Evaluation of a superabsorbent wound dressing, patient and clinician perspective: a case series

Objective: The primary objective of this study was to evaluate the fluid management capabilities of a superabsorbent wound dressing (Zetuvit Plus Silicone), with secondary objectives related to parameters that support whether the dressing enables undisturbed healing.
Method: This study was an open labelled non-comparative study. Patients included in the study were selected by the clinical investigator(s) according to whether the patient required a dressing for the management of moderately to highly exuding wounds.
Results: A total of 50 patients were included in the study. Results related to the primary objective demonstrated that the superabsorbent wound dressing was able to absorb all levels of exudate across the range (low to high). At each assessment time point these results show that in 98% of assessments the superabsorbent dressing was rated as 'very good' (91%) or 'good' (7%) at exudate management. Secondary objectives relating to wound bed preparation, healing and management of pain were also positive. Additionally, at the end of each patient treatment, the dressing's fluid management capabilities were rated overall as 'excellent' (100% of cases). There was little pain associated with the wound or at dressing change throughout the study and its flexibility/conformability allowed for comfort and patient satisfaction aligned with increased quality of life. Additionally, inclusion of a silicone adhesive layer allowed painless and atraumatic removal of the dressing, increasing patient comfort, both during wear and at dressing removal, and supported the description of enabling undisturbed wound healing.
Conclusion: The superabsorbent wound dressing achieved the primary objective relating to wound exudate management in all the assessments undertaken in this study. In addition, the silicone interface allowed for undisturbed healing as evidenced by little or no adherence of the dressing to underlying tissue, preventing damage to periwound skin. Overall, the superabsorbent wound dressing with the addition of the silicone interface could offer advantages over other superabsorbent polymer dressings (that might adhere to the wound surface) or silicone wound dressings (that might not have the absorbent properties of this type of dressing).
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exudate management • moderate-to-high exudate • pain reduction • superabsorbent wound dressing • wounds • Zetuvit Plus Silicone

Acute and hard-to-heal wounds present a variety of clinical challenges that must be overcome in order to achieve a successful healing outcome. These challenges include wound exudate control and undisturbed wound healing.

In terms of wound exudate control, primarily wounds 'leak' fluid (exudate). This may be blood from an acute traumatic or surgical wound, or it may be exsanguinous fluid originating from the interstitial tissue.

Wound exudate under normal circumstances is beneficial to wound healing in that it contains many components such as biochemical modulators, growth factors and cells, such as macrophages, that are intimately involved and beneficial to the healing process.[2,3] However, in some hard-to-heal wounds there is dysfunction and prolongation of normal phases and this can lead to further damage of tissue within and around the wound area by, for example, matrix metalloproteinase (MMPs).[4,5]

In most cases, the level of wound exudate may be minimal and can be managed effectively by simple dressings, such as gauze pads or foam dressings. However, in some wounds, exudate levels can be moderate or heavy.[1,6] This level of exudate must be managed in order to prevent adverse event sequelae, such as wound/periwound maceration or excoriation, that result from prolonged contact with exudate and the MMPs contained therein.[7,8] Leakage of exudate through or around a wound dressing can cause soiling of clothing, odour and discomfort for the patient.[1] This in itself can result in psychological stress that can have a negative impact upon the patient and their quality of life (QoL) and the healing process.[9]

A wound consists of friable tissues that are liable to be damaged by any undue external influences, such as excessive pressure, friction or trauma related to dressing removal.[10,11] Therefore, the clinician has to obviate

