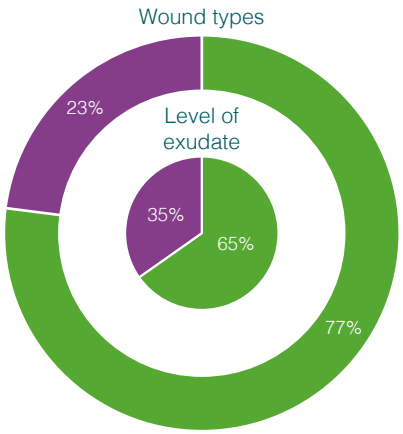
# kliniderm®
# superabsorbent

## Results of 52 patient Clinical Study

This evaluation was conducted to rate **Kliniderm® superabsorbent** dressings performance and effectiveness in managing exudate and exudate retention from 2 healthcare professionals*, for **52 patients** in clinical practice over a **2 month** period in Hungary, EU.

**52**
**patients**




Average age: 67

Female 46%; Male 54%

- Acute wounds = **40** (77%)
- Chronic wounds = **12** (23%)

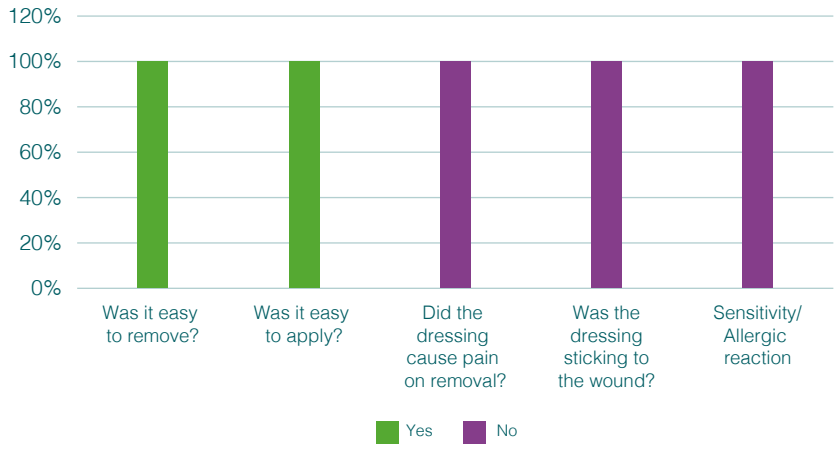
- Low level of exudate = **34** (65%)
- High level of exudate = **18** (35%)

All dressings were changed within 4 days and were used as a primary dressing.

## Results

27 (52%) dressings were used under compression. 96% of these patients said the absorption is excellent and another 78% said the absorption AND the exudate retention (there was no leakage) was not only good but excellent.

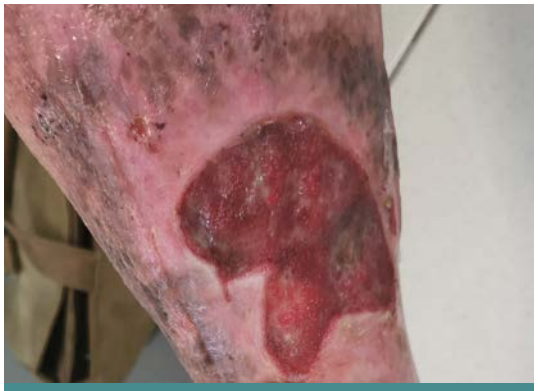
100 percent of the responses said that the following five factors were exceptional:



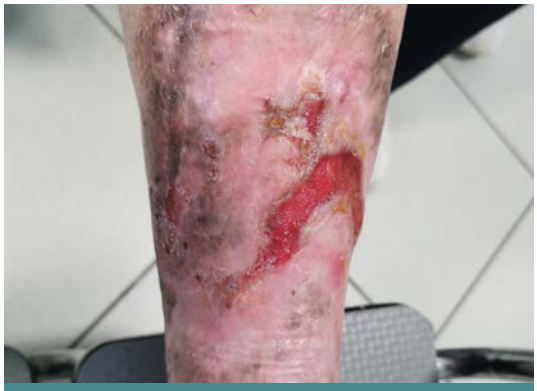

Average of
*'How did the patient rate the conformability of the product during wear of time on a scale of 1-10'*:

**9.7**

One of the patients treated with a venous pressure ulcer:

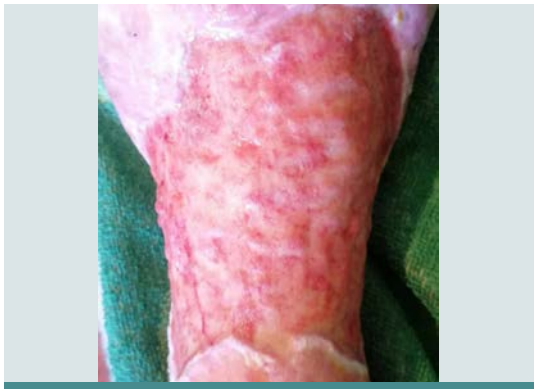


Before



After

Another patient treated with venous pressure ulcer in the study:



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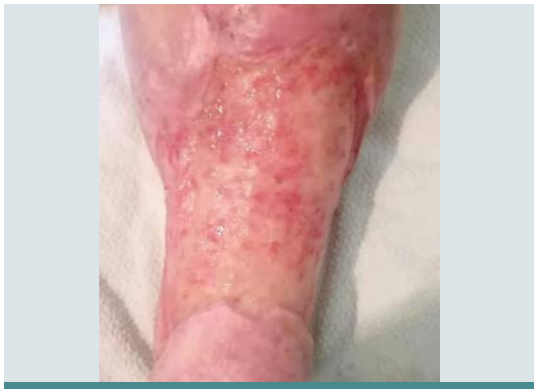

After

**All patients recommended using the product: 100%**

## Conclusion

The results of this evaluation are favourable in terms of clinical use, clinical effectiveness, and patient satisfaction. **Kliniderm® superabsorbent** dressings are safe and very effective for use under compression and in the management of moderate to highly exuding chronic and acute wounds.

The patients rated the product exceptional in the terms of ease and (no) pain on removal, application, (no) allergic reactions and (no) sticking to the wound. 100% recommend the product.

*Dr. István Komocsin, Surgeon, County Hospital Siófok, Hungary & Dr. Sándor Horváth, Surgeon and Rehabilitation Physician, Erzsébet Hospital Zirc, Hungary

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**2nd of December, 2024**

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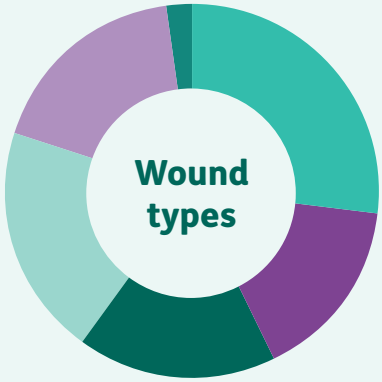
kliniderm®
**superabsorbent**

# Results of 355 patient Post-Market Clinical Follow-up (PMCF)[1]

This evaluation was conducted to rate **Kliniderm superabsorbent** dressings performance and effectiveness in managing exudate and exudate retention from **56** healthcare professionals, for **355** patients in clinical practice over a **10** month period.

**355**
**patients**




- Leg ulcers = **95** (27%)
- Pressure ulcers = **58** (16%)
- Postoperative wounds = **62** (17%)
- Traumatic wounds = **70** (20%)
- Oncology wounds = **63** (18%)
- Other = **7** (2%)

## Results

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

**98%**
Exudate management

**98%**
Exudate retention

**99%**
Ease of application

**100%**
Ease of removal

## Conclusion

The results of this evaluation are favourable in terms of clinical use, clinical effectiveness, and patient satisfaction. **Kliniderm superabsorbent** dressings are safe and effective for use under compression (n=122 of evaluated patients) and in the management of moderate to highly exuding 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.

AM174-1

1. Data on file. KLIN014. User survey report as part of Post Market Clinical Follow-up (PMCF) of Kliniderm superabsorbent dressings, 2022.

# Rapid exudate absorption, even under compression

**Medeco**'s Kliniderm Superabsorbent dressings are a market leader in terms of cost, effectiveness and patient preference. The four-layer superabsorbent dressings are held together by a unique patented seal, are indicated for moderate-to-highly exuding chronic and acute wounds, and can be used under compression. Susan Mason, a tissue viability nurse and senior clinical adviser for NHS shared business services, explains why she favours the dressing.

Although exudate is a vital part of wound healing, chronic-wound patients often think of it in terms of disgust, channelling it into feelings of self-loathing and low self-esteem. If mismanaged, it can also lead to further physical damage, increased pain and a greater risk of already debilitating wounds becoming infected. As they assess, find causes for and act to manage exuding wounds, care providers need to keep all of this in mind.

Kliniderm Superabsorbent dressing can take up to 33 times its weight.

"We look at the whole of the patient, not the hole in the patient," says UK wound care expert Susan Mason. A former manager for tissue viability in a large NHS primary care trust, she now spends two days a week as a tissue viability nurse and the other three as a senior clinical adviser for NHS Shared Business Services. With her range of experience and responsibilities, she's as well placed as anyone to practice what she preaches.

## Patient first

It's because of patients that Mason wants to speak about Kliniderm Superabsorbent, which she is quick to recommend for treating foot, leg and pressure ulcers, lymphoedema and more. Comprising a hydrophilic wound contact layer, an absorbent core that can take in up to 33 times its own weight, a fluid-repellent backing layer and an ultrasonic seal that removes the risk of reactions to the glue used, all held together with a patented seal, the product is indicated for moderate-to-highly exuding wounds. It's designed to rapidly absorb exudate even under compression, locking it in while being comfortable for the patient over a long wear time, conformable, and easy to apply and remove. At the same time, Kliniderm Superabsorbent dressings are 34–79% cheaper than competitors.

*"It's all about quality of life for the patient and you can't equate that with cost because everybody's so different. It's about ensuring that the patient's quality of life is enhanced. To make sure products are of a standard you would accept, you involve patients."*

"It's all about quality of life for the patient," Mason continues, "and you can't equate that with cost because everybody's so different. It's about ensuring that the patient's quality of life is enhanced. To make sure products are of a standard you would accept, you involve patients."

In her previous management role, Mason tested Kliniderm's product against the exudate management dressings already in the trust's formulary. "The product we were using at the time was quite costly, and we were still having issues with suppuration," she explains. "We did an evaluation with that product and the Kliniderm range and saved a phenomenal amount of money with no detriment to the patient."

In fact, patient feedback about Kliniderm dressings' wearability, conformability and comfort was extremely positive. Clinicians praised the ease with which the product could be applied and removed, as well as how beneficial it was for patients. "It was a no-brainer for us," Mason laughs. "I wish all our decisions were like that."

Equally, the Humber Foundation Trust's 2015 study into superabsorbent dressing use in the three months before and after its implementation of Kliniderm products found costs fell from £61,372.06 to £21,366.77 and 26% fewer dressings needed to be applied. Apparent cost savings can prove to be a false economy if the suitability of wound care products isn't considered, but, as Mason stresses, these changes were not achieved at the patient's expense. Indeed, in Humber's product evaluation, 27 of 30 clinicians rated Kliniderm superabsorbent's ability to manage exudate as 'very good' or 'excellent', and 18 rated the improvement in the wound bed in the same terms. As

a result of the study, the Kliniderm dressing was added to the Humber Trust Formulary as the first-line superabsorbent product. Since then, the organisation has been able to reconsider the number of nursing visits required to provide care.

Kliniderm Superabsorbent dressings' best feature is their ease of use.

"One size doesn't fit all," notes Mason. "I'm patient-led, not product-led. That's how I work with companies. I will never be product-led because I'm going to be a patient one day. So if it's a dressing that the patient warrants and it's beneficial to them, then I will use it, and we've had no issues with this product. It's been used very successfully and effectively."

