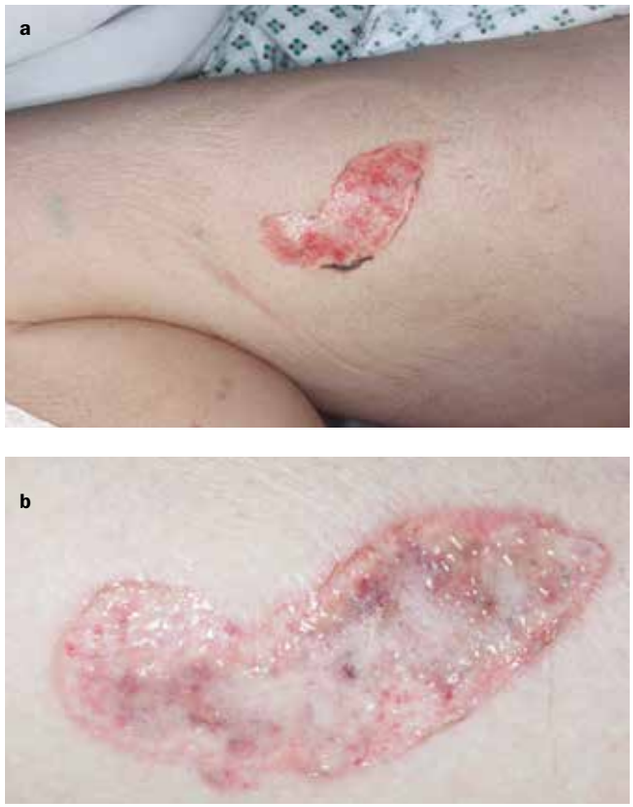

Figure 4. Case study 3: the skin breakdown on the thigh resulting from a reroofed blister caused by fluid overload: the wound at presentation (a); after 3 weeks of treatment with the soft silicone foam dressing, 50% of the wound had healed and the remaining area was epithelialising (b)

The patient presented with two sacral category II pressure ulcers (European Pressure Ulcer Advisory Panel (EPUAP)/National Pressure Ulcer Advisory panel (NPUAP)/National Pressure Injury Advisory Panel (PPPIA), 2019), as well as skin breakdown on her left thigh resulting from a reroofed blister caused by fluid overload. The pressure ulcers measured 2 x 1 cm and 1 x 0.8 cm (*Figure 3a*) and had minimal slough and exudate. The wound on the thigh measured 7 x 3 cm, and was producing a moderate level of exudate, but was also granulating (*Figure 4a*).

Following a wound assessment, Kliniderm foam silicone border was applied to the left thigh to absorb the exudate and promote a moist wound environment. A primary dressing containing 100% manuka honey was used to autolytically debride the pressure ulcer and the Kliniderm foam silicone border to manage the exudate. The honey dressing was discontinued at the end of week 1 because the wound was completely debrided. From thereon, only the soft silicone foam dressing was used to treat the pressure ulcers (*Figure 3b*). As a wound progresses through the healing continuum, health professionals are advised 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).

The range of sizes and shapes for this dressing enabled an appropriate selection for the sacrum. The dressing was used in conjunction with the a SSKINg bundle (NHSI, 2018) prevention strategy. After 3 weeks, the pressure ulcer had fully healed *(Figure 3c)* and 50% of the thigh wound had healed, with the rest epithelialising *(Figure 4b)*.

Conclusion

Good wound management involves a holistic approach to care; without considering the whole person, the wound management might not be as good as it could be. The optimal goal of effective exudate management is containment, protection and healing. This is alongside the promotion and maintenance of patient comfort, safety, quality of life and provision of patient education and collaboration. Selecting the right product every time and creating an optimal wound healing environment by managing wound exudate is paramount. The cases presented here indicate that Kliniderm foam silicone border and Kliniderm foam silicone lite dressings are effective in the management of both acute and chronic wounds and are safe, effective and acceptable to both health professionals and patients. **BJN**

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KEY POINTS

- Treating patients with cancer involves multiple modalities, all of which have a direct impact on wound healing
- Many cancer treatments can make wound management challenging
- Good wound management involves a holistic approach to care that considers the whole person
- Effective exudate control is an essential requirement of wound management
- The Kliniderm foam silicone range of dressings is effective in the management of both acute and chronic wounds. They are safe, effective, and acceptable

NOTES

A Comparison of a Gentle, Absorbent Silicone Foam Wound Dressing with Two Market Leading Products in Terms of Fluid Absorption and Peel Force

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Introduction

Effective management of wound exudate is essential to create the optimal environment for wound healing and to prevent maceration of the surrounding skin[1]. For the treatment of chronic wounds, wound dressings need to perform under compression and also need to be easily removed. This allows for minimal pain and can prevent damage to new epithelial cells[2]. Pain and trauma during removal of a dressing can cause delayed healing and be distressing for the patient[3]. Wound dressings that can effectively manage wound exudate and be easily removed can improve patient experience.

Aims

- To investigate the free swell capacity of Product K* and two market leading products.
- To investigate the fluid absorption capabilities whilst under compression of Product K and two market leading products.
- To determine the amount of force required to peel Product K and two market leading products from porcine skin explants under dry and exuding wound conditions.

Methodology

1. Free swell absorption was measured according to methods adapted from EN 13726[4].
2. Absorption under compression was assessed using a mass equivalent to 40 mmHg using methods adapted from EN 13726[4].
3. The peak force required to remove dressings from porcine skin explants was measured. Dressings were adhered to 100 cm^2 porcine skin explants. Following a 30 minute contact time, the dressing was removed using a digital peak force meter. The peak force required for dressing removal was recorded.
4. The peak force required to remove dressings from porcine skin explants following an introduction of fluid, was also measured. Dressings were adhered to 100 cm^2 explants and incubated overnight. Each day, 2 ml of phosphate buffered saline (PBS) was injected through the underside of the explant in order to mimic an exuding wound (Figure 1). Dressings were removed at 24, 48 and 72 hours using the digital force meter.

Figure 1. A photograph demonstrating phosphate buffered saline being injected into a porcine skin explant prior to peel force assessment.

Results

The average free swell absorption and absorption under compression were comparable for Product K and Market leader B. Market leader A absorbed and retained a greater volume of fluid than Product K or Market leader B (Table 1, Figure 2).

Parameter	Average Solution A absorbed (ml)		
	Product K	**Market leader A**	**Market leader B**
Average free swell absorption	9.44	13.17	7.96
Average absorption under compression	8.80	11.29	8.15

Table 1. Average free swell absorption and absorption under compression of three wound dressings.