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Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion eriteria
● Aged ≥18 years ● Patient with any wounds that have moderate to high levels of wound exudate in need of management ● Signed consent form	● Aged <18 years ● Patients with known allergy/ hypersensitivity to any of the superabsorbent dressing components ● Patients who will have problems following the study protocol ● Patients with severe underlying disease(s) judged, by the investigator, to interfere with the study treatment

such events[11–,13] and many dressings are designed to protect and provide an optimal environment for the healing process.[14,15] In recent years, the ability of a wound dressing to provide not only physical and chemical characteristics conducive to healing, but also prevent further trauma to the wound and its newly formed tissue or surrounding intact skin, has become a major consideration. When choosing the most suitable dressing for a wound, clinicians consider that undisturbed wound healing optimised by proper dressing choice significantly improves wound outcomes.[16,17]

However, in some instances, if used inappropriately, wound dressings can themselves cause damage. For example, if they provide limited or poor exudate management this can allow exudate pooling and/or leaking, resulting in maceration/excoriation.[18] Adherence of the wound dressing to the wound/surrounding skin enables the dressing to be retained in place. However, the potential for disturbance or damage to the wound bed and periwound skin upon removal of the dressing can cause re-injury which hampers the healing process.[16,19,20] Associated pain at dressing change can cause a high degree of patient suffering with some patients requiring analgesia at dressing changes.[21] Dressing removal is particularly important in older patients, whose periwound skin and new wound tissue is often fragile and easily wounded[22] by, for example, skin stripping.[23]

Superabsorbent wound dressings meet the challenges of exudate management and undisturbed wound healing. These dressings have been developed with the aim of providing extra fluid-handling capacity above and beyond standard dressings such as foam dressings. They are designed to be used on wounds of varying aetiologies that produce moderate-to-high volumes of wound exudate.[24] Effective exudate absorption reduces the risk of leakage and maceration[25] and in recent years there has been an increase in the number of wound dressings containing superabsorbent polymer (SAP).[26,27] Non-adherent superabsorbent dressings require a secondary bandage, while others have adhesive borders to keep them in place. If the wound has fluctuating volumes of exudate, or a heterogeneous healing process, a superabsorbent dressing with a built-in atraumatic contact layer may be more suitable for managing the many needs of such heterogeneous wounds.[28]

Silicone has been used extensively for over a decade in wound care, primarily to provide an atraumatic wound contact (adhesive) layer that interfaces with the wound and the surrounding skin.[29] This interface has been shown to reduce tissue trauma allow for undisturbed periwound skin and enable better healing progression.[30] Importantly, from a patient perspective, the atraumatic removal of silicone dressings reduces pain and increases the patient's QoL.[17,31]

Our aim is to provide 'in use' clinical data of a superabsorbent wound dressing with a silicone interface adhesive (in patients with moderately to highly exuding wounds), with the superabsorbent component providing superior exudate management and the silicone adhesive interface component supporting 'undisturbed healing'.

Methods

Product

The superabsorbent dressing used in this study (Zetuvit Plus Silicone, Paul Hartmann Ltd., UK) is indicated for the treatment of moderate-to high exudate in acute and hard-to-heal wounds, including pressure ulcers (PU), diabetic foot ulcers (DFU), venous leg ulcers (VLU) and arterial ulcers.

Research method and patients

This study was an open labelled non-comparative study. Patients included in the study were selected by the clinical investigator(s) according to whether the patient required a dressing for the management of moderate-to-high exudate. Patient participation was voluntary and they were required to complete patient consent forms to allow further use of their data in educational or commercial settings. All patients had the right to refuse to enter the study.

Patient inclusion and exclusion criteria are identified in Table 1.

Terms of study and ethics approval

Formal ethical approval was deemed not to be required by the clinical investigator and/or local ethics

Table 2. Patient population characteristics

	Patient number	Age (years)	Standard deviation	Wound duration (range)
Male	31	73.6	9.5	1 week to >52 weeks
Female	18	78.2	12.4	
Total number of separate wound assessments=307				

committee due to the fact that the superabsorbent wound dressing was a product that was being used according to the manufacturer's instructions and patients were not being treated outside normal regimens available to the participating institutions. All study participants were provided with patient information and were asked to sign an informed consent form before inclusion in the study, which was carried out in accordance with the Declaration of Helsinki[26] and applicable regulatory requirements.