## Patient throughout

Kliniderm Superabsorbent dressings are also tailored to address the precise problems that impair healing in highly exuding wounds. The product is a powerful protease modulator, restricting matrix metalloproteinases (MMPs) that remove damaged extracellular matrices during normal wound healing, but are often too abundant in chronic wounds, creating a highly destructive wound environment that struggles to repair itself. In fact, in vitro studies have shown that Kliniderm superabsorbent dressings can completely remove MMP-2 within 24 hours and are 74% more effective at restricting MMP-9 activity versus control dressings.

Still, a chronic wound is much more than its biology. "Not all wounds heal," says Mason grimly. "Some patients don't want them to." When she talks about looking at the whole of the patient, this is what she wants to be taken into account. "Everybody thinks that if you had a wound, you'd want it to heal, but some people don't because they don't see anybody apart from their nurses. They just love that connection – love sharing a cup of tea."

It's in this context that Mason calls Kliniderm superabsorbent dressings' ease of application "the biggest plus ever". It means patients can sometimes change their dressings themselves, reducing their reliance on nurses and allowing them to achieve a greater degree of autonomy.

"They can take control over their wounds," Mason explains. "They can go shopping more easily and feel more comfortable. We're getting younger patients with leg ulcers and this really matters to them. From their perspective, the dressing means they're in control of the ulcer more than the ulcer is controlling them. In each respect it's a win-win." ●

## For further information

www.medeco.org

# kliniderm®
# superabsorbent

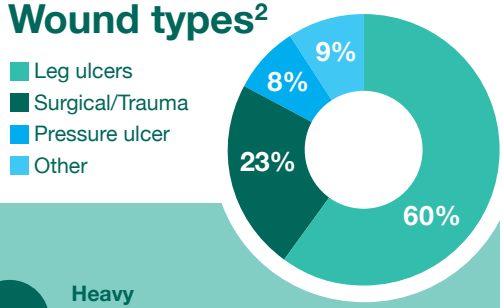
## Results of a multicentre product evaluation[1]

## Summary

**Patients**
**49**

**Average age**
**72**

**Wound types[2]**




**Exudate level[3]**

Light 18%

Moderate 26%

Heavy 56%

## Results

**From 156 dressing changes**

Superior results, rated good/very good compared to previous regime[4]

| Patient comfort | Ease of application | Ease of removal | Conformability to wound | Exudate management |
|---|---|---|---|---|
| 92% | 97% | 82% | 89% | 93% |


**Equal or better performance than current formulary product**


**Would recommend Kliniderm for formulary inclusion**

h&r healthcare
delivering innovation

References 1. Data on file. KLIN09. 2. 82% of stated responses. 3. 55% of stated responses. 4. Previously used dressings: KerraMax Care®, Zetuvit®, Zetuvit® Plus, Kliniderm® foam silicone, Eclypse®, Xupad™, Granuflex® Border.



AM127-1

# A 49 patient observational evaluation of the clinical benefits and acceptance of a superabsorbent dressing within 5 NHS sites in the UK

Author: Claire Stephens Independent Consultant Nurse and Complex Wound Manager Woundcare4heroes email: claire@woundcare4heroes.org.uk

## Introduction

Exudate management to maintain an optimum moisture balance for wound healing to occur is well documented in the literature and is one of the most challenging and costly aspects of wound management. Excessive volumes of exudate severely limit dressing life and can lead to many complications including peri wound maceration, further tissue destruction, wound infection and consequently wounds that increase in size and fail to heal impacting enormously on the patients Quality of Life (QoL).

Superabsorbent dressings have become a mainstay dressing choice to manage moderately to highly exuding wounds, extending dressing wear time leading to savings from reduced clinical visits and clinician time, reduced dressing material consumption and budget spend.

A literature review revealed Barrett (2015) published an annual cost savings forecast of £160,021 following an evaluation of a superabsorbent dressing in Humber NHS Foundation Trust.

The evaluations reported below are the NHS Trust potential formulary inclusion evaluations to explore the clinical effectiveness and patient acceptability of the superabsorbent prior to undertaking the potential cost saving analysis.

## Method

Five centres within England and Scotland independently agreed to evaluate a new superabsorbent dressing for potential formulary inclusion to explore its clinical effectiveness in terms of fluid 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 49 patients were evaluated across the 5 sites, (53%) female, (43%) male (4%) gender not stated, age range 47-101 years with an average recorded age of 72 years. A variety of exuding wound types including leg ulcers (60%), pressure ulcers (8%), complex surgical and trauma wounds combined (23%) and (9%) reported as other.

A total of 156 dressing changes were recorded within the data however only 121 data forms were completed sufficiently for reporting.

Exudate levels recorded as (56%) Heavy, (26%) Moderate and (18%) Light.

Exudate management 121 responses (62) very good, (52) good, (3) average, (0) poor and (4) very poor (93%) rated in good and very good. Rated as superior, very good and good (93%) equivalent (7%).

Conformability to the wound 126 responses (81) very good, (31) good, (10) average, (0) poor and (4) very poor (89%) rated in good and very good.

Patient comfort a total of 121 responses (53) very good, (58) good, (7) average, (0) poor and (3) very poor compared to previously experienced superabsorbent products (92%) rated in good and very good.

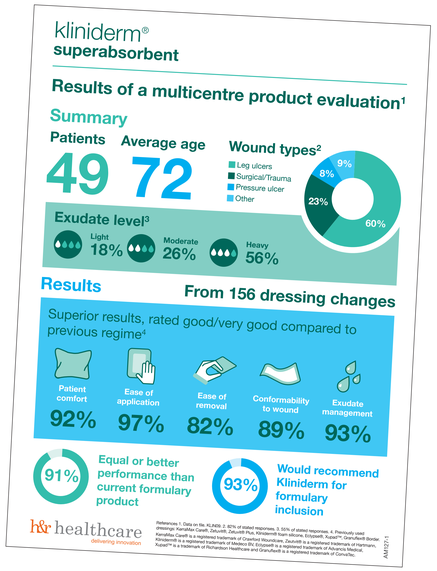
Ease of use application 124 responses (83) very good, (38) good, (3) average, (0) poor and (0) very poor (97%) rated in good and very good.

Ease of use removal 121 responses (71) very good, (29) good, (13) average, (5) poor and (3) very poor (82%) rated in good and very good.

No adverse events or patient withdrawals were reported.

(91%) of clinicians rated product performance equal to or better than current formulary listed superabsorbent and (93%) stated yes that they recommended the product for future formulary listing.

Positive patient and clinician feedback statements were recorded.




## Discussion/Summary

The results are positive with ease of application rated (97%) good and very good, conformability to the wound (89%) good and very good, exudate management (93%) good and very good, patient comfort (92%) good and very good and ease of removal (82%) good and very good.

The evaluation product was used on light exudate volumes (18%) of participants which is outside the recommended indications for use highlighting a potential training need.

One centre did not provide all of the dressing change data therefore the results presented for exudate are only representative of 121 of the 156 dressing changes recorded.

A limitation to this data is that it would have further benefitted from data capture on dressing life extension, number of visits, dressing materials used, peri wound skin assessment and wound bed condition to further validate the clinical benefits and aid the clinical cost analysis moving forward in light that (93%) of evaluators wished to take it to next stage of formulary consideration. Dressing unit cost analysis (Drug Tariff, 2020) revealed significant potential savings of up to 63% compared to other leading brands and has resulted in formulary inclusion.

## Conclusion

The results of these evaluations are favourable in terms of clinical use, clinical effectiveness and patient benefits. Dressing unit cost benefits of up to 63% have been highlighted and has resulted in Kliniderm superabsorbent dressings subsequent to this evaluation being included on the Trust formularies in all cases.

References
Barrett S (2015) General Woundcare: Cost-effective management of wound exudate. Wound Essentials 10(1): 66-73. Drug Tariff (2020) Prices correct from November 2020, based on 10 x 10cm dressing.

AM131-1

# An *In Vitro* Assessment of the Fluid Absorption and Bacterial Sequestration Properties of an SAP Wound Dressing

Westgate, S. J. and Thomas, H.

## Introduction

The ability of a wound dressing to retain moisture under pressure is critical in the treatment of moderate to highly exuding wounds. It helps to support moist wound healing whilst minimising the risk of peri-wound breakdown resulting from seeping wound exudates.

## Aim

To investigate free swell, absorption under pressure and bacterial sequestration properties of Kliniderm Superabsorbent wound dressing.

## Methods

1. Free swell absorption was measured according to an adapted EN13726 method.

2. Absorption under compression was assessed using a mass equivalent to 40 mmHg.

3. Bacterial sequestration under compression study was repeated using a bacterial inoculum. Following a 10 second suspension stage dressings were transferred onto agar for 30 seconds or 18 hours. Agar was incubated overnight at 37°C and then photographed. One gram of the inner core was dissected and viable recoverable bacteria were quantified, stained and visualised using epi-fluorescent microscopy. Tests were carried out in triplicate.

## Results

### Absorption

The average free swell absorption and absorption under compression are detailed in Table 1.

| Parameter | Result |
|---|---|
| Average free swell absorption | 1.72 ml/cm$^2$ |
| Average absorption under compression | 0.98 ml/cm$^2$ |

**Table 1.** Free swell and absorption under compression results.

### Retention

An average of 1.85x10$^4$ cfuml$^{-1}$ viable bacteria were recovered from 1 gram of the inner core.

When the wound dressing was removed from the agar after 30 seconds, bacterial growth was close to confluent however when the dressing remained *in situ* overnight no bacterial growth was observed under the dressing (Figure 1). Fluorescent microscopy also evidenced viable bacteria within the dressing core (Figure 2).

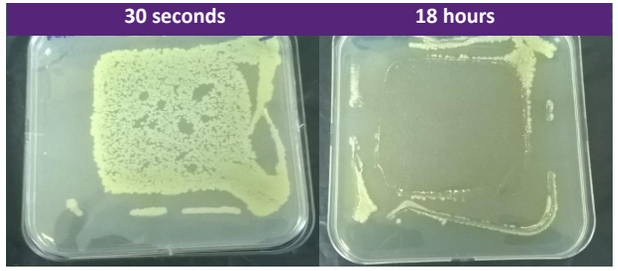



**Figure 1.** Photographs of bacterial growth following 30 seconds and 18 hours contact time with agar.

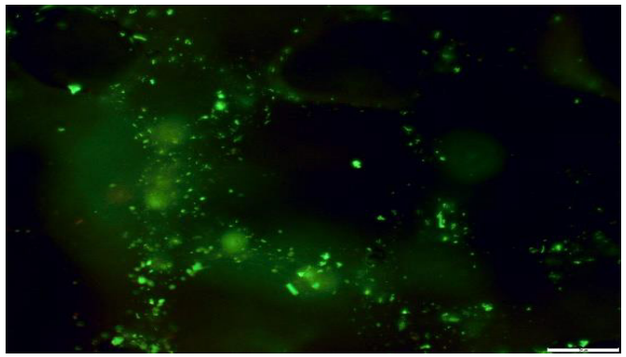


**Figure 2.** Fluorescent micrograph of bacteria retained in the inner core of the SAP dressing.

## Discussion

Fluorescent microscopy images and agar plate photographs supported the quantitative assessment results in that viable bacteria were present within the dressing core. Collectively this suggests that the bacteria were sequestered and retained within the dressing overnight.

This study was carried out over a short time period and since the wear-time of wound dressings is typically 3 days, further testing would be required in order to confirm that the performance demonstrated would be sustained over the entire recommended wear-time.

## Conclusions

Kliniderm Superabsorbent wound dressing absorbed and retained fluid and bacteria whilst under compression for 18 hours. Further study is required to determine the dressing's abilities over a longer period.