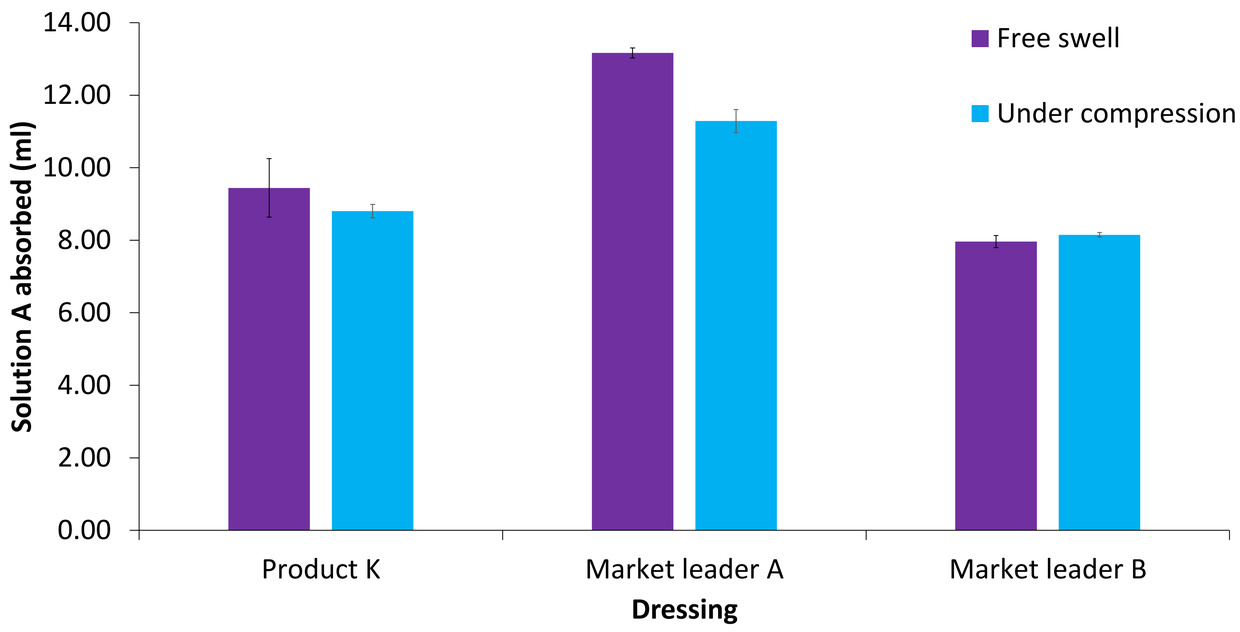

Figure 2. Average free swell absorption and absorption under compression of three wound dressings.

The average peak force required to remove wet and dry dressings from porcine skin explants was comparable for all dressings regardless of the model used; approximately three newtons of force was required to peel each dressing from the porcine skin. This was observed for both the dry and wet porcine models.

Discussion and conclusions

Product K demonstrated equivalence to Market leader B in terms of free swell absorption and fluid absorption under compression. The active area of Product K was smaller than the two market leading dressings suggesting a potentially greater performance per cm^2. Market leader A outperformed Product K and Market leader B in terms of the amount of fluid absorbed in each test condition.

The three test dressings demonstrated equivalence in terms of the amount of force required to remove the dressings from a porcine skin explant. The daily addition of 2 ml PBS did not have a significant effect on the force required to remove the wound dressings.

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* Product K - Kliniderm Foam Silicone. Market leader A - Foam dressing with proprietary adhesive. Market leader B - Foam dressing with silicone gel adhesive.

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A clinical evaluation of 21 patients using Kliniderm foam silicone lite

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.

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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.

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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

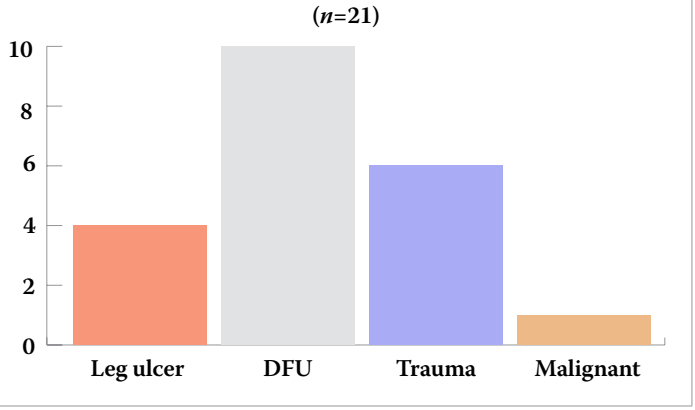


Figure 2. Wound durations

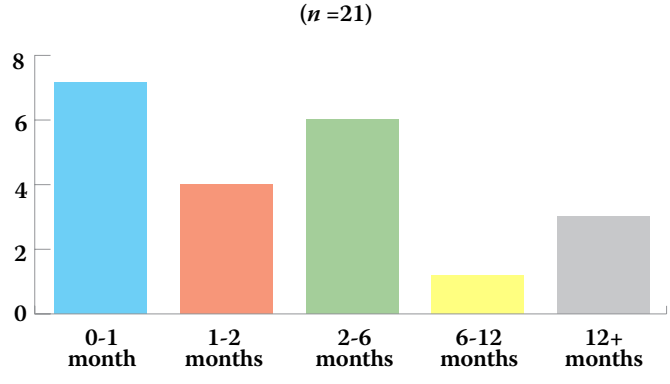


Figure 3. Wound sizes

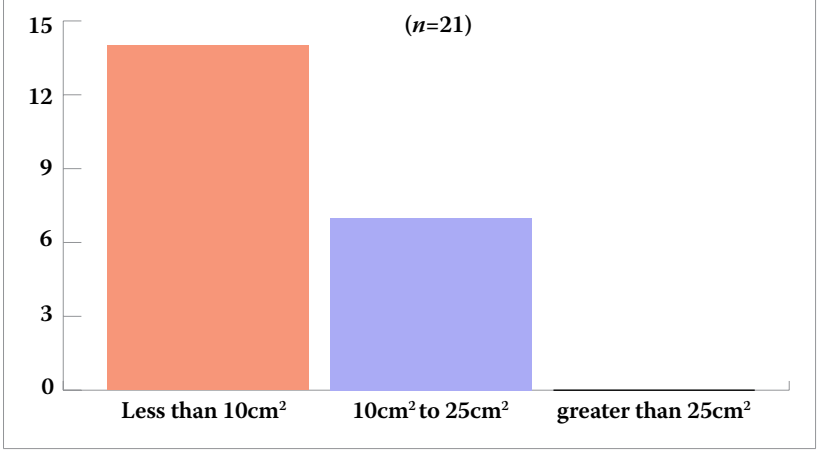
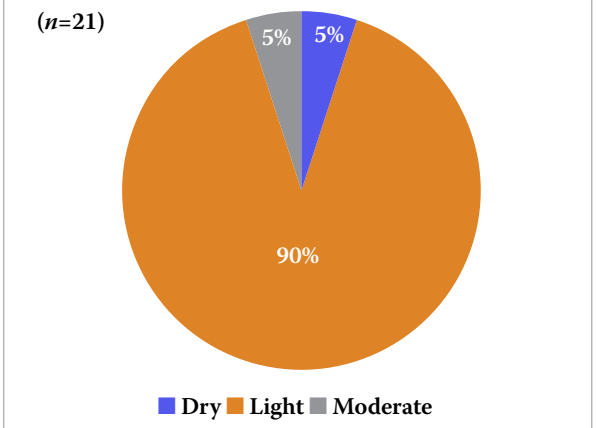


Figure 4. Exudate levels



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	Conformability	Exudate management	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