Clinical evaluation

The clinical evaluation was undertaken using a formal case study evaluation form. Both qualitative and quantitative evaluations were undertaken according to the primary and secondary objectives of the study as outlined below.

Primary objectives

- Exudate management: assessed at each assessment point in both a subjective and semi-quantitative manner. Assessment of exudate management was assigned as follows: 'poor' (0–25%), 'adequate' (26–50%), 'good' (51–75%) or 'very good' (76–100%). Reasons for dressing change related to exudate management was also reported and included 'a scheduled change', 'leakage', 'strike through' or 'maximum exudate-handling capacity of dressing reached'. Additional reasons for dressing removal, such as fixation issues or the requirement to remove the dressing in order to observe the wound's progress, were also reported
- Impact of exudate management on wound edge and periwound skin: rated subjectively and assessment of exudate effect on skin was assigned different skin states: 'healthy', 'dry', 'eczematous', 'excoriated', 'inflamed', 'macerated', 'hyper-hydration' or 'other". The skin assessments were to be described in a comments box on the case study evaluation form.

Secondary objectives

- Wound bed preparation: subjective evaluation of the percentage of the wound area (% wound covered by necrosis, slough and granulation tissue) at each assessment time point. The presence of devitalised tissue (necrosis or slough) and the development of granulation tissue and re-epithelialisation was assessed
- Healing progression: wound area (width x length, cm) was measured as an indication of wound progression
- Localised tissue trauma: subjective evaluation of tissue trauma due to dressing removal and related to dressing adherence. Parameters assessed included damage to wound and/or periwound skin, bleeding upon removal of the dressing and any tissue infiltration into the matrix of the dressing
- Pain: scored according to the validated visual analogue scale (VAS) at both dressing change and between dressing changes
- Dressing assessment: an overall dressing assessment, with the patients' and clinicians' own views on the dressing, was undertaken at the end of each patient evaluation and were noted in the evaluation form
- Wear time: assessment of the duration of time between dressing changes. Wear time was assessed for three different wear time groups, <4 days, 4–5 days and >5 days (6–21 days).

Data presentation and statistical analysis

Only descriptive statistical analyses were undertaken on the relevant data, for example, mean, standard deviations (SD) or trendlines, where appropriate.

Results

Patient withdrawals

A total of 50 patients were included in the study. The majority of patients had only one wound. Where there were more than one wound only one was followed, this was chosen by the health professional. A single patient from the first patient group was excluded from the analysis because incorrect recording of dates made it difficult to assess wear time. Data used for analysis were all the assessment points in the study of the 49 patients. The initial proposal stated that each patient should be evaluated for up to two weeks (or a minimum of four dressing changes, where possible), depending on the clinical requirements of the wound with regards to exudate management. Due to the effectiveness of the product in managing exudate, some nurses continued using the superabsorbent wound dressing (and reporting) beyond the two weeks required. This data was also used for the final analysis.

Epidemiological information

Patient characteristics are presented in Table 2. In this study 49 wounds and a total of 307 assessment time points were assessed.