This project was carried out by Perfectus Biomed Ltd and funded by H&R Healthcare (Kliniderm Superabsorbent, manufactured by Medeco and distributed by H&R Healthcare)
Perfectus Biomed is an independent testing laboratory. SciTech Daresbury, Keckwick Lane, Cheshire, WA4 4AD Tel +441925 864 838 Mob: +447841 342 904, E-mail sam@perfectusbiomed.com

# Sequestration and Modulation of MMP-2 and MMP-9 by a Superabsorbent Wound Dressing

Sellars, L., Thornhill, S., Thomas, H., Westgate, S. J.

## Introduction

Matrix metalloproteinases (MMPs) are involved in the removal of damaged extracellular matrix (ECM) during normal wound healing. As well as being secreted by cells involved in wound healing, proteases can be produced by immune cells stimulated by an inflammatory process or infection. Evidence suggests that there is elevated protease activity in wounds that fail to heal and that elevated MMPs can result in a highly destructive wound environment.

Reducing excess protease activity within a non-healing wound may transition the wound towards a healing state. Consequently, MMP modulating wound dressings present with useful clinical implications.

## Methodology

- Recombinant human MMP-2 and recombinant human MMP-9 were prepared to known concentration.
- Test dressings Kliniderm® superabsorbent and negative control N-A® Knitted Viscose Primary dressings were prepared to (0.5 $cm^2$) and placed in a 24-well plate, 0.5 ml of protease was added to each sample.
- Plates were sealed and incubated at 37° C ± 2°C and 50 rpm ± 5rpm for 1, 4 or 24 hours.
- Following incubation remaining supernatants were collected, and the concentration of the proteases within the supernatant was determined using MMP specific ELISA kits. ELISA kits were processed according to manufacturer's instructions.

## Results

### *MMP-2*

An average of 0.33 ± 0.22 $ngmL^{-1}$ and 0.05 ± 0.06 $ngmL^{-1}$ MMP-2 were recovered after incubation with Kliniderm® superabsorbent for 1 and 4 hours respectively. This equated to a reduction of 84% and 95% respectively compared to the negative control. MMP-2 was not detected in wells incubated with Kliniderm® superabsorbent for 24 hours (Figure 1).

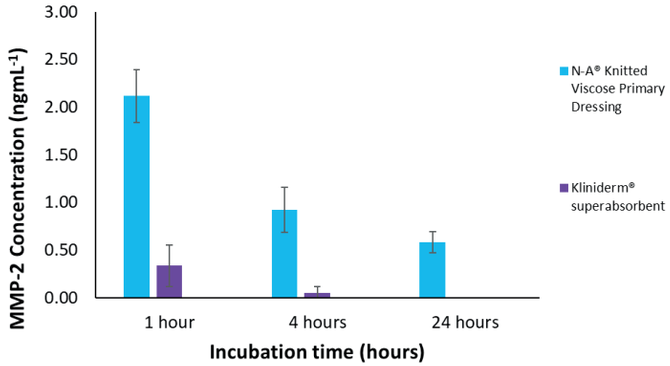



*Figure 1. Concentration of MMP-2 remaining in supernatant following 1, 4 and 24 hours incubation with test dressings.*

### *MMP-9*

The concentration of MMP-9 detected in Kliniderm® superabsorbent decreased by 5.02$ngml^{-1}$, 2.02 $ngml^{-1}$ and 9.15$ngmL^{-1}$ following 1, 4 and 24 hours incubation respectively compared to the control. This equated to reductions of 62%, 32% and 74% however the differences between the time points were not significant.

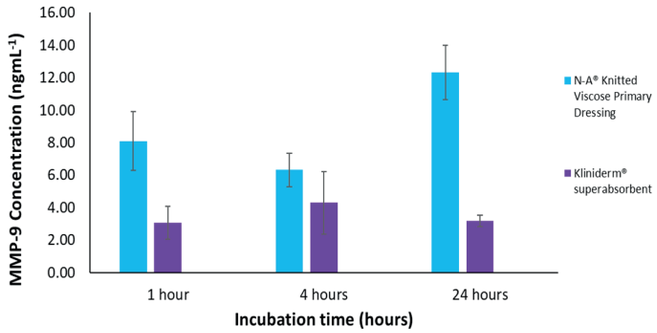



*Figure 2. Concentration of MMP-9 remaining in supernatant following 1, 4 and 24 hours incubation with test dressings.*

## Discussion and Conclusions

Advanced wound dressings have been developed to sequester MMPs and control proteases within chronic wounds. Removal of these proteases from the wound bed is suspected to support successful wound closure.

This study demonstrates that Kliniderm® superabsorbent sequestered MMP-2 *in vitro* within 24 hours and reduced the concentration of MMP-9 by 74% in comparison to negative controls. This data suggests that application of Kliniderm® superabsorbent could help to reduce elevated protease levels within a wound, supporting successful wound healing. Further studies are required on patients with chronic wounds, in order to confirm this observation in a clinical scenario.

**This project was carried out by Perfectus Biomed Limited and funded by H&R Healthcare**
**Perfectus Biomed, Techspace One, Sci-Tceh Daresbury, Keckwick Lane, Cheshire, WA4 4AB.**

# Use of a superabsorbent dressing in the management of exudate in hard-to-heal wounds


## Abstract

With the shift in demographics towards an ageing population with multimorbidity, the number of hard-to-heal (chronic) wounds is increasing each year. This poses a challenge for both health professionals, for whom wound management is becoming more complex, and for patients, who have to cope with exudate production, malodour and pain.

This article summarises understanding of healing in such wounds and how best to meet the challenge of exudate, which is a ubiquitous hallmark of hard-to-heal wounds. The role of superabsorbent dressings is considered, with particular reference to Kliniderm superabsorbent in the management of people with these challenging wounds.


■ Hard-to-heal wounds ■ Exudate ■ Malodour ■ Superabsorbent ■ Quality of life


**June Jones, Sylvie Hampton**

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The global prevalence of wounds is predicted to increase by approximately 11% per annum (Guest et al, 2017), with a burgeoning cost to the NHS. The most recent publication from Guest et al (2020) on the health-economic burden of wounds to the NHS found that the annual prevalence had increased by 71% from 2012/2013 to 2017/2018, with an associated increase of 48% in real terms for patient-management costs.

Almost all (about 90%) of wound care is delivered in the community (Dowsett et al, 2014), accounting for 40% of community nurses' caseload. Given the increasing size of the older population, coupled with the rising incidence of long-term, high-risk conditions, the number of people with hard-to-heal wounds is likely to rise still further. The problem is not restricted to the ageing population, as younger people can also be affected by hard-to-heal wounds, which can hamper both their ability to work and their personal lives (McCaughan et al, 2018), potentially leading to psychosocial problems. Therefore, it is vital to understand what causes wounds to become hard to heal and how to manage them.

At present, wound management is being complicated by the unprecedented circumstances brought about by the COVID-19 pandemic. There is a need to maximise resources and reduce risk to already overburdened clinicians, which has meant building on work already underway around empowering patients to self-care, as well as increasing involvement of family and carers (Wounds International, 2016). This move has been supported by increased use of digital and social media platforms, not only for patients but also for staff, with online support provided to clinicians by tissue viability nurses (TVNs). These strategies are likely to remain even after the pandemic ends, as the days of nurses being able to dress all wounds are long gone; this is not sustainable or, indeed, necessary. Practically, reduced home visits will mean optimising strategies, such as exudate management, for example, by ensuring effective absorption and retention through judicious dressing selection.

## Hard-to-heal wounds

Most hard-to-heal wounds are a consequence of systemic disease and/or poor overall health. *Box 1* lists some examples of the different types of hard-to-heal wounds, including those with atypical aetiologies.

A comprehensive, structured patient assessment is required to identify the underlying wound aetiology and any comorbidities that might delay healing. As part of NHS England's Improving Wound Care Project, Coleman et al (2017) devised a minimum data set (MDS) with domains that need to be considered during assessment. These domains can be used to monitor

| Box 1. Examples of hard-to-heal wounds |
|---|
| Pressure ulcers |
| Diabetic foot ulcers |
| Pyoderma gangrenosum |
| Dehisced surgical |
| Fungating |
| Hidradenitis |
| Pilonidal sinus |

any improvement or deterioration in the wound and can be summarised as follows:

- General health information, such as patient risk factors, that might delay healing
- Baseline wound information, such as the number, location, duration and type of wound(s), treatment objectives and assessment frequency
- Wound assessment parameters, such as wound size, wound bed characteristics, full description of the wound margins and surrounding skin, presence of undermining and tunnelling
- Wound symptoms, such as ongoing or intermittent pain, exudate volume and nature, malodour and signs of localised or systemic infection
- Need for specialist referral.

Patient-related barriers to healing include diabetes, ischaemia, poor nutrition, advanced age, impaired mobility, smoking and use of corticosteroids (Gray et al, 2018) (*Box 2*). Local factors include the ulcer size and duration, its anatomical location, the condition of the wound bed, the presence of biofilm and/or infection, hypoxia, raised temperature and foreign bodies (Vowden, 2011). The sooner these problems are detected, the easier they are to manage (European Wound Management Association (EWMA), 2008).

## Normal wound healing

All wounds progress through the same overlapping phases of healing: haemostasis, inflammation, proliferation and contraction (Martin and Nunan, 2015). In uncomplicated acute wounds, these phases are progressive and uneventful. Exudate in uncomplicated acute wounds contains growth factors, nutrients for cell metabolism, cytokines, matrix metalloproteinases (MMPs) and white blood cells, all of which help to stimulate healing (World Union of Wound Healing Societies (WUWHS), 2019). In normal wound healing, these factors are tightly controlled and are thus beneficial to the wound.

| Box 2. Barriers to wound healing | |
|---|---|
| Diabetes | Pain |
| Obesity | Corticosteroids |
| Age (>60 years) | Immunosuppressants |
| Smoking | Malignancy |
| Impaired mobility | Poor concordance |
| Peripheral vascular disease | Stress |
| Malnutrition | Depression |

## Hallmarks of hard-to-heal wounds

Hard-to-heal wounds are stuck in a persistent and exaggerated inflammatory phase, where they are unable to regenerate new tissue and progress towards healing (Frykberg and Banks, 2015; Bjarnsholt et al, 2017). These wounds usually with high levels of exudate, are characterised by reduced growth factor signalling, with an associated increase in levels of degrading proinflammatory cytokines and proteases and reactive oxygen species (ROS); furthermore, fibroblast cell senescence is affected, with the cells becoming unresponsive to typical wound-healing signals and less able to proliferate (Telgenhoff and Shroot, 2005; Martin and Nunan, 2015). Meanwhile, the release of tissue inhibitors of metalloproteinases (TIMPs) is reduced, and the wound bed becomes more alkaline, which impairs fibroblast proliferation (Shukla et al, 2007). This leads to the protease-mediated destruction of vital components of connective dermal tissue, such as collagen and fibronectin. The diminished proliferative capacity of fibroblasts in hard-to-heal wounds is directly correlated with the failure of a wound to heal (Frykberg and Banks, 2015).

Hard-to-heal wounds are prone to infection and biofilm formation. A biofilm is a community of multispecies microbes protected within a protective matrix of sugars and proteins (Phillips et al, 2010), which makes it difficult to treat (Murphy et al, 2020). A vicious cycle ensues of chronic and protracted inflammation, coupled with increased exudate production, leading to further biofilm development. Biofilm is implicated in the stimulation of chronic inflammation (WUWHS, 2016) and is thought to be present in at least 78% of hard-to-heal wounds (Bjarnsholt et al, 2017). It is often a precursor to overt infection and tends to form where exudate is not under control (Metcalf and Bowler, 2013).

If not managed, the corrosive proteolytic enzymes in the high-volume exudate associated with chronic inflammation can delay healing and damage the peri-wound skin. Trengrove et al (2008) suggested that chronic wound exudate should be regarded as a wounding agent in its own right because of its potential to damage the peri-wound skin.