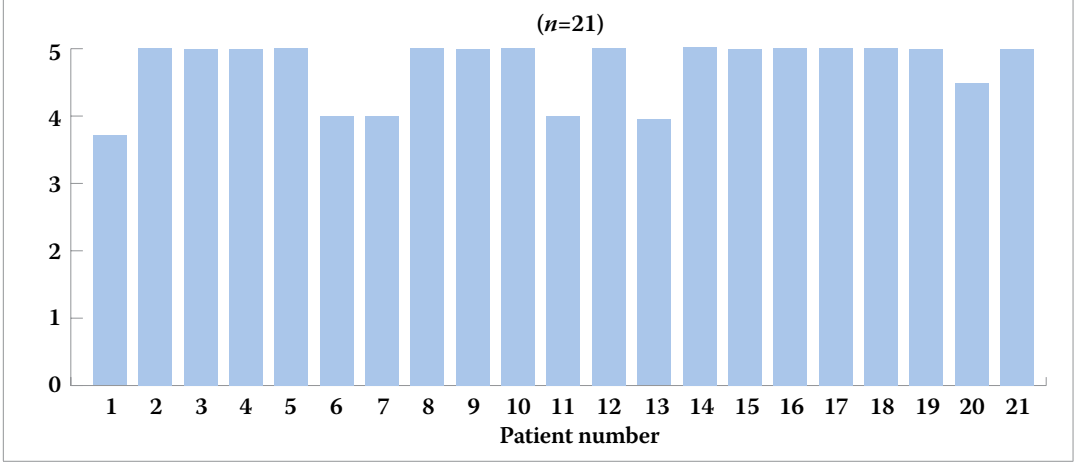
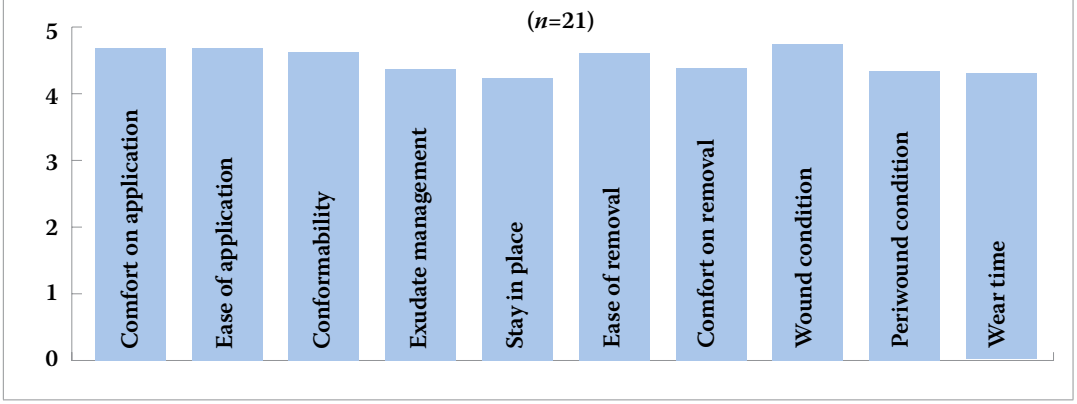


Figure 6. Evaluation criteria



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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An audit of patient outcomes in the management of skin tears using silicone dressings

KEY WORDS

- Nursing homes
- Silicone dressings
- Skin tears
- Wound healing

This article reviews the literature on skin tear (ST) management and presents the results of an audit of silicone dressings in nursing homes. Fifty nursing homes were contacted and asked whether they would like ST training, backed up with a ST audit of their residents. Forty-two teaching sessions took place. The ST training covered the physiology of the skin, ST prevention, risk factors, STAR classification and first aid management. Four silicone dressings were used: Allevyn Gentle Border, Mepilex Border, Advazorb Border and Kliniderm Border. Dressing changes were performed and monitored by the tissue viability nurse consultant on days 1, 3, 7 and 14. Dressing performance in relation to the peri-wound skin, maceration, dermatitis, inflammation, irritation and dryness was evaluated. The amount of exudate was recorded by weighing the dressing after removal. Ease of dressing removal was noted. The analysis found similar age, body mass index, Waterlow scores and Malnutrition Universal Screening Tool scores. The differences in sizes of the STs was not significantly different and they healed within consistent time frames. Healing time increased with ST size and STAR classification. The Advazorb Border dressing was significantly better at staying in place and was removed more easily than the other dressings.

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For the first time in history, there are 11 million people aged 65 or over in the UK and 3 million people aged 80 or over (Office for National Statistics, 2014). The number of people over age 85 in the UK is predicted to double in the next 20 years and nearly treble in the next 30 years (Office for National Statistics, 2013). In the light of these facts, skin tear prevalence can be expected to escalate in line with the ageing population (Carville et al, 2007); therefore a challenge facing clinicians treating the increasing elderly population will undoubtedly be the increase in the number of skin tears.

Skin tears commonly occur in individuals at the extremes of age, or in those who are critically ill or medically compromised and who require assistance with personal care (Carville et al, 2007; Payne and Martin, 1990, 1993). Patients who are dependent on others for total care needs are at the great risk. Frequently, skin tear injuries are linked to the use of wheelchairs, blunt trauma and patient transfers (Banks and Nix, 2006; Le Blanc et al, 2008). Dependent patients frequently acquire skin tears during routine activities, such as washing, dressing, repositioning and transferring, with the second highest at-risk group being independent, mobile patients. The majority of skin tears occur on lower limbs (Le Blanc et al, 2011). Patients within care homes are vulnerable to skin tears. A 2011 audit of 52 care homes with a total of 2,200 patients over a 12-week period identified 49 patients with skin tears (Stephen-Haynes et al, 2011).

The incidence of skin tears is increasing in both the acute and community settings but the actual incidence and cost to the NHS is unknown (Stephen-Haynes et al, 2011). This is because these wounds go largely unreported, especially in the community (Malone et al, 1991; White et al, 1994), where patients may self-treat them at home or be treated by a community nurse or GP. Skin tears are under-reported in healthcare settings due to poor assessment and inadequate

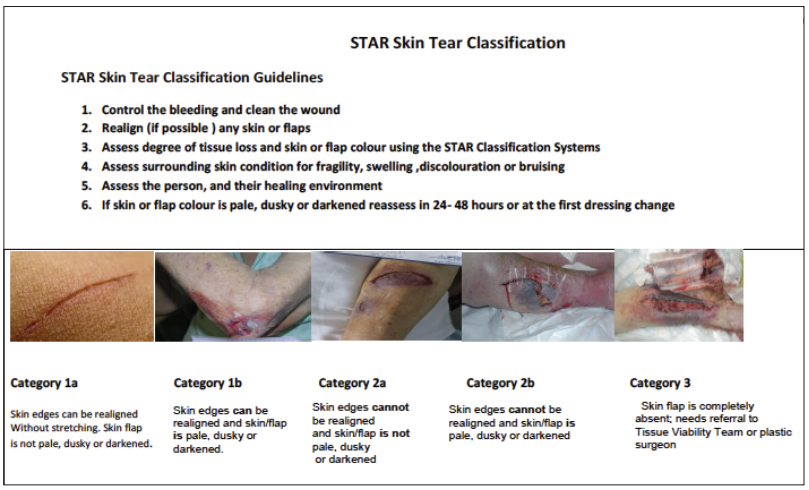

Figure 1. STAR skin care classification cards given to staff to aid in the management of skin tears (adapted from Carville et al, 2007)

management (Le Blanc et al, 2011). They can be complex in the elderly, particularly if the wound becomes infected or if the person has comorbidities that can lead to a delay in wound healing. Patients are often taken to accident and emergency or minor injury units for assessment and may require hospital admission.

SKIN PHYSIOLOGY AND RISK FACTORS FOR SKIN TEARS

Physiological changes to the skin become apparent as ageing progresses. Intact skin is a major part of the body's immune system that provides a mechanical barrier to the ingress of microorganisms and waterproofing with lipids (Butcher and White, 2005). With age, skin tends to thin, have reduced elasticity due to changes in collagen structure, and be increasingly dry due to a reduction in the number of sweat glands and reduced sebum production (Timmons, 2006). In the elderly the propensity for dry skin occurs most often on the lower legs, hands and trunk (Norman, 2003). Natural oils are removed from the skin surface when bathing, which exacerbates the potential for dry skin, particularly in the elderly as natural oil production is diminished; replacement with emollients is therefore essential (Le Blanc and Baranoski, 2009). Using alkaline soaps increases the skin's pH, thus reducing its protective acid mantle (Le Blanc et al, 2008; Le Blanc and Baranoski, 2009). Other influencing factors are the weather, which can dry out the skin in the colder months, and central heating, which dries the air (Le Blanc et al, 2008).