Fig 1. Change in wound edge skin condition

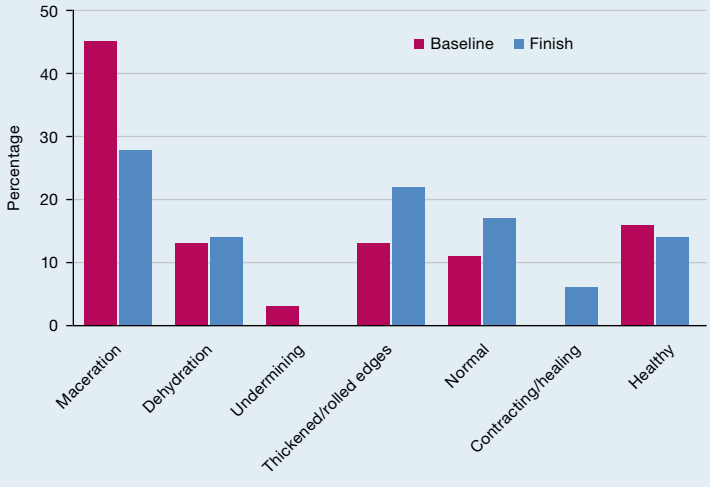
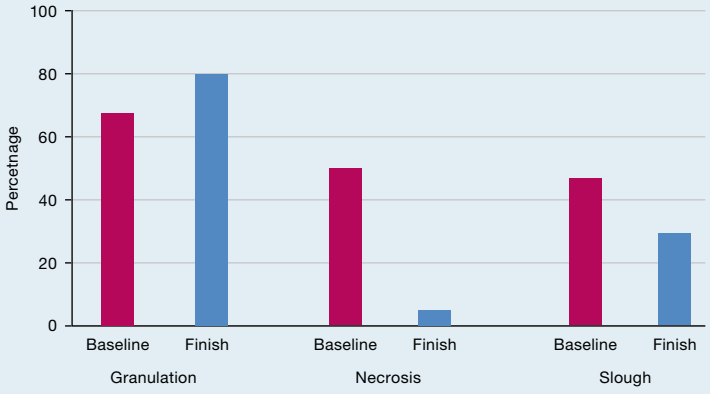


Fig 2. Wound bed changes over evaluation period



The predominant wound type was mixed aetiology ulcers (55.3%) followed by VLUs (12.8%) and DFUs (8.5%). Of the evaluated wounds, 38.3% had a duration of between seven and 52 weeks, and 36.2% had been present for more than one year.

The results for types of wound dressings used before inclusion in this study indicated that superabsorbent dressings were the predominant class of dressings being used to treat wounds (36%), followed by antimicrobial wound dressings (30%) and foam dressings (20%).

Primary objective results

The ability of the superabsorbent wound dressing to manage exudate was rated as 'very good' (91%) or 'good' (7%) when looking at all 307 time point assessments. Only 1% reported as 'adequate' and 1% as 'poor'.

Wound edge skin condition

Examination of the wound edge skin condition over the course of the evaluation period showed an improvement in exudate management-related skin condition (Fig 1).