In addition, the increased levels of MMPs in chronic wound exudate degrade the extracellular matrix (ECM), preventing cell migration and thus the wound's progression to the proliferative phase of healing. One of the defining features of hard-to-heal wounds is the alternating pattern of healing (which is often delayed) and skin breakdown or ulcer recurrence (Martin and Nunan, 2015).

## Exudate

Exudate is produced during the inflammatory stage of healing (Lloyd Jones, 2014). When controlled (Faucher et al, 2012), it

helps create a moist environment, which aids cell migration and facilitates autolysis of damaged tissue, thereby promoting healing.

The volume and properties of exudate, such as its consistency, type, odour and colour (all of which must be documented), can indicate whether or not the wound bed is infected or inflamed (Faucher et al, 2012; WUWHS, 2019). The volume and type of exudate can vary and change throughout the wound healing process, again indicating its progression towards healing (WUWHS, 2019).

As stated above, a moist wound environment will promote healing. Therefore, it is important to achieve a moisture balance. Uncontrolled excess exudate is often associated with malodour, pain, infection and strikethrough, whereas a dry wound bed will interfere with autolysis and the nutrient flow necessary for epithelial cell migration and effective wound healing.

## Quality of life

For patients and their families, the psychosocial cost of hard-to-heal wounds is immeasurable, with exuding, unhealed wounds impairing quality of life (Gibson and Green, 2013; Green et al, 2014; Murray, 2019). Hard-to-heal wounds, such as venous leg ulcers (the most commonly treated wound in the UK), have both physical and psychosocial effects, with patients often experiencing concomitant distress, sleepless nights, low self-esteem and depression (both clinical and low mood) (Jones et al, 2008; Guest et al, 2015). Leg ulcers, in particular, have a profoundly negative impact on mobility and quality of life (Gonzalez de la Torre et al, 2017). Having a chronic wound with no endpoint in sight disrupts daily lives, often resulting in a loss of independence and/or control, as symptoms make it difficult to plan beyond the next dressing change.

Frequently reported patient issues associated with poor control of symptoms of hard-to-heal wounds include discomfort, pain, malodour, leakage (Jones et al, 2008; Faria et al, 2011) and reduced ability to perform daily activities, including work, shopping, cooking and socialising with family and friends (Gorecki et al, 2009). Uncontrolled exudate can be particularly damaging, as it causes malodour as well as excoriated and macerated peri-wound skin, which adds to the burden of living with a hard-to-heal wound, presenting a key challenge for health professionals (Jones and Barraud, 2014).

In situations where exudate is poorly managed, patients can quickly lose confidence in the treatment regimen, which affects adherence, a specific challenge with prolonged compression therapy (Gardner, 2012). Many patients are extremely concerned about dressings leaking, as exudate can stain clothes, bedding or furniture, causing feelings of being unclean and leading to withdrawal from social contact (Tickle, 2016). Assessment of the patient's home situation and how likely it is they will adhere to the mutually agreed treatment plan will help determine which wound management therapies should be selected.

## Wound management

The foundation of any management plan, which should be devised in collaboration with the patient wherever possible, is to treat the underlying wound aetiology. This is supplemented by local wound treatment, which includes adequate preparation of the wound bed to accelerate healing (Wiegand et al, 2011). A wound bed that has not been prepared for healing with thorough cleansing and debridement (Mahoney, 2020) will most likely contain slough, devitalised tissue and biofilm, and produce a high volume of exudate (WUWHS, 2019), making it hard to heal. Wound debris such as pus, slough, extracellular products, biofilm and exudate must be removed, as these provide an ideal medium for microbial growth (Edward-Jones and Flanagan, 2013).

## Role of dressings

Dressings alone do not heal wounds, but, rather, help to provide an environment that is conducive to healing (Browning, 2014). Importantly, they also help promote patient comfort and quality of life (Romanelli and Weir, 2014). Dressings are still the mainstay for the management of wound exudate. The WUWHS (2019) consensus document on exudate provides guidance on the types of dressing that can be used to manage moderate-to-high volumes of exudate, namely, those with alginate, carboxymethylcellulose (CMC), foam and superabsorbent polyacrylate (SAPs) as the main ingredients. These absorbent dressings should be able to prevent leakage and increase wear times to protect the wound bed and peri-wound skin. The dressing should conform to the wound bed, be comfortable and, as a result of exudate absorption, help to reduce any malodour. This will avoid disturbing the wound healing process (Rippon et al, 2015) and reduce the potential for distress and pain at dressing change (Solowiej and Upton, 2012).

## Superabsorbent dressings

Superabsorbent (SAP) dressings have a greater absorption capacity than traditional foam dressings, whose fluid handling capacity can be suboptimal (Hughes and Jones, 2017), particularly under compression, allowing leakage of exudate and resulting in maceration (Schulze et al, 2001). SAPs, with their high fluid retention capacity, can be a useful adjunct under compression when a venous leg ulcer is heavily exuding, causing strikethrough between dressing changes. SAPs can maintain fluid-retention capacity under compression, while also providing additional cushioning (WUWHS, 2019). Although increased wear time is important (particularly during the COVID-19 pandemic), this should not be the primary driver. If, for example, the wound is infected or the patient is in pain or distressed, the dressing must be reviewed. Nonetheless, this must be balanced with the need to consider the importance of undisturbed healing (Rippon et al, 2015), and reducing the number of painful dressing changes (Docking et al, 2018).

SAPs also help reduce the concentration of inflammatory cells in the wound bed, as they can bind wound exudate and lock it within their core due to their wicking action (Faucher et al, 2012; Jones and Barraud, 2013). In this way, the unwanted components of exudate—bacteria, proteases and inflammatory mediators—are trapped, which inhibits microbial growth (Wiegand et al, 2011) and reduces MMPs levels, as well as avoiding potential leakage and the associated risk of maceration. Therefore, they provide

a moist wound environment conducive to wound progression and healing.

## Kliniderm superabsorbent dressing

Kliniderm superabsorbent is a dressing that can be used as either a primary or secondary layer. It is indicated for the control and removal of excess exudate in moderately to heavily exuding acute and chronic wounds. Due to its ability to handle MMPs and sequester bacteria in chronic wound exudate (Westgate and Thomas, 2016), it is classed by the Drug Tariff as both a protease modulator and a superabsorbent dressing. Kliniderm superabsorbent is easy to use and, due to its low profile, can be applied under compression bandaging. Its high absorbency can result in fewer dressing changes being required, which is beneficial to wound healing, the patient experience and NHS costs (Wicks, 2017; Barrett et al, 2020).

Kliniderm superabsorbent dressing has a four-layer construction, with a hydrophilic wound contact layer, an intermediate layer, an absorbent core and a fluid-repellent backing layer, which is held together with a hypoallergenic seal, removing the risk of reactions to the glue used. It has the capacity to absorb large amounts of exudate and hold it within its core, preventing transfer of fluid back onto the peri-wound skin, thus reducing leakage, maceration and irritation (Barrett, 2015; Stephens, 2020).

## Case studies

### Case study 1

This case concerns a 95-year-old woman with wet wounds on both legs. The treatment and outcome for each leg is described in turn here.

The patient presented with a high fluid loss from multiple leg ulcers on her left leg (*Figure 1*). She had a history, of several years' duration, of painful leg ulceration (the self-reported pain score was 7 out of 10), involving hyperkeratosis throughout the lower left leg. She also had osteoarthritis and walked using a Zimmer frame. Previous treatments included topical steroid therapy for dermatitis and hydrofibre dressings covered by silicone foam, orthopaedic wool padding and light bandaging. Daily dressing changes were required to avoid strikethrough. The patient lived in a nursing home but was able to care for herself almost independently.

The leg ulcers were assessed by a tissue viability consultant, who undertook a Doppler assessment and ankle brachial pressure index (ABPI), with a score of 0.5. This, combined with the presence of leg pain, precluded the use of compression therapy as the ulcers were of mixed aetiology, confirming the vascular assessment made 8 months previously. The patient declined referral for further vascular investigation. The constant exudate had caused maceration and dermatitis, and the daily dressing changes added to the patient's pain and discomfort. The aim was to manage the exudate, reduce pain and eventually heal the wounds.

Given the multiple number of ulcers present (*Figure 1*) and the discomfort caused by the dermatitis, it was not possible to measure the wounds. The main wound was over the lateral malleolus, but the dermatitis was circumferential from below the knee to the foot. The wounds were all 100% sloughy. The patient's quality of life was affected due to the pain, which was severe, in addition to the malodour. She was concerned that the odour would upset her family when they visited.

Following assessment, the patient's leg was cleansed with antimicrobial fluid, and an emollient was applied. The leg was then dressed with Kliniderm superabsorbent dressings. The dressing-change frequency decreased from daily to three times a week in the first 7 days, at the end of which time the pain score had reduced from 7 to 4. The maceration had reduced and the dermatitis was not as red, although some hyperkeratosis was still present (*Figure 2*). There had been no occurrences of strikethrough due to the dressing's efficient exudate management, unlike previous dressing regimes.

The dressing was changed twice during the second week of treatment. After 2 weeks, the maceration and dermatitis had improved further, the pain score had reduced significantly and was now 2, and the surrounding skin and wound appeared healthier. The Kliniderm superabsorbent dressing protected the skin by absorbing and retaining the exudate. Once-weekly dressing changes were now required due to the effectiveness of Kliniderm superabsorbent in managing the exudate. The emollient therapy also continued for 4 weeks.

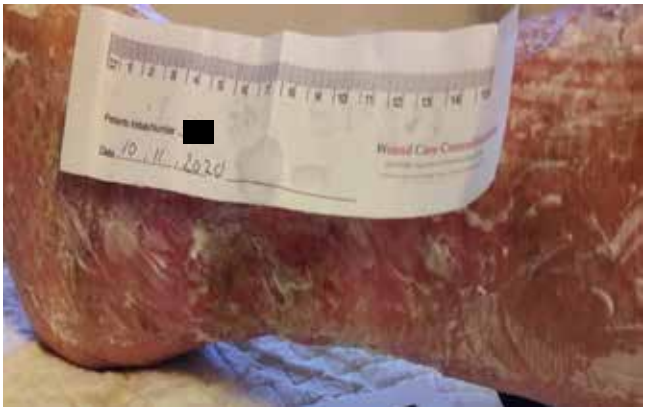

**Figure 1.** Case 1 (left leg): The leg is very wet from dermatitis and maceration.

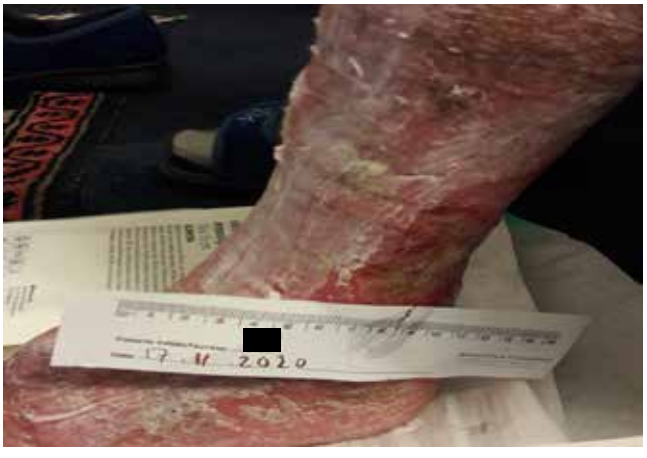

**Figure 2.** Case 1 (left leg): Day 7 of treatment with Kliniderm superabsorbent.

The dressing was comfortable and absorbed all the fluid between dressing changes. There was no pain associated with the dressing, either in removal or when in situ.

The patient was able to see her visitors with confidence, as any fluid loss was never visible and the odour had disappeared by week 2.