The epidermis and dermis weaken as the papillae lose strength and the skin flattens (Beldon, 2012). This flattening, along with natural thinning of the skin, begins after age 70 and increases skin's susceptibility to moisture and friction (Cooper, 2006), while reducing its resistance to shear forces (Voegell, 2010). The 20% reduction in the thickness of the dermis layer causes a reduction in blood supply, the number of nerve endings and amount of collagen (Baranoski and Ayello, 2004). This results in reduced sensation, poor temperature and moisture control, and rigidity (Cooper, 2006).

Subcutaneous fat is also lost with age and veins become more prominent and easily damaged (Nazarko, 2007). The amount of elastin in the skin is reduced, leading to reduced suppleness and increased risk of injury (Beldon, 2012). Malone et al (1991) identified specific areas of the body where the subcutaneous layer becomes thinner and atrophy and skin tears occur; namely the face, neck and dorsal aspect of hands. The vascular bed becomes more fragile, which can result in bruising that can lead to skin tears (White et al, 1994). Consequently, the smallest knock or bump can result in skin damage (LeBlanc et al, 2011). The very young and very old, the critically ill and end-of-life patients produce immature skin cells, and are thus more susceptible to skin tears (LeBlanc et al, 2011).

An international consensus panel defined skin tears as: "A wound caused by shear, friction and or blunt force resulting in separation of skin layers. A skin tear can be partial thickness (separation of the epidermis from the dermis) or full thickness (separation of both the epidermis and dermis and dermis from underlying structures)" (LeBlanc et al, 2011). The development of taxonomy for skin tear classification began over 20 years ago. The first was the Payne–Martin classification system (1993). In Australia, Carville et al (2007) developed the STAR classification for skin tears:

- S: Select appropriate dressing
- T: Tissue alignment
- A: Assess
- R: Review and reassess.

The audit by Stephen Haynes et al (2011) proved the STAR classification to be easy to use

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and helped in the development of guidelines to standardise timely and appropriate care. The STAR acronym enables appropriate assessment and treatment of skin tears (Stephen-Haynes and Carville, 2011).

SILICONE DRESSINGS

Current best practice dictates that skin tears should be managed by providing comfortable and appropriate dressings to maintain an optimal wound environment that does not create trauma on removal. Soft silicone dressings reduce damage to the skin surrounding pressure ulcers and decrease the maceration and trauma associated with dressing change (Meaume et al, 2003). These types of dressings protect vulnerable and fragile skin, minimising friction and shear (Meuleneire and Rucknagel, 2013).

Silicones are synthetic compounds that take the form of oils, rubbers or resins (Meuleneire and Rucknagel, 2013). Soft silicone is hydrophobic and is made malleable and 'tacky' so that it lies on the surface of the wound bed, while only adhering to the dry skin and leaving the bed wound free from damage. This makes silicone dressings ideal for fragile skin. The silicone is designed to protect the wound bed and be non-traumatic on removal, but allows the passage of exudate (Meuleneire and Rucknagel, 2013).

AIM AND OBJECTIVES

The aim of the audit was to determine the clinical efficacy and cost-effectiveness of four silicone dressings (Advazorb Border, Allevyn Gentle Border, Mepilex Border and Kliniderm Border) in 80 patients' wounds in the nursing home setting. The primary objective was to determine whether there was any difference between the four silicone dressings in absorbing exudate, improving the peri-wound skin and reducing the frequency of dressing change. How much the exudate weighed on dressing removal was also measured. The secondary objectives were to evaluate:

- Odour, infection and wound healing
- The costs of silicone dressings

METHODOLOGY

The managers of 50 nursing homes were contacted and asked whether they would like to undertake skin tear training, supported by a skin tear audit on their residents. There were 30 nursing homes that participated in the audit. Permission for the audit to take place was obtained from the local tissue viability team and managers from the participating nursing homes. Forty-two teaching sessions took place. The skin tear training was delivered to registered and unregistered staff, and covered the physiology of the skin, skin tear prevention, risk factors, STAR classification and first aid management. Most staff stated they had not had training on skin tear management at all. Once trained, staff received a first aid bag with which to manage skin tears; this contained saline, Steri-Strips, dressing pack including a selection of Advazorb Border, Allevyn Gentle Border, Mepilex Border and Kliniderm Border dressings in various sizes, bandages and adhesive removal spray. Additionally staff members were given laminated A6-size STAR classification cards (*Figure 1*) to keep in their pockets. An A4 size version was provided for clinical rooms and offices, as was a flow chart of the audit.

Table 1. Demographics and test scores for patients in the dressing groups

Dressing group	M/F (*n*=20)	Mean age (years)	Mean body mass index	Mean Waterlow score	Mean MUST score
Advazorb Border	7/13	90.0	20.0	20.0	0.60
Allevyn Gentle Border	4/16	88.0	21.0	90.0	0.95
Kliniderm Border	5/15	86.9	21.0	20.0	1.25
Mepilex Border	4/16	89.6	19.9	19.9	0.70

Key: M/F: males/females in group; MUST: Malnutrition Universal Screening Tool

Patient identification and recruitment

Nursing staff contacted the tissue viability nurse consultant (TVNC) and informed her that their nursing home had a patient who had sustained a skin tear. The TVNC checked that staff had applied the randomly selected silicone dressing from the first aid bag, and that they had carried out the first aid correctly. She then arranged a time to assess the patient within 24 hours of the injury. Written consent was obtained from the patient or a relative when possible. Where the patient was unable to give consent, the senior nurse in the nursing home authorised the TVNC

Table 2. Location and number skin tears that were included in the audit

Location of tear	Number
Tibia	25
Forearm	23
Elbow	12
Hand	11
Upper arm	4
Knee	3
Ankle	1
Head	1

Table 3. STAR classifications for skin tears that occurred during the audit

Dressing	Classification				
	1a	1b	2a	2b	3
Advazorb Border	0	10	6	2	2
Allevyn Gentle Border	1	8	6	1	4
Kliniderm Border	2	9	8	1	0
Mepilex Border	2	12	2	2	2

Table 4. Sizes of skin tears in the four dressing groups

Measurement	Advazorb Border	Allevyn Gentle Border	Kliniderm Border	Mepilex Border
Length in cm (ANOVA p=0.29)				
Mean	4.3	3.7	3.1	3.5
Standard deviation	2.7	1.8	1.6	2.0
Median	3.0	3.2	3.0	3.2
Low	2.0	1.5	1.0	1.0
High	13.0	8.0	7.0	8.0
Width in cm (ANOVA p=0.16)				
Mean	2.1	2.8	1.8	1.8
Standard deviation	1.3	2.2	1.6	1.2
Median	2.0	2.25	1.5	1.5
Low	0.5	0.2	0.2	0.5
High	7.0	9.0	7.0	5.0
Area in cm^2 (ANOVA p=0.51)				
Mean	10.5	11.5	6.8	7.7
Standard deviation	12.1	12.6	10.7	9.7
Median	6.8	7.5	3.0	4.6
Low	1.25	0.3	0.7	0.75
High	49.0	54.0	49.0	40.0

to deliver the dressing change in the best interest of the patient and took photographs for clinical purposes only. This was recorded in the patient's notes and care plan.

To be included in the audit, patients had to be aged 18 years or older, consent to participate (written, informed consent/witnessed verbal consent/consultee agreement) and expected to comply with the follow-up schedule. Patients were excluded if they expressed that they were unwilling to participate or would not keep the dressing on due Alzheimer's disease, had clinically-infected wounds or had a changeable condition that compromised normal treatment.