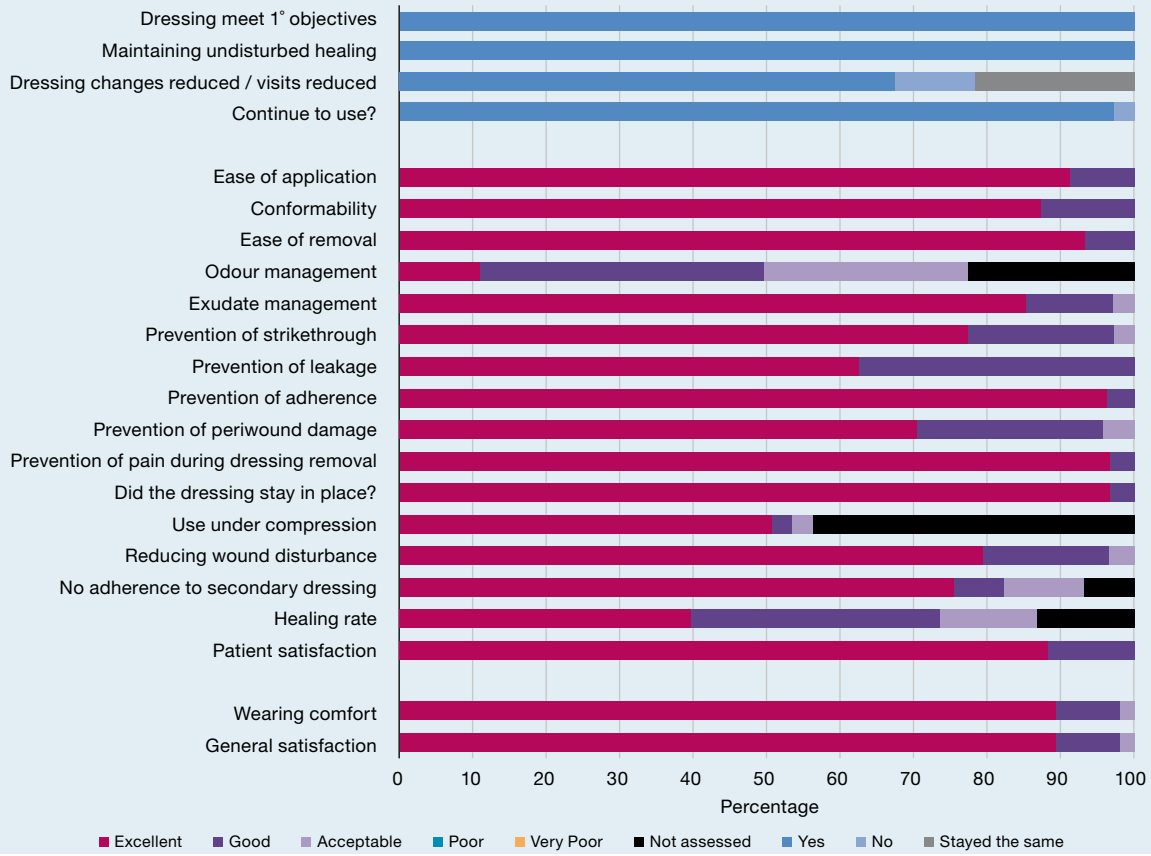
Over the course of the evaluation period, periwound skin condition showed an improvement (33%) in exudate management-related skin condition, 53% of wounds were unchanged and 14% had deteriorated.

Secondary objectives

Changes in the status of the wound bed from baseline to the end of the study are presented in Fig 2.

Mean wound pain scores 'at dressing change' and 'between dressing change' were, in both cases, relatively low with only small changes in VAS rating scores. The average pain score at dressing change reduced from 2.5 (SD: 3.0) to 1.4 (SD: 2.0), and the average pain score between dressing changes reduced over the course of the study from 1.9 (SD: 2.2) to 1.4 (SD: 1.7).

Fig 3. Overall dressing assessment



Overall dressing assessment

At the end of the study, the clinical investigators were provided with an evaluation form that summarised their impressions of the treatment with the superabsorbent wound dressing with silicone, the results from this are presented in Fig 3.

Comments

Patients and clinicians were asked to provide written comments at the end of the study regarding the impact that the dressing had on them (or their patient) during their treatment. They were asked to report on both negative and positive points relating to their treatment. This data was then quantified by counting the number of times comments relating to specific parameters occurred (Fig 4).

Wear time data

A summary of days between dressing changes is presented in Table 3. Fig 5 demonstrates the frequency of days between dressing changes. Wear time distribution between each designated group was: <4 days, 58.1%; 4–5 days, 30.6%; and >5 days ,11.2%.