This patient's right leg was also affected by ongoing fluid loss, which was due to inflammation from the dermatitis, but this was due solely to dermatitis and involved a much smaller area (*Figure 3*). The leg was extremely painful (the self-reported pain score was 8 out of 10) and constantly wet due to the dermatitis. Again, the previous treatment had comprised steroid therapy and hydrofibre dressings, a silicone foam, padding and light bandaging, but these failed to manage the dermatitis and relieve her pain, resulting in the skin becoming sore and breaking down following contact with the proteases in the exudate. The ABPI for this leg was also 0.5. The wounds were from mid-calf to the toes.

The patient was assessed by a TVN consultant, who applied a zinc paste bandage containing 63% oxide BP and 2% Ichthammol on the affected skin, and Kliniderm superabsorbent was used to absorb the excess fluid. Ichthammol provides a moist wound-healing environment, helps to reduce skin irritation, soothes and protects the surrounding skin and is used in the management of leg ulcers and to treat chronic eczema and dermatitis.

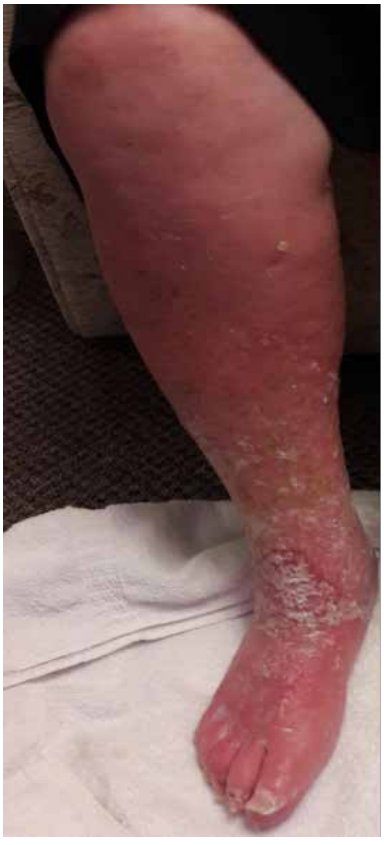

**Figure 3.** Case 1 (right leg): At presentation. The leg is very wet and painful.

The dressing was changed twice weekly; there was no strikethrough at dressing changes. As the skin was no longer coming in contact with the exudate, its condition improved, and the dermatitis settled.

After 2 weeks of treatment with Kliniderm, the dermatitis had cleared completely, and the pain score reduced to 2 (*Figures 4* and *5*). By week 3, the leg was completely dry. The ulcer continues to heal.

**Figure 4.** Case 1 (right leg): By week 2, the wounds are almost completely dry and healing. Icthopaste treatment continues, and pain is no longer a problem.

**Figure 5.** Case 1 (right leg): By week 2, the leg is looking healthier and is healing: there is no dermatitis or pain, and the skin looks healthy.

## Case study 2

An 82-year-old woman had a wound on the left lateral malleolus that had developed while she was lying in bed (she constantly lay in bed in the same position at night). Her GP and practice nurse had diagnosed and treated the wound as a leg ulcer (*Figure 6*) and not a pressure ulcer, and she was advised to keep her legs elevated. This is a common misdiagnosis but its round shape and location over the ankle bone is indicative of pressure injury. Although elevation was helpful, the single most important advice for this wound should have been to remove the pressure through offloading. The patient lived in her own home and was fairly independent, despite having limited mobility.

The patient had some mild oedema in her left foot, which was not related to heart disease (confirmed by her GP). The wound was malodorous and painful (colonised but not clinically infected), but she continued with her everyday activities and pastimes, in an attempt to prevent her wound from impairing her quality of life.

The patient used a Revitive machine, which is designed to improve circulation by stimulating the muscles in the legs and feet with professional-strength electrical muscle stimulation. For this reason, she did not want her foot to be covered with bandages. A double layer of blue line tubular bandage, positioned from toe to knee, was used to support the prescribed dressing, which was a hydrofibre dressing and a foam dressing with a silicone border.

The patient's daughters undertook a 60-mile round trip to take her to the local practice nurse for the twice-weekly dressing changes required to avoid strikethrough. The woman was independent but relied on her daughters for transport.

The GP practice referred the patient to a TVN consultant. Doppler and an ABPI assessment revealed a result of 0.65, which is indicative of peripheral arterial disease. The pulse was bi-phasic. The capillary refill time was slow, at 4 seconds, but the foot was warm to touch, indicating that there was still a good blood supply. The patient's self-reported pain score was 8 out of 10. The peri-wound area was red due to contact with proteases in the wound exudate. Proteases are enzymes that damage skin cells and 'burn' the skin. The nurse consultant diagnosed the wound as a category 3 pressure ulcer, and following conversation with the patient, concluded that it had resulted from her lying still in bed for long periods on her left side. There was an element of arterial disease, which would increase the potential for pressure injury over the feet. Her skin elsewhere was not showing signs of pressure injury.

To address the underlying aetiology, the patient was advised not to lie on her left side. To avoid this, she placed a pillow under her back when in bed to stop her from rolling onto her left side.

The wound was round, which is common for pressure ulcers over the malleolus, due to the shape of the bony prominence beneath. It was 100% sloughy and was classified as a category 3 pressure ulcer measuring 4.5 cm in diameter.

The patient was distressed that she could no longer lie on the side that was most comfortable but was informed that if she continued to expose it to pressure, the wound would not heal. She was provided with a foam dressing for the right lateral malleolus (the non-injured foot) and was advised to try to keep that ankle for any pressure.

The decision was made to switch from foam to superabsorbent in order to control the exudate and to provide more padding over the malleolus. The wound was dressed with Kliniderm superabsorbent (*Figure 7*). The first dressing change took place after 1 week, at which point the peri-wound skin looked healthier (*Figure 8*), and the patient's self-reported pain score reduced from 8/10 to 5/10. The redness had disappeared. The circumference of the wound remained at 4.5 cm, but the wound bed was filling. The wound had approximately 95% slough, but the granulation was showing through. The wound was cleansed with an antimicrobial cleansing solution, as it was too painful to

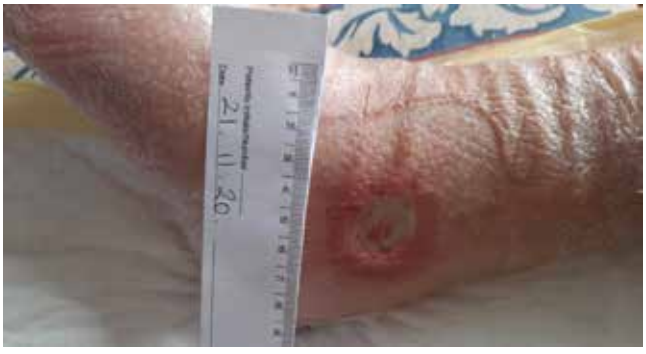

**Figure 6.** Case 2: The wound before Kliniderm superabsorbent was first applied: its edges were painful with surrounding redness due to the pressure. The wound was sloughy and classified as a category 3 pressure ulcer.

**Figure 7.** Case 2: After 1 week. Kliniderm superabsorbent (the dressing is held by the patient).

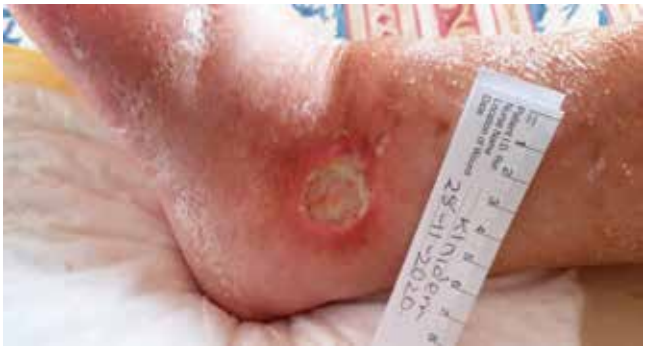

**Figure 8.** Case 2: The skin is no longer painful as the dressing has absorbed and retained the exudate.

debride with a monofilament pad. It is not known whether an antimicrobial cleansing solution was used previously.

At the next dressing change, 1 week later, the patient's pain had reduced to 2 out of 10. The wound was no different in width or in the amount of slough, but the wound bed continued to fill. The patient was delighted to be almost completely pain-free and no longer had to ask her daughters to take time off work to drive her to her local GP for the dressing changes, as the specialist TVN visited at home weekly in order to change the dressing and monitor the wound.

There were no obvious signs of distress on the patient's part, but her daughters were very obviously concerned. The wound did not heal in the evaluation period but continues to slowly heal.

## Case study 3

Mrs K is a 79-year-old woman with two long-standing, recurrent ulcers on the right leg in the gaiter area due to venous disease. She has had these wounds for many years, too many for her to remember, and the one in the present case had recurred 6 months previously. Mrs K is married with two children and six grandchildren, all of whom visit regularly; they are concerned for her welfare and care for her. Her husband had a stroke, but she finds it difficult to cope due to her leaky and ulcerated legs and, although she attended clinic 3 times a week, there was still strikethrough on her bandages at each dressing change. Mrs K worked at a newsagents part-time, for 15 hours a week.

She also finds it difficult to socialise, as she is always concerned that fluid will come through her bandages, causing, as she states it, 'a snail trail across my friend's floor'. She changed her dressing daily in order to cope with the heavy fluid loss.

Mrs K needs to continue to work and is limited by the leg ulcer. She is obese, a non-smoker and is otherwise generally quite healthy. Her leg was dressed three times weekly in the clinic, and her daughter changed the dressing on the days she was not at clinic and on days when the exudate was not held by the dressings. The dressings were hydrofibre held in situ with orthopaedic wool and retention bandage.

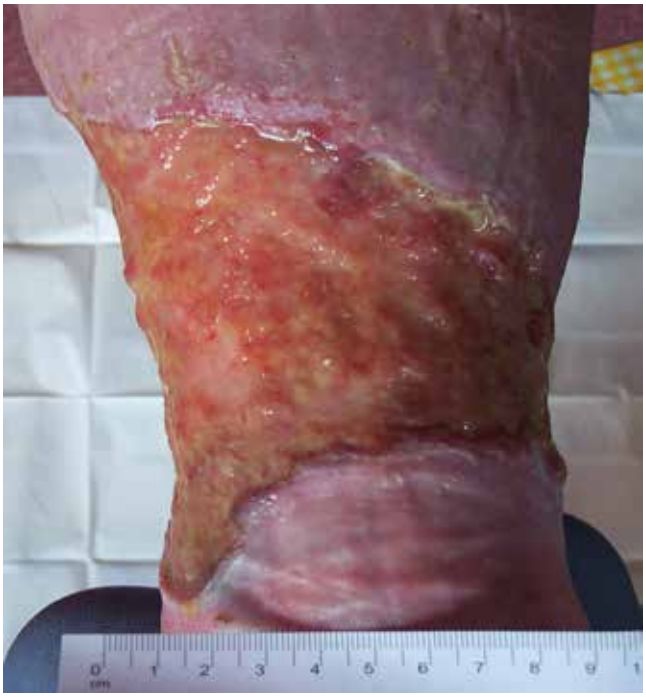

**Figure 9.** Case 3: The 100% sloughy wound at presentation, with a slimy biofilm.

The wound almost circumnavigated the gaiter area, was 100% sloughy and malodorous due to colonisation (*Figure 9*). It was not considered possible to use Doppler to calculate the ABPI, as the presence of oedema might have caused inaccurate readings. There was difficulty in assessing whether the size of the limb was due to lymphoedema, oedema or obesity. Stemmer's sign was negative, so this was not thought to be lymphoedema, and there was no pitting oedema. Therefore, the large leg was thought to be a combination of venous oedema and obesity. However, her foot was warm to the touch, and capillary refill was brisk. ABPI had been assessed 6 months previously and was well within normal limits at that time (1.2 for the left leg and 0.9 for the right leg), which would suggest Mrs K was suitable for compression therapy. However, it should be remembered that arterial disease can be progressive and the ABPI measurement should be attempted once there is a reduction in oedema.