Assessment and dressing regimen

All skin tears were assessed using the STAR classification system by the same TVNC assessor. Patient demographics, age, sex, nutritional status, medical conditions, wound information, site of the skin tear(s) and duration of the wound were recorded along with the STAR classification. The location of the wound and the time of day the skin tear was sustained were also noted.

The silicone dressing was used as a primary dressing. Data were collected on the frequency of dressing change and the dressing products involved. Every patient had their dressing change performed and monitored by the TVNC on days 0, 3, 7 and 14. The time frames were the same as those used in the audit by Stephen Haynes et al (2011). The absorbance capacity, the amount of peri-wound skin, maceration, dermatitis, inflammation, irritation and dryness were evaluated. The amount of exudate was recorded by weighing the dressing that was removed and comparing it to the weight of the unused dressing. The exudate characteristics were recorded (World Union of Wound Healing Societies, 2007). Any additional dressing changes and their frequency were recorded. Every assessment followed the TIME (Tissue management, Inflammation and infection control, Moisture balance, Epithelial (edge) advancement) framework (Dowsett, 2008). All wounds were photographed and clinical assessments included wound exudate measurement and odour. Wound healing progress was noted in relation to the type of skin tear. If a patient withdrew from the audit for any reason, this was noted. These data were excluded from the analysis. All data were recorded manually on paper and then input into Microsoft Excel.

Data analysis

Audit data were analysed by an independent statistician using Microsoft Excel and VassarStats (http://vassarstats.net/). All continuous variables were analysed. Where data were apparently non-Gaussian or ordinal, non-parametric statistical tests (Mann–Whitney, Kruskal–Wallis or χ^2 tests) were used. For Gaussian data, student t-testing was applied.

Table 5. Sizes of dressings used

Size of dressing	Number used
10 cm × 10 cm	35
7.5 cm × 7.5 cm	20
15 cm × 15 cm	9
10 cm × 12.5 cm	8
12.5 cm × 12.5 cm	5
15 cm × 17.5 cm	2

RESULTS

Ninety-three patients were recruited, 13 of which did not complete the audit (six died, six were withdrawn as they were non-concordant with keeping the dressing *in situ*, and one patient was admitted to hospital). The audit therefore reports on 80 patients in nursing homes, with 20 patients in each of the silicone dressing groups (*Table 1*). The baseline demographics showed no significant difference between the ages in the four groups, which ranged from 70 to 107 years, or in body mass index (BMI). The mean Waterlow scores did not significantly vary, however there were differences in the mean Malnutrition Universal Screening Tool scores. In the Kliniderm Border group, the mean MUST score was higher than in the other dressing groups, but not statically significantly so. The majority of patients (n=53) were very immobile, being either wheelchair- or bed-bound. In addition to this, the majority of patients (n=60) were cognitively impaired or had dementia.

The location of the skin tears varied (*Table 2*). There were no significant differences between the groups regarding the sites of the skin tears. The day was broken down into three periods: morning, afternoon and night. Thirty patients sustained skin tears in the morning, 32 patients in the afternoon, and 18 patients at night. There were no significant differences relating to the time of day at which a skin tear occurred (p=0.27). When time of day *versus* STAR classification was tested by simple correlation

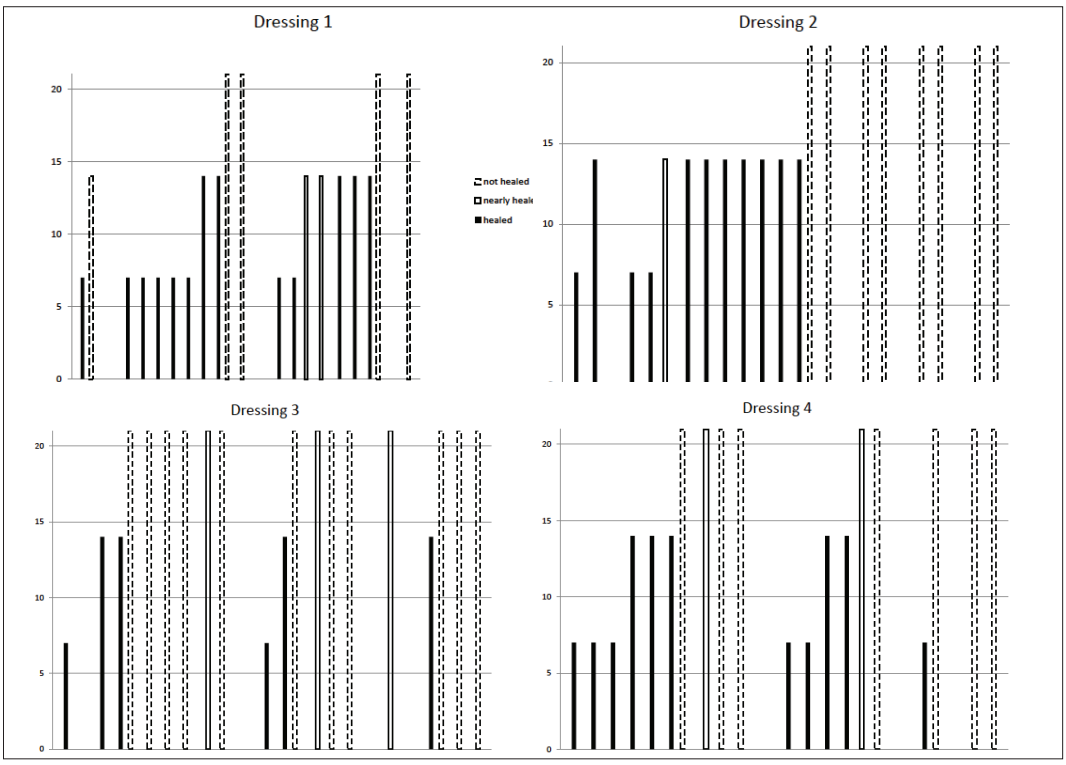

Figure 2. Skin tear STAR classification and healing time for the four dressings

Table 6. Ability of the dressings to stay in place

Dressing group	Number that stayed in place (%)	Number that did not stay in place (%)
Advazorb Border	55 (98.2)	1 (1.8)
Allevyn Gentle Border	48 (82.8)	10 (17.2)
Kliniderm Border	44 (89.8)	5 (10.2)
Mepilex Border	41 (74.5)	14 (25.5)

Table 7. Ease of dressing removal and the use of adhesive removal spray in the different dressing groups

Dressing group	Dressing removal		Spray required	
	Difficult (%)	Easy (%)	Yes (%)	No (%)
Advazorb Border	18 (21.2)	67 (78.8)	18 (21.2)	67 (78.8)
Allevyn Gentle Border	38 (63.7)	22 (36.6)	49 (94.2)	3 (5.8)
Kliniderm Border	43 (63.2)	25 (36.8)	59 (95.1)	3 (5.8)
Mepilex Border	33 (49.2)	34 (50.2)	48 (76.2)	15 (23.8)

(r=0.125; t=1.111; df=78; 2-sided p=0.27), the differences were not significant. Each group's STAR classifications were compared (*Table 3*). These classifications were similar, however there were no STAR 3 skin tears in the Kliniderm Border group.

There were no significant differences in skin tear size (*Table 4*). This demonstrates that the STAR classifications were evenly distributed across the dressing groups.

The four brands of dressings are available in various sizes, ranging from 7.5 cm × 7.5 cm to 15 cm × 15 cm. There was no significant difference in the sizes of dressings used between groups. The most frequently used size of dressing was 10 cm × 10 cm (*Table 5*).