Fig 4. Testimonial comments

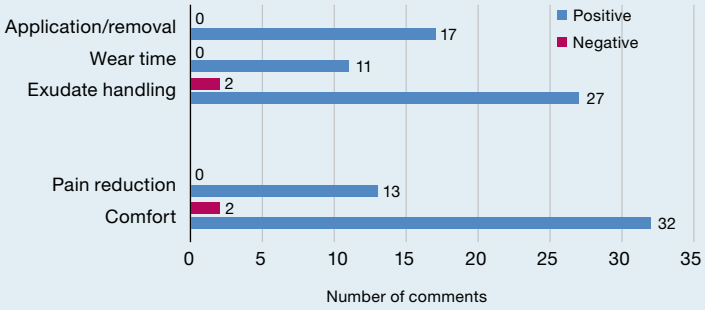
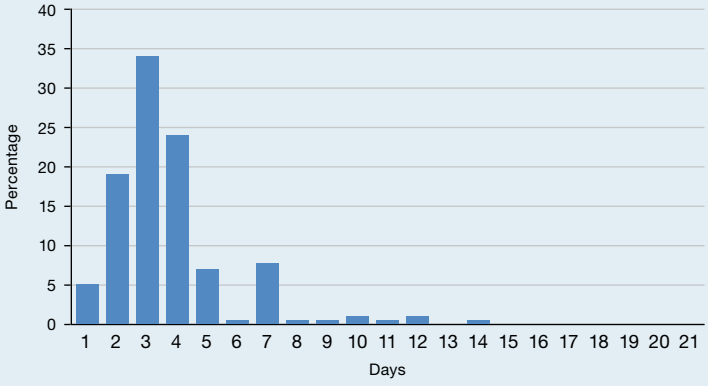


Fig 5. Frequency of days between dressing changes



Discussion

Wound exudate is vital to the normal healing process as it provides a moist wound environment;[32] enables the diffusion of immune mediators and growth factors across the wound bed;[3] acts as a medium for the migration of tissue-repairing cells across the wound bed, supplies essential nutrients for cell metabolism and promotes the separation of dead or damaged tissue.[28]

However, excessive exudate (more usually seen in hard-to-heal wounds) is a significant challenge for health professionals and can impact negatively on the patient.[33] For example, increased wound exudate that is not managed adequately can cause wound/periwound maceration which in turn can lead to localised infection and enlargement of the wound.[6] Additionally, the patient may experience increased pain/discomfort and/or anxiety and stress,[34] and psychosocial issues.[35] Furthermore, leakage of exudate may cause soiling of clothes which may be embarrassing and physically challenging for some patients.[1] Consequently, the test for clinicians is to identify appropriate dressings that can meet the challenges of balancing moisture levels in the wound environment—too much leads to maceration, too little and the wound dries out and will not heal. The detrimental impact and the importance of managing wound exudate is exemplified in a recent World Union of Wound Healing Societies' (WUWHS) consensus document.[28] This document also underlines the necessity of using appropriate wound dressings that can effectively manage the differing levels of exudate (low–moderate–high) seen in various wound types. In the case of wounds that exhibit moderate to high levels of exudate, superabsorbent polymers are among those recommended. Aligned with these recommendations, the evidence presented in this study shows that a relatively new superabsorbent polymer wound dressing has been successfully developed to optimise the conditions for healing, even under the demanding and adverse conditions associated with such wounds.

Before the start of the study, 20% of wounds were being treated with foams. This is noteworthy as the use of foam dressings in the situation of high wound exudate has come under some scrutiny and they are not now considered first line treatment for such wounds.[15]

The superabsorbent wound dressing was successful in managing wound exudate from all the various types of wounds in this study in 98% of assessments. Thus, in terms of managing wounds with moderate to high levels of wound exudate the super absorbent wound dressing demonstrated a comparable level of effectiveness versus that of Zetuvit Plus (a similar dressing but without the silicone layer). Additionally, there was a shift in the proportion of wounds exhibiting high exudate levels to some showing moderate or low

Table 3. Summary of days between dressing changes within patients (n=49)

	Total number (assessments)	Mean (days)	SD	Median (days)	Range (days)
Total	258	3.7	2.2	3	1 – 21

levels of exudate production. These results corresponded with the reduction in levels of wound infection and the promotion of wound progression. Although the superabsorbent wound dressing is not indicated for low exuding wounds, this study has shown that the dressing was suitable for use on wounds where exudate levels were reduced to 'low' and that there was no adherence of the dressing to underlying tissue due to the presence of the silicone layer.