Mrs K's obesity was partly responsible for the problem of non-healing (Gates et al, 2005), but she was unwilling to listen to advice about weight loss as she felt she had 'enough to worry about with a sick husband.'

The aim of treatment was to reverse the venous hypertension and, thus, reduce the oedema, while managing the wound fluid loss that was of such great concern to the patient. In order to do this, and in light of previous vascular assessments, a short-stretch compression bandage was applied from toe to knee with a 50% overlap and, due to an ankle circumference measurement of over 25 cm, a second short-stretch bandage was applied in the opposite direction, from ankle to knee (Williams, 2002). Applying two layers on a large limb ensures that the pressure applied by the bandages is at a therapeutic level.

It was also necessary to use a dressing that was capable of managing the high levels of exudate. This required a superabsorbent dressing. Kliniderm superabsorbent was selected, as it had been shown to be effective under compression bandaging (Stephens, 2020). It was used as a primary dressing.

Mrs K was reassessed by the TVN at 3 days, then 6 days and then weekly for a further 3 weeks. Exudate was managed extremely well, with the dressing retaining any excess fluid. At the start of the treatment, the wound was obviously covered by a biofilm in 100% slough. This was indicated by the slimy appearance of the wound. Although it appeared superficial, it actually sloped to a fairly deep level, which was impossible to measure. The wound progressed at each visit, with slough visibly reducing gradually until the final wound assessment (*Figure 10*), when there was 100% granulation and no odour or pain. The depth seen in centre of *Figure 9* had filled level with the skin surface, indicating a wound in an excellent healing state. Further, the surrounding skin had not been too problematic at the beginning of treatment, but had certainly improved by the final visit, although there was no reduction in oedema.

Following the initial assessment, the dressing changes went from daily, to twice weekly after the third visit and then

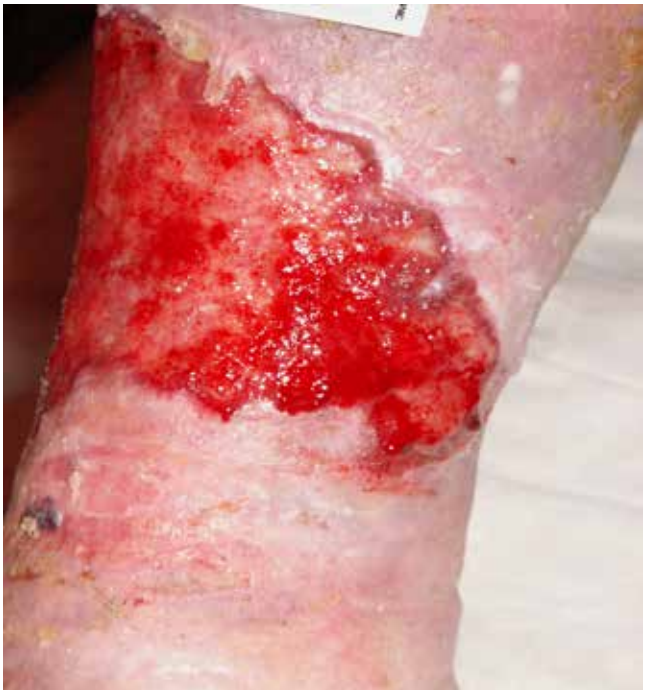

**Figure 10.** Case 3: After 4 weeks of treatment with Kliniderm, the ulcer was clean and healing.

weekly. Any pain associated with the wound had disappeared. Mrs K found the dressings comfortable, and the Kliniderm superabsorbent did not feel bulky even after absorbing fluid for over a week. She was completely free of any pain associated with dressing change.

Mrs K tolerated the compression very well and, although the wounds had never been very painful (the pain score remained at 0), the legs had previously felt heavy and uncomfortable, but she said that this discomfort had gone.

After 4 weeks, the ulcer was clean and healing (*Figure 10*). There was 100% granulation, with fluid loss being greatly reduced. There was no reduction in the size of the limb, which confirmed that the large leg was due to obesity rather than oedema. Her quality of life improved, and she was able to see her friends and to slowly return to work at the newsagents, although the number of hours per week was reduced to 10.

With the use of Kliniderm superabsorbent dressings and compression, fluid loss was minimised, so that dressing change was required only weekly instead of daily, and she was able to visit her friends without fear of oozing on their floor. The reduction in fluid loss was possibly largely due to the compression, but the Kliniderm superabsorbent dressing supported this by reducing the potential to leak so that the compression could be maintained. There was no discernible odour at this point.

It is not always the healing that is the patient's problem; pain, fluid loss and odour can cause stress, which is a physical reaction that reduces the lumen of the arterioles, which in turn reduces the amount of oxygen and nutrients available to the wound. When the stress is reduced, the wound is more likely to heal (Gouin and Kiecolt-Glaser, 2011). The treatment made it easier for Mrs K to care for her husband, as her walking improved and she spent less time having her dressings changed.

The improvement in her wound was due to compression and absorption of fluid, which increased her confidence to go out more and mobilise. She said she was delighted to be 'back on the scene!'

## Conclusion

Chronic or hard-to-heal wounds are on the increase largely due to changing demographics and complexity of patients and their wounds. We are increasing our understanding of wound healing and the major factors impacting on their ability to heal in often exceedingly difficult and challenging circumstances. For the patient this can often translate to living with wounds that are wet, malodorous, and painful, adversely affecting their quality of life.

Exudate remains one of the main challenges for health care professionals in managing wounds particularly in the community where visits must be planned in advance. Health care professionals and patients need to have confidence in the capability of the dressings selected since dressings remain the mainstay of exudate management, together with management of the aetiology. Superabsorbent dressings play a vital role in the management of moderate to highly exuding wounds.

All three patients whose cases were presented agreed that the levels of exudate had reduced with the use of Kliniderm superabsorbent, and that, when odour had been present, the superabsorbent dressing had controlled it. They felt more confident about socialising. **CWC**

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# Cost-effective management of wound exudate

This clinical evaluation explores the complex challenges involved in managing exudate as part of a holistic wound treatment plan. The benefits of using Kliniderm® (Aria Medical) superabsorbent dressings for patients, nurses and the National Health Service (NHS) will be explained in this article. Quality and cost-effective outcomes will be considered, comparing the test dressing to two well-established Trust formulary superabsorbent dressings. As part of the evaluation, a simple questionnaire assessed nine dressing changes per patient and established feedback that reflected positively in favour of the Kliniderm superabsorbent dressing. A cost analysis was done by comparing data collected over a 3-month period during which Kliniderm superabsorbent dressings were not used with data compiled over 3 months during which only the test dressings were used.

*"Superabsorbents have been designed for managing wounds with high levels of exudate. They have a greater fluid-handling capacity than traditional dressings, requiring less-frequent changing."*

SIMON BARRETT
*Tissue Viability Lead*
*Humber NHS Foundation Trust*
*East Riding of Yorkshire*

The National Health Service (NHS) continues to seek cost-effective treatments, while striving to maintain the standard of care offered to patients in the UK. This general goal also applies to the field of wound care.

Leg ulcer patients whose wounds produce exudate, causing malodour, often express feelings of disgust, self loathing and low self esteem (Herber et al, 2007). The mismanagement of exudate can lead to excoriation, maceration, increased pain, infection and, ultimately, skin breakdown or a further increase in wound bed size. Wound exudate can cause anxiety and distress to patients of all ages undergoing treatment for a wound. When considering treatment options, there is the human cost to consider, as well as the cost to the NHS. Traditionally, we may have looked at unit cost when trying to make financial savings in the way that we deliver wound care. This is potentially a false economy if the suitability of wound care products for inclusion on a Trust formulary is not evaluated.

Ideally, when choosing a product that may have a lower unit cost than the one currently being used, the focus is also on its performance — it would be expected to perform as well as, if not better than, the previous product. In the case of exudate management, it would be ideal if the product absorbed the exudate, locked it in, were comfortable for the patient, conformable, easy to apply and remove, and had a long wear time.

It is essential that wound exudate be managed effectively. To achieve this, it is neccesary to spend time assessing the patient, their social circumstances and the wound bed. It is also crucial to develop a patient-practitioner relationship. This will let the clinician make a diagnosis on which to base an

effective treatment plan that meets the patient's needs, as well as the treatment challenges posed by the wound bed.

### What is exudate?

Wound exudate is fluid that has leaked out of the blood vessels and closely resembles blood plasma. It contains molecules and cells that are vital to the wound healing process, including:

- Electrolytes
- Nutrients (glucose)
- Proteins (cytokines)
- Inflammatory mediators
- Matrix metalloproteinases (MMPs)
- Growth factors
- Various cell types, such as leucocytes, macrophages, neutrophils and platelets
- Microorganisms

(Cutting, 2004; White and Cutting, 2006).

### The role of exudate

Exudate is a vital part of wound healing. It prevents the wound from drying out and provides nutrients for all cell metabolism, which enables the migration of epithelial cells and the separation of necrotic tissue from the wound bed by autolysis (World Union of Wound Healing Societies [WUWHS], 2007).

### Management of exudate

Over 50 years ago, George Winter (1962) produced a paper on moist wound healing. Since this work, it has been established that moisture control is critical to the management of wounds. Yet, despite increased knowledge in this area, it is common for clinicians continue to change dressings many times a day to manage the level of exudate produced by a wound over a 24-hour period.

### Exudate assessment

The assessment of exudate forms a vital part of any wound evaluation (Ousey and Cook, 2012). A correct assessment requires observation of the wound bed, closely examining the exudate using the following factors:

- Colour
- Consistency
- Odour
- Amount.

It is also crucial to measure the exudate volume, using the following characteristics (WUWHS, 2007):

- Dry
- Moist
- Wet
- Saturated.

### Managing exudate

It is critical to establish an underlying cause for the exudate before attempting to manage the wound's exudate levels. The appropriate use of dressings is the responsibility of the clinician until treatment of the underlying cause is addressed. Conditions that may lead to excessive wound exudate are as follows:

- Lymphoedema
- Venous ulceration
- Congestive cardiac, hepatic or renal failure
- Obesity
- Malnutrition
- Surgery
- Fungating wounds
- Infection.

Clinicians must work as part of the multidisciplinary team to address, where possible, the above conditions to reduce excess exudate and manage the wounds more appropriately.

The ideal dressing for managing wounds with exudate should have the following qualities (Adderley, 2008; Stephen-Haynes, 2011):

- Highly absorbent
- Ability to lock away exudate
- Ability to prevent maceration/ excoriation of the periwound skin
- Ability to use under compression bandaging without being bulky
- Ability to minimise trauma and pain at removal
- Comfort and acceptability to the patient
- Conformability to the wound site
- Cost effectiveness.

### Superabsorbents

Superabsorbents have been designed to manage wounds with high levels of exudate. They have a greater fluid-handling capacity than traditional dressings, requiring less frequent changing (Tadej, 2009). The ideal dressing will remove excess exudate from the wound site and surrounding skin while maintaining high humidity in the wound bed (Bale, 1997).

Superabsorbents may vary in ability to absorb and retain fluid, and function under compression. Some superabsorbents can lock fluid and bacteria in the dressing. They are cost effective, due to their enhanced fluid-handling capacity and their absorbency designed for longer wear times and reduced maceration (Wicks, 2012).

Kliniderm superabsorbent consists of four layers: a hydrophilic wound contact layer; an absorbent core; a fluid-repellent backing layer; and an ultrasonic seal that removes the risk of reactions to the glue used.