There were no significant differences in rates of healing between the dressing groups when tested using analysis of variance (ANOVA) and student's t-test (p=8.5). The duration to healing times for each of the STAR classifications were comparable (*Figure 2*), with the more severe STAR classification taking over 20 days to heal. The time to healing related to the size of the wound.

The Advazorb dressing was significantly better at staying in place than the other dressings (χ^2=3.95, p=0.26) (*Table 6*). Compared to the other groups, dressing removal was significantly easier in patients in the Advazorb Border group (χ^2=36.5, $p\leq0.0001$) and the use of adhesive removal spray was significantly lower in this group (χ^2=121.69, $p\leq0.0001$), *Table 7*.

The weights of the dressings at removal were recorded, but there was minimal exudate and therefore no significant difference. The odour was found to be minimal due to the type of wound under audit.

None of the patients had indications of an infection at any time during the 14-day audit period. After this time, two patients developed lower grade cellulitis and were given antibiotics. Both patients had skin tears to their lower legs and had lymphoedema as a long-standing medical condition.

Cost of dressings

All dressings are available for sale in the UK and the prices were taken from the March 2016 *Drug Tariff* (*Table 8*). The price of the 50 ml Easy Peel™ spray was £7.10. One unit lasted 3–4 weeks per patient.

DISCUSSION

The patients included in this audit were taken from a convenience sample and were characteristic of patients at risk of skin tears. The analysis found age, BMI, and Waterlow and MUST scores to be similar. The ages of the participants in this audit ranged between 70 and 107 years, which agrees with Woolhouse and Moola's (2014) statement that patients over the age of 65 years are more susceptible to skin tears due to changes in the ageing skin. All patients had BMI scores in the healthy category, as demonstrated by the mean scores given in *Table 1*. The Waterlow score indicated that all patients were at very high risk for pressure ulcers, which in turn correlates with an increased risk of skin tears. This risk includes factors of advancing age, impaired mobility, poor nutrition and comorbidities.

The results of this audit concur with previous studies on the locations of skin tears, the highest numbers being the on the tibia, forearm, elbow and the hands. Stephen-Haynes and Carville (2011) state that skin tears in the elderly are often sustained on the extremities, such as the upper and lower limbs and the dorsal aspect of the hand. Interestingly, this audit found no differences in the time of day skin tears occurred (p=0.27). LeBlanc et al (2011) state that skin tears frequently occur during routine activities such

as dressing, bathing, repositioning and transferring patients, which are more likely to occur during the day.

The sizes of the skin tears did not differ significantly between groups and healed in consistent time-frames. The higher STAR 3 tears in this audit took slightly longer than 21 days to heal. This is consistent with the findings from other studies. Holmes et al (2013) demonstrated a healing time of 10 days for category 1, and 14–21 days for categories 2 and 3. Payne and Martin (1993) demonstrated that category 1 skin tears healed within 10 days, and categories 2 and 3 healed in 14–21 days. Stephen-Haynes and colleagues' recent evaluation showed that skin tears healed at between 7 and 21 days (Stephen-Haynes et al, 2016).

The silicone dressings were changed on days 1, 3, 7 and 14, which resulted in effective wound healing. Despite the majority of patients being cognitively impaired, most silicone dressings stayed in place. The most frequently used dressing size was 10 cm × 10 cm, followed by 7.5 cm × 7.5 cm. The cost of the 10 cm × 10 cm dressing ranged from £1.63 (Kliniderm Border) to £2.10 (Advazorb Border). Given that the Advazorb Border dressings stayed in place longer and were removed more easily, rarely requiring the use of an adhesive removal spray, the additional cost can be justified. Dressing changes in patients with cognitive impairment and dementia can be challenging for practitioners and upsetting for the patients, so having a silicone dressing that can be removed without using an adhesive spray can be very beneficial to the patient.

Nurses should be aware of the risk factors associated with patients sustaining a skin tear and know how to manage tears effectively. Education relating to the older person's skin and its appropriate management can optimise healthcare resources. Woolhouse and Moola (2014) undertook a project promoting best practice in the management and ongoing treatment of skin tears to improve outcomes in an elderly care setting. They concluded that ongoing education on skin tears and the development of an evidence-based care pathway can help to improve skin integrity and prevent skin tears. The development of strategies to reduce the incidence of skin tears, such as falls prevention, medication management and behaviour management, are required. In the current audit, nurses in the nursing homes found the evidence-based skin tear management protocol invaluable. Anecdotally, due to the staff's increased awareness of skin tear prevention there was a decrease in the number of skin tears in their nursing homes. The first aid kit and skin tear care pathway, plus the option of contacting an expert if there were any problems, enabled staff to effectively manage skin tears *in situ*. Some of the STAR 3 tears were thus managed in the nursing home, avoiding a hospital admission.

Table 8. Product size and price (*Drug Tariff*, March 2016)

Dressing group	Dressing size	Price per dressing
Advazorb Border	7.5 cm x 7.5 cm	£1.19
	10 cm × 10 cm	£2.10
	12.5 cm × 12.5 cm	£2.58
	15 cm × 15 cm	£3.15
Allevyn Gentle Border	7.5 cm × 7.5 cm	£1.49
	10 cm × 10 cm	£2.19
	15 cm × 15 cm	£4.00
Kliniderm Border	7.5 cm × 7.5 cm	£1.18
	10 cm × 10 cm	£1.63
	15 cm × 15 cm	£3.95
Mepilex Border	7.5 cm × 7.5 cm	£1.39
	10 cm × 12.5 cm	£2.72
	15 cm × 17.5 cm	£4.74

Limitations

This audit had a few limitations. As the sample size was small, a larger controlled/comparative trial in multi nursing homes was used to confirm and establish the results identified in this audit. A large sample size would allow healing rates to be compared against the STAR classification categories. Data were only collected over a 6-month period, which will not demonstrate whether the decrease in skin tears noticed was incidental or due to training and increased awareness, and if so whether it was sustained.

All patient assessments were undertaken by one TVNC, which could introduce bias. To overcome this, the statistical analysis was undertaken independently and was totally blinded. The recruitment of patients with the same type of wounds (skin tears) resulted in a

Box 1. Recommendations for clinical practice

- Always use an atraumatic dressing
- Always remove with adhesive spray, if skin is considered at risk of further damage
- Redress STAR classification 1–2a skin tears on day 3 and every 7 days thereafter
- Redress STAR classification 2b skin tears on day 3 and every 4 days thereafter to monitor for infection.

participant pool consistent with the classic at-risk population; however, patients' ability to consent was limited. Written consent was obtained from the patient or a relative when possible. In other cases, the senior nurse in the nursing home gave witness assent. It was not possible to gain patient's perceptions of the dressings due to most patients having dementia.

CONCLUSION

Silicone dressings have been widely used to manage skin tears. This audit on silicone dressings has provided a valuable insight into the management of skin tears in patients in a nursing home environment. All of the silicone dressings used in this audit had positive clinical outcomes, with healing or progression to healing in all cases. Of the four dressings audited, the Advazorb Border dressing was the easiest dressing to remove and rarely required adhesive removal spray.

The results of this audit endorse best practice in skin tear management, which avoids further trauma, prevents infection, manages exudate and uses moist wound therapy to heal the skin tear in a timely fashion. Delays in healing due to infection and other complications can add to healthcare costs, whereas comprehensive assessment and the effective management of skin tears can expedite healing in this very vulnerable client group. WUK

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Is Kliniderm foam silicone a suitable, cost-saving alternative to other silicone foam dressings?

KEY WORDS
- Silicone foam
- Kliniderm foam silicone
- Cost effectiveness

This product evaluation was undertaken to explore patients' satisfaction after changing from one silicone foam dressing to Kliniderm silicone foam. The evaluation involved 22 patients with a variety of wounds being cared for at a large primary care organisation. The data was collected over eight dressing changes and the author looked at the dressing's performance in terms of symptom management, exudate control and comfort. Clinician and patient satisfaction were examined as well as the potential for any financial savings that could be made by making a switch to Kliniderm foam silicone in one CCG's formulary.

In 2014, prescriptions of silicone foam dressings in England cost the NHS £28.7 million — 20.15% of the total prescription spend on wound care in that year (Health and Social Care Information Centre, 2015). In Sheffield CCG alone the amount spent on three types of silicone foam dressings size 10x10cm was just over £100,000 for 11 months in 2014–15 (data supplied from Sheffield Medicine Management). This figure does not reflect the amount spent on other sizes or silicone dressings with added antimicrobials. As the NHS seeks to improve outcomes and reduce costs it has become incumbent on nurses to try to prescribe dressings that are the most cost effective. Dressings need to be chosen which will improve or maintain the clinical outcome while also reducing costs.

With this in mind a decision was made to evaluate the impact of a change in dressing product before the local formulary review at Sheffield CCG. Nine district nursing teams were asked to select patients with wounds who were being treated with a silicone dressing other than Kliniderm foam silicone (Aria Medical). Kliniderm silicone was then used for up to eight dressing changes as an alternative product and then patient and clinican satisfaction were surveyed. The author then considered the financial impact of the change.

BACKGROUND

Foam dressings are generally made from polyurethane that has been heat treated to provide a smooth contact surface. They provide thermal insulation, do not shed fibres or particles and are gas permeable. The foam surface is hydrophilic which means it attracts moisture (Pudner, 2001). Foams use vertical wicking which absorbs the exudate upwards into the dressing avoiding maceration to the surrounding skin (Benbow, 2008). The mode of action varies but the majority of foam dressings available are designed to 'absorb and lock away' the exudate thus providing high absorbency and wear time (Cook and Barker, 2012)

Over the past 10 years, foam dressings have been adapted to have a soft silicone contact layer. Soft silicones are a particular family of solid silicones which are soft and tacky. Soft silicone foams were developed to minimise the problems of pain and trauma at dressing change and to protect the peri-wound skin (Lawton and Langeon, 2009). Majan (2006) showed that when removed from the skin, soft silicone dressings do not cause trauma to the wound or peri-wound skin. Soft silicones conform and adhere well to dry surfaces, they have low toxicity making adverse reactions rare and they cannot be absorbed into the body (Thomas, 2003).

It is well recognised that wound healing progresses most rapidly in an environment that is

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clean and moist but not wet (Brett, 2006). Excessive exudate can be challenging to manage in terms of clinical time and cost accrued in repeatedly changing soiled dressings and when addressing the impact the wound exudate has on the patient's quality of life. Effective exudate management must aim to treat the underlying cause, enhance quality of life, optimise the wound bed, remove moisture, and prevent exudate-related problems such as peri-wound changes, odour and pain (World Union World Health Societies, 2007).

Dressings facilitate wound healing by providing the optimal environment for healing (Vuolo, 2009). An optimal environment for healing requires a dressing which provides: a moist environment; thermal insulation; is non-adherent; requires infrequent dressing changes; is safe to use; provides mechanical protection; is comfortable and conforms; has good absorption; is impermeable to micro-organisms; acceptable to the patient; is cost effective and sterile (Morgan, 1999). Inappropriate dressing selection can lead to delayed healing, increased pain, increased infection and higher costs as well as having a detrimental impact on the patient's quality of life (Ousey and Cook, 2011),

Silicone foams can be used on a variety of wounds including pressure ulcers, leg ulcers and traumatic wounds. While other dressings are available to manage such wounds, Matsumura et al (2012) found in a comparative study that dressings with silicone adhesive removed less stratum corneum from the wound when compared with hydrocolloid and polyurethane foam using an adhesive. Timmons et al (2009) found the use of silicone dressings improved patients' quality of life by reducing pain on removal, reducing anxiety and ultimately speeding up the healing process.

METHOD

The six-week evaluation took place at the Sheffield Community Care Group (CCG). Ethical approval was not required as this was an evaluation of a product that is already available on prescription but patient consent was obtained regarding the change in regimen. Approval was gained from the Tissue Viability Network via the Sheffield Wound Group. Nine district nursing bases were selected from the four localities in Sheffield. Eight dressing changes for each patient were considered enough to assess patient and nursing satisfaction. The evaluation did not assess wound healing but the dressing's ability to manage symptoms. Patients who were already receiving treatment for wound management with products on the trust's formulary were recruited. Twenty-two evaluations for 22 patients were collected over the period allocated. The evaluation took place as part of a formulary review and also considered cost-effective alternatives to the current dressings in view of rising prescription costs issued by the medicine management department.

Verbal explanation of the rationale for the evaluation was provided to all participants and consent was received and documented. Other members of the nursing team were also informed and educated about the purpose of the evaluation. The following aspects of the patient evaluation were recorded:

- Patient age and gender
- Current regimen
- Type of wound
- Aim of management
- Wound duration
- Exudate level
- Patient comfort on application and removal
- Exudate management and conformability
- Clinician feedback
- Size of dressing used.

Comfort and exudate management were assessed using a five-point scale where 1 was very poor and 5 was excellent.

RESULTS

All 22 patients were seen in a primary care setting for management of a variety of wounds (*Figure 1*). The ratio was 15 men to seven women and the average age was 71 with the age range being 38–88 years old. Of the 22 evaluations received, 16 stated the type of wound the silicone foam dressing was used for, three were used for mixed reasons and three did not state the wound. Foam dressings are suitable for the management of pressure ulcers, surgical wounds and traumatic wounds and so Kliniderm was considered suitable for all the 22 patients. *Figure 2* demonstrates the dressing of choice before the evaluation. All but one patient were receiving treatment with either a foam dressing or a silicone foam before the product evaluation.

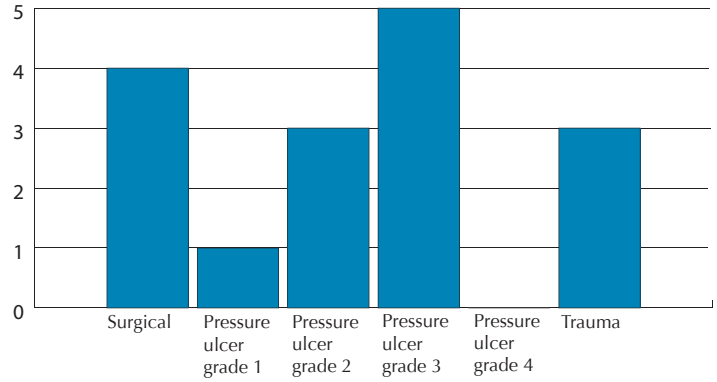

Figure 1. Participants' wound type.

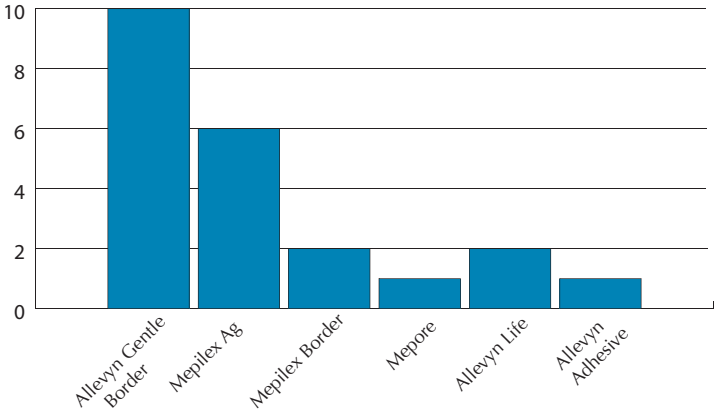

Figure 2. Dressing used before the evaluation.