The key benefits of using the test dressing are as follows:

- Savings of up to 73% on the unit cost, depending on the superabsorbent currently used (National Health Service Business Services Authority, 2015)
- Excellent absorption properties compared with other superabsorbent dressings (Biomedical Ltd, 2015).
- Rapid fluid intake
- Reduces the risk of maceration and excoriation to periwound tissue
- Can be used under compression
- Minimises fluid strikethrough
- Hypoallergenic (no glues or adhesives as the edges have an ultrasonic seal to keep the super absorbent in the centre)
- Easy to use
- Available in a range of sizes and varying shapes. It does not come in an adherent version at the point of going to press.

### Cost analysis

To assess the financial impact of making a product switch, it is important to

consider the unit cost and the quantities of the dressings used. It would be inappropriate to use a slightly less-expensive dressing that resulted in more frequent dressing changes because it was not be able to manage the exudate levels produced by the wound bed.

There are many products on the market that claim a health-economic benefit to NHS organisations by justifying a higher unit cost as a trade-off for increased wear time that could reduce the number of nursing contacts required. This might show an overall benefit to a dressing switch. Effectively using such dressings would rely upon nurses following the product guidance and not changing the product too frequently, out of habit.

After evaluating the Kliniderm superabsorbent product and including it on the Trust formulary, the author was able to compare the quality of the test dressing with the superabsorbent currently normally used. The team examined the unit cost as a like-for-like switch and also the total expenditure, looking at the volumes of dressings through an online non-prescription ordering system (ONPOS).

Before the evaluation, the team were concered that the low unit cost may equate to reduced quality, resulting in more nurse contacts if the product did not perform as well as the superabsorbent dressing normally used. The previous expenditure on superabsorbent dressings over a 3-month period totalled £61,372.06. After making the formulary switch to the Kliniderm superabsorbent, the amount spent on superabsorbents over the following 3-month period was £21,366.77. This represents a saving of 65.18% and would result in an annual Trust saving of £160,021 (ONPOS data, 2014-15).

The worry remained that the significant reduction in expenditure may have a negative effect on increasing the nursing contact visits. When looking at the 3 months before the switch, the team used 22,235 superabsorbent dressings; during the following 3 months that the test product was used, 16,475 dressings were used (ONPOS data, 2015). This is a decrease of 5,760 dressings used over a 3-month period, equating to a 26% reduction in dressings used.

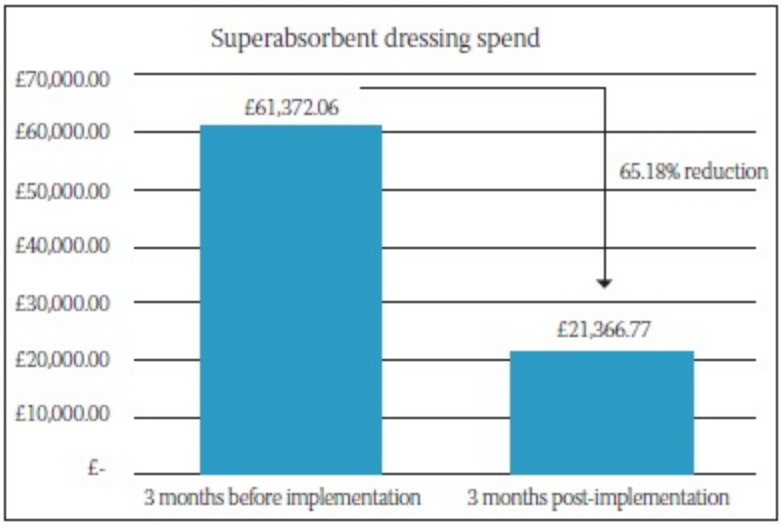


*Figure 1.* ***This figure shows a 65.18% reduction in cost over a 3-month period when the test dressing was used.***

If a community nurse contact costs £39.00 per patient visit (Curtis, 2014) and the wound needed to be redressed as frequently as the number of dressings supplied, this would save the organisation an additional £898,560 per annum in nursing costs. This value would not represent a true saving, as the nurses would still be employed and providing other services. It may also be the case that the patient would have more than one dressing applied during each visit.

## Aim

A decision was made to evaluate the test dressing with a view to including the product on organisation's wound Formulary if it performed well both clinically and financially when evaluated on patients over a maximum of nine applications and compared with existing Trust superabsorbents, namely Sorbion® (H&R Healthcare) and Flivasorb™ (Activa Healthcare). The trigger for the evaluation was the Trust's increasing spend on superabsorbents.

The organisation had provided training on appropriate product selection and cost-effective use of products post-holistic assessment, yet the spend on superabsorbents has continued to escalate beyond a figure of £200,000 per year. This was not sustainable within the current dressing budget.

## Method

The evaluation process took place in Humber NHS Foundation Trust community care setting. The product was evaluated for a maximum of nine applications on 30 patients, replacing the superabsorbent product currently being used. The only variable to the existing treatment plan was the introduction of the test dressing.

For the evaluation, 30 forms were completed. Sixteen patients were male; 14 patients were female. Oral explanation of the evaluation was provided to the patients. Consent was gained and documented in the nursing notes. The local investigators were informed of the reason for the evaluation and the product properties when considering application to appropriate

patients. The evaluation was approved by procurement and members of the clinical network team representing the Trust's tissue viability network. In accordance with local Trust policy, appropriate information was provided for the correct use and disposal of the dressing.

A product evaluation form was used to gather information on the test dressing in comparison to the superabsorbent dressings currently being used. Information was gathered with regards to the following:

- Age
- Gender
- Care setting
- Relevant medical history
- Relevant medications
- Wound type
- Primary dressing
- Wound characteristics, including duration, wound size and level of exudate
- Current treatment aim.

The evaluation form then allowed for documentation over the nine applications to consider the following:

- Patient comfort (with dressing *in situ*)
- Ease of product application
- Ease of product removal
- Conformability to wound
- Ability to manage exudate
- Improvement in condition of the wound.

This was done by the following scoring system of 1–5 comparing it to the existing product for each patient: 1 = very poor; 2 = poor; 3 = average; 4 = very good; 5 = excellent.

There was then a question on how it was thought the dressing compared to the existing product overall. The options were 'worse', 'equally' or 'better'. The evaluation then asked the clinician to answer 'yes' or 'no' as to whether they would recommend the product for inclusion on the

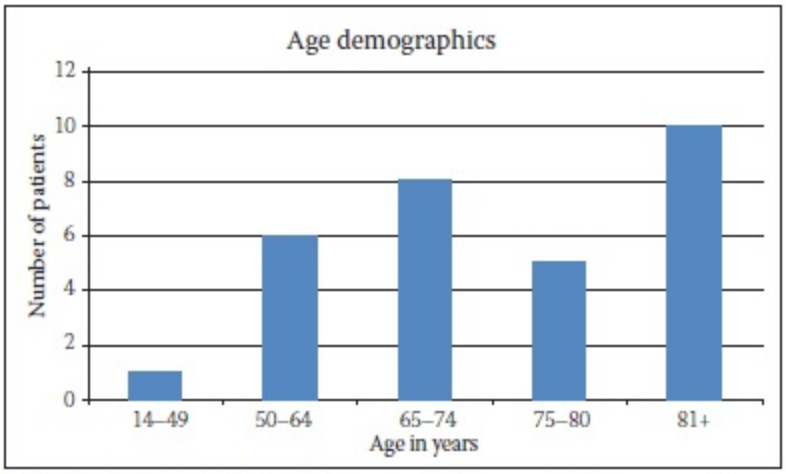


*Table 1.* ***The table indicates that people of 81 years and older are most likely to suffer with a wound that has exudate as a significant issue, requiring management using a superabsorbent or foam dressing.***

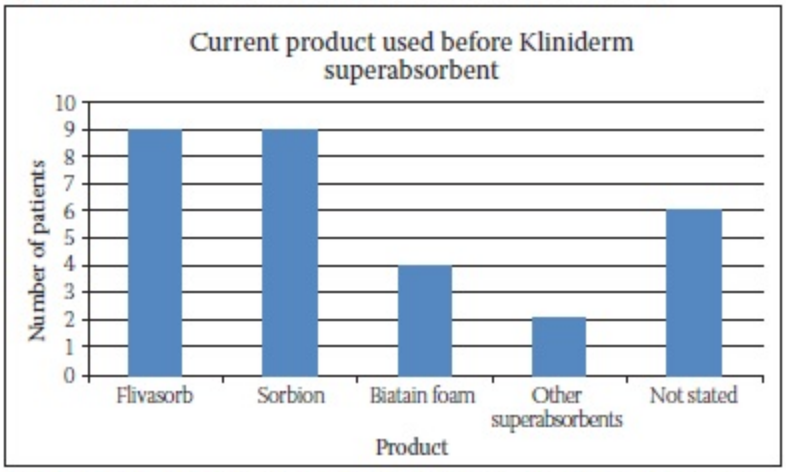


*Table 2.* ***The table indicated an equal usage on this cohort of patients on Sorbion and Flivasorb.***

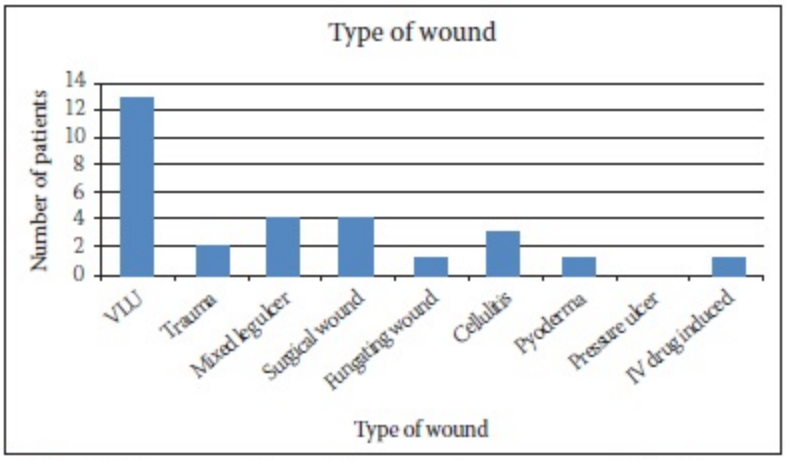


*Table 3.* ***Of the 29 wound types documented, 13 were recorded as being venous leg ulcers (VLUs).***

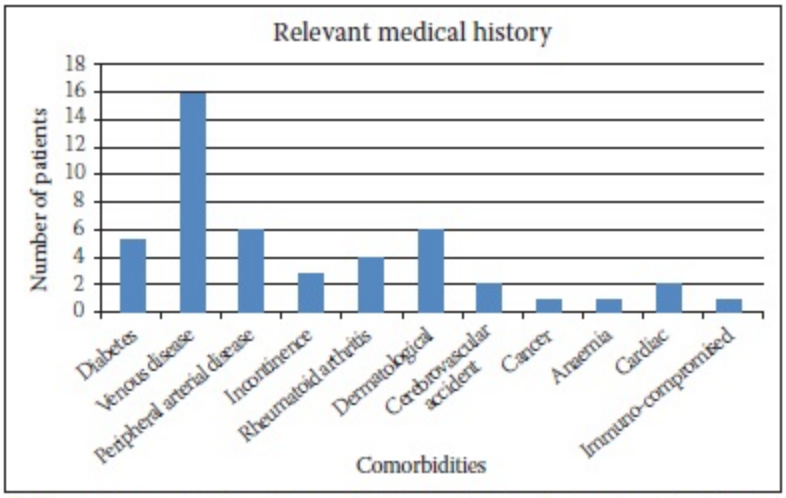


*Table 4.* ***There are 47 listed co-morbidities, indicating that each patient has 1.5 or more, with venous disease being the most frequently documented.***