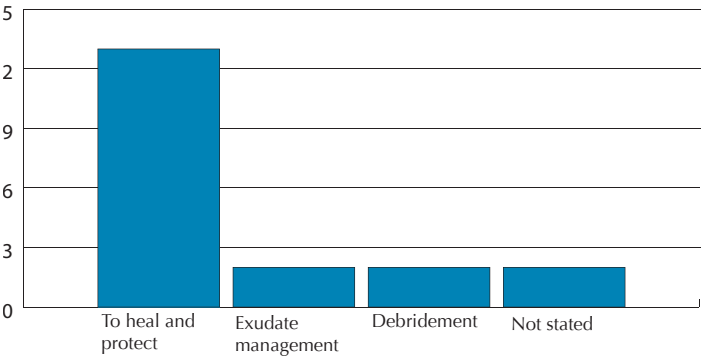

Figure 3. Clinicians' treatment aims.

Figure 3 shows the clinicians' aim when selecting the dressing. The treatment aims for 15 of the 22 evaluations was to heal and protect the wound while only two stated wound exudate management as the desired outcome of using the wound dressing. *Figure 4* shows wound duration. Six of the 22 wounds were acute wounds, a further five had been present between five and 12 weeks, 11 wounds were chronic with 10 of these wounds having been present for 24 weeks or more.

The exudate levels were taken as an average of each of the 22 patients' exudate ratings over the course of the evaluation length of up to eight dressing changes (*Figure 5*). Foam dressings are appropriate for light to moderate exudate levels. Sixteen of the 22 patients had light moderately exudating wounds. These levels were determined by the clinician. Local guidelines for this were followed which are based on the national descriptions of dry, moist, wet, saturated and leaking (EWMA, 2007). Consideration was also given to the amount of exudate retained in the dressing, the number of dressing changes required in 48 hours and a visual inspection of the wound.

Figure 6 shows comfort upon application and removal and exudate management. This was taken as an average of all 22 scores. The options were 1 (very poor), 2 (poor), 3 (average), 4 (good) and 5 (excellent). All averaged 4 or above for Kliniderm when compared with the dressing previously used.

DISCUSSION

From the scoring system for comfort, ease of application, removal and exudate management, all participants scored four or above when comparing Kliniderm to the previous regimen. This indicates overall satisfaction with the regimen change.

Eighteen of the 22 community nurses' evaluations indicated that Kliniderm's performance was equal to the previous product used while only two stated that the performance was worse, one did not reply and one stated that the performance was better. Eighteen of the 22 evaluations suggested recommending the product for the local formulary when asked yes or no.

When asked about Kliniderm, 20 patients were happy with the product while only two were not due to reported poor absorption. The majority [*n=21*] of patients declared the product to be very comfortable.

Kliniderm foam silicone has been shown in this small evaluation to be an acceptable alternative to other silicone dressings in terms of patient comfort and clinicians' satisfaction and so the cost of a switch to Kliniderm was calculated.

In Sheffield CCG the cost of 10x10 silicone dressings was £100,157.05 in an 11-month period in 2014–2015. This has been calculated as 38,988 Alleyvn Gentle Border and 5,574 Mepilex Border

giving an overall approximation of 44,562 10x10 silicone dressings prescribed in 11 months. The cost of the same number of Kliniderm dressings would have been £72,636 giving a potential saving of £27,521 alone. This is based on the premise that a switch to Kliniderm would necessitate an equivalent number of dressing changes. The wear time of the different dressing types has not been covered in the evaluation and further investigation should be made to test this conclusion.

There are limitations to this small evaluation. A study that compared the number of dressings used until the wound healed using different silicone dressings and the subsequent dressing costs accrued would more accurately indicate the extent of the savings that could be made by switching to Kliniderm. This evaluation shows that Kliniderm — a cheaper dressing that those currently on the formulary — can manage symptoms and is considered a satisfactory alternative to other silicone dressings by clinicians and patients.

CONCLUSION

Nurses are expected to give high quality evidence-based care while also considering cost saving. This small evaluation may suggest that Kliniderm could be a cost effective addition to CCGs' formularies although further investigations should be made. WUK

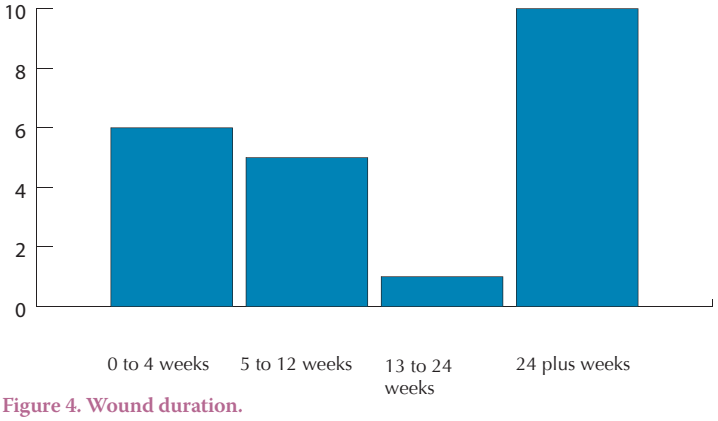

Figure 4. Wound duration.

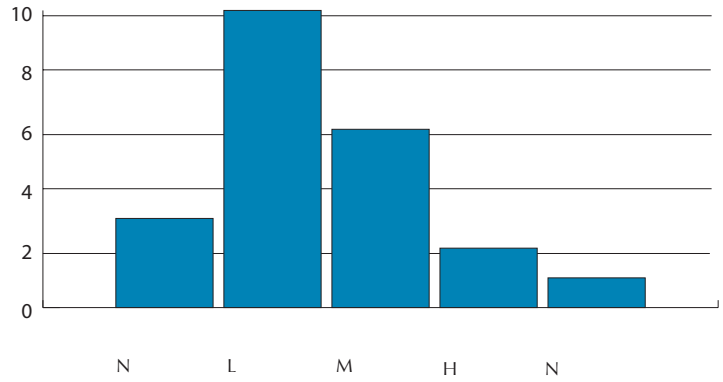

Figure 5. Exudate levels.

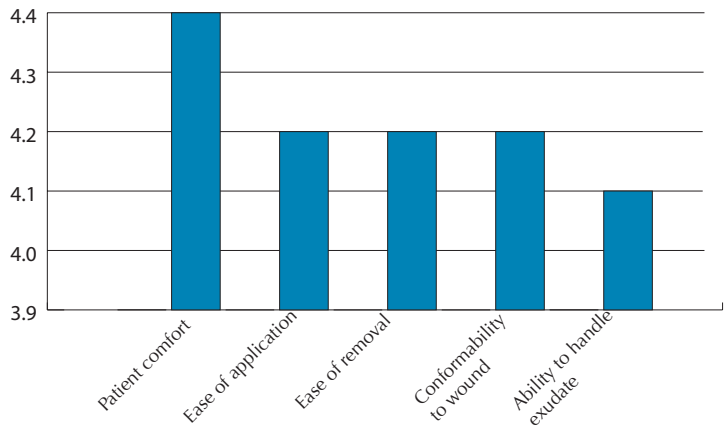

Figure 6. Comfort, ease of application and removal, conformability and ability to manage exudate as rated on a 1–5 scale.

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