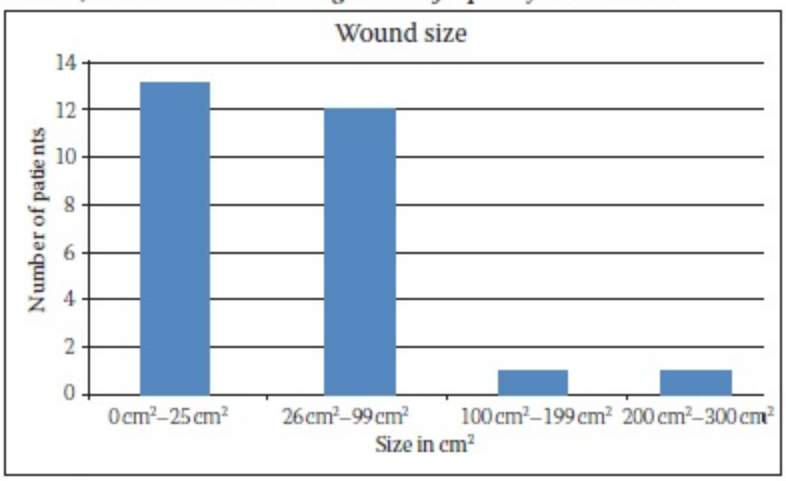


*Table 5.* ***There were 27 documented wound sizes, the vast majority being less than 100 cm2 (10x10 cm). All the wounds were documented as being 1cm in depth or less, except one documented having a depth of 5 cm.***

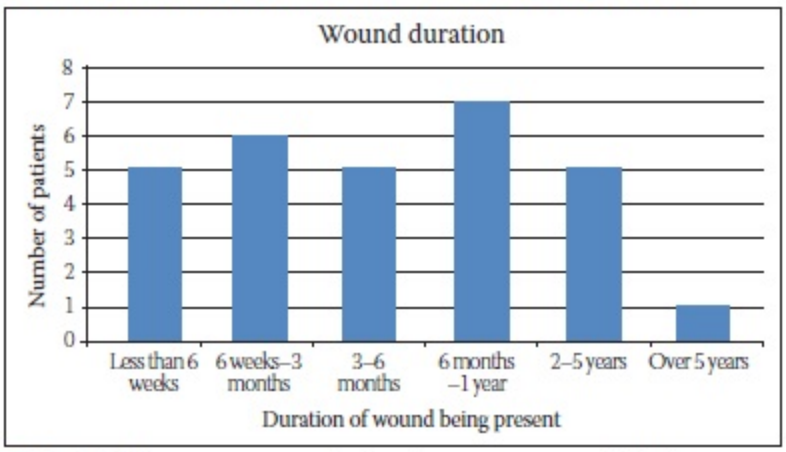


*Table 6.* ***Of the 29 responses, each duration category was similarly populated, except over 5 years.***

formulary. There was also a section for any other comments.

## Results

The patients were selected randomly from five centres within Humber NHS Foundation Trust, and all had exudate management issues. The patient demographics are summarised in *Table 1*. All 30 patients completed the evaluation. The only discontinuation of treatment was for wounds that healed prior to the nine dressing changes.

*Table 2* indicates that the Flivasorb and Sorbion superabsorbents were the most commonly used products in the 30-patient evaluations, before the switch to Kliniderm superabsorbent for the comparative evaluation.

*Table 3* shows that venous leg ulcers were the most prevalent wound type the Kliniderm superabsorbent was used on, in combination with compression therapy where safe and appropriate.

*Table 4* demonstrates that the patient group had one or more co-morbidities, the most prevalent being venous hypertension. There were also a significant number of patients with peripheral arterial disease, diabetes and dermatological conditions which, in fact, are linked to increasing age. In fact, the most prevalent age category was 81+ years, comprising 33% of the patients.

*Table 5* shows that over 80% of all the wounds documented were less than 99 $cm^2$ (i.e. 10x10 cm dressing size). This might be an interesting indication for stock ordering of dressings, or it may be sometimes wrongly assumed that wounds are generally much larger.

*Table 6* highlights a largely even spread of wound duration between less than 6 weeks and up to 5 years.

*Table 7* shows that, of the wounds included in the evaluation, 26 out of 30 had moderate to highly exuding wounds, indicating the appropriate use of the superabsorbent product in those cases.

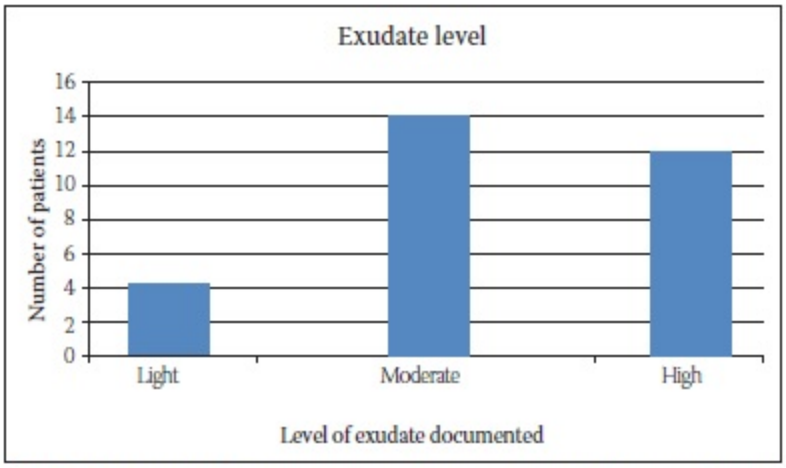


*Table 7.* ***The number of responses was 30, the vast majority being moderate to highly exuding wounds.***

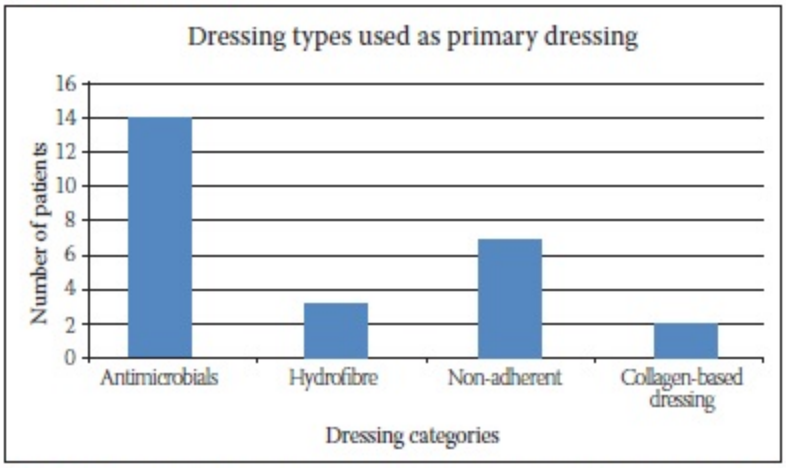


*Table 8.* ***There were 30 responses; 4 of these responses did not use a primary dressing under the existing product.***

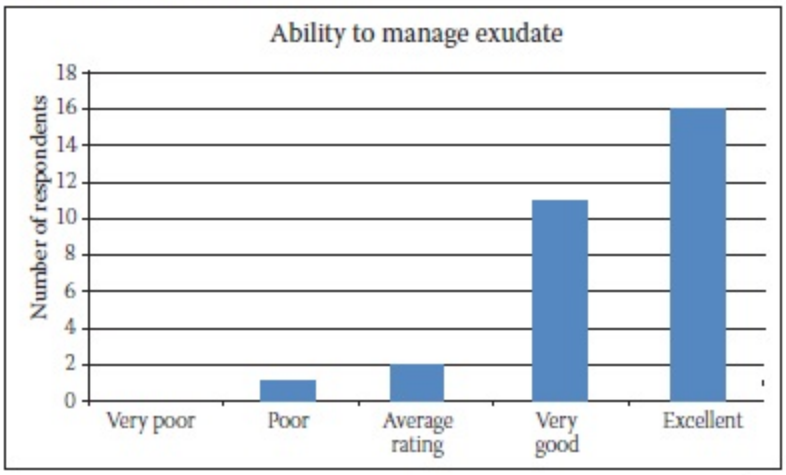


*Figure 9.* ***Of the 30 responses from practitioners, 27 rated the test dressing performance as 'very good' or 'excellent.'***

*Table 8* highlights that the practitioners have used primary dressings on 26 of the 30 subjects who took part in the evaluation. This may or may not be appropriate, as it may affect the absorbency effect of the dressings used.

*Table 9* shows that it was thought that the Kliniderm superabsorbent performance was 'very good' or 'excellent' in 27 of the 30 case evaluations. Interestingly, the ones who stated 'poor' (no = 1) or 'average' (no = 2) had only low levels of exudate. Thus, the issue may not have been the dressing but the clinician's skill in assessing and appropriately managing the wound using the right dressing for a wound with low levels of exudate.

*Table 10* indicates that there was an average to excellent improvement in the wound bed in 29 of the 30 evaluations. One evaluation scored 'very poor.' This may be an indication of the primary dressing's performance as opposed to the superabsorbent's performance.

Finally, 29 out of 30 evaluations would suggest that the Kliniderm superabsorbent performed as well, if not better, in the evaluation. Meanwhile, 28 out of 30 completed evaluations would recommend the product for inclusion in the Trust formulary. The clinicians were then asked to state whether they would recommend Kliniderm superabsorbent for formulary inclusion.

## *Summary*

The switch to Kliniderm superabsorbent resulted in less dressings being used, while maintaining wound management clinical outcomes. This represents an annual forecast in savings of £160,021, based on the 3 months of ONPOS data analysis.

It is the author's opinion that the test dressing has the potential to provide large-scale financial savings to the NHS without compromising the quality of patient and wound care based on the evaluations within Humber NHS Foundation Trust.

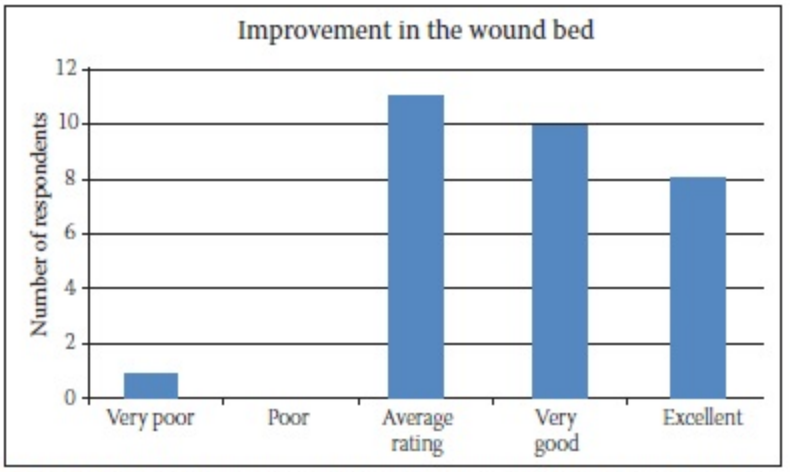


*Figure 10.* ***Of the 30 responses, 18 rated improvement in the wound bed as 'very good' or 'excellent.'***

## Recommendations for practice

Due to the success of the evaluation on an initial pilot of five patients, which was then extended to 30 patients, the organisation has added the product to the Trust Formulary as the first-line superabsorbent product. This has allowed the Trust to make significant financial savings in the first 3 months as stated in the cost analysis, without compromising the quality of care being delivered. It has also allowed the organisation to reconsider the number of nursing visits required to provide care. The Kliniderm superabsorbent has now been implemented into all base stock cupboards with the general feedback being very good, in the author's opinion.

## Conclusion

Exudate management is a critical part of any wound management treatment plan, while simultaneously attempting to maintain a moist wound healing environment.

The clinicians within the Trust need to continue to complete a holistic assessment of the patient, making a good quality treatment plan with clear aims and objectives that direct towards the correct and appropriate use of products that are on the Trust Formulary. According to the author, Kliniderm superabsorbent has proven, both in the evaluation, and latterly while on the formulary for the 3-month period, that it is cost- and quality-effective, and that it can and has enhanced the care provided in Humber NHS Foundation Trust. WE


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