Wounds contain MMPs that (normally) contribute to tissue breakdown and remodelling. However, in hard-to-heal wounds the control mechanisms are awry and excessive levels of MMPs occur (specifically MMP-9). This leads to protease-mediated destruction of important components of dermal connective tissues, such as collagen and fibronectin, and is causal in the persistent nature of hard-to-heal wounds. Several different dressing types have been developed to try to modulate such excessive levels. For example, some dressings are composed of collagen that provides a sacrificial substrate that diverts the MMPs thus reducing their negative impact.[36] Alternatively, some superabsorbent wound dressings can absorb and sequester the MMPs or their cofactors within their matrix to prevent the damaging action upon wound tissue matrix components.[37]

Of the dressing changes performed, 91% were scheduled according to the patient's normal treatment regimen. The main reason for any unscheduled changes were due to exudate handling and strikethrough, although even in these cases, the level of fluid transmitted through the dressing was low and did not cause the patient or clinician any undue concern. This extended wear time together with this level of exudate would, in all probability, be the reason for the dressing change. It is noteworthy that from the comments made by both clinicians (data on file), reference is frequently made by both the patient and clinician as to the superabsorbent wound dressing's superior fluid handling capacity compared with that of other dressings previously used. The results have showed that, generally, dressings were changed after a period of 2–4 days and that this regimen managed wound exudate more than adequately. This is in accordance with standard practice relating to the use of superabsorbent polymers in wounds that are showing moderate to high exudate levels.[38]

A variety of wound edge and periwound skin conditions presented in this case series. The results show that the incidence of maceration decreased from 45% at the start of the evaluation period (baseline) to 28% at the end of the study (finish).

In periwound skin, the incidence of maceration decreased over the course of the study period from 28% at the start of the evaluation period to 13% at the end of the study. The improvement of periwound skin condition with the superabsorbent wound dressing was also exemplified in one patient who presented with bilateral varicose eczema and cellulitis with high levels of wound exudate that improved by showing a reduction in periwound inflammation/erythema and corresponding levels of exudate over the period of the treatment.

It is also noteworthy that some patients stated that the dressing reduced the pain of excoriation associated with their wound (data on file, patient testimonials). In addition, some patients suffered a great amount of pain associated with the wound/periwound and they stated that there was significant pain reduction when they were wearing it and at dressing change, indicating that the dressing did not stick to the wound or surrounding skin. This is supported by the summary data presented in Fig 5 it shows that: the dressing was easy to remove (94%); there was no dressing adherence to the wound or surrounding skin (97%); the dressing prevented periwound damage (71%); caused no/reduced pain upon removal (97%); and a reduction in wound disturbance (80%). This evidence supports the premise that the superabsorbent wound dressing enabled undisturbed healing.

Healing progression, as measured by changes in wound area (width x length, cm), was also undertaken. Overall, combining and averaging the data showed that, although there was a slight increase in the mean wound area, there was no actual significant difference between the baseline and the final measurement. However, due to the short treatment period (two weeks), this is not unsurprising and many of these wounds had been static for weeks or months. It is noteworthy that some wounds did, however, show a reduction in wound area as a result of treatment with the superabsorbent wound dressing and this is also reflected in the positive comments from health professionals (data on file). Overall, the wound area results are deemed an acceptable response when compared with healing data obtained from other studies that have shown healing responses in hard-to-heal wounds occurring over much longer periods of time than the interval evaluated in this study.[39–41]

Pain levels were generally low (1 or 2 VAS) throughout the study. This is unusual because patients presenting with these types of wounds generally have high levels of pain associated with them[42] and dressing changes causes pain upon removal of the dressing.[43] However, the use of dressings with a silicone adhesive interface is now synonymous with reduced pain and, more importantly, undisturbed healing.[16] This data would therefore appear to show that the superabsorbent wound dressing was highly effective in enabling the management of wound pain in these patients.

Testimonials highlight the positive experiences of both patients and clinicians with this superabsorbent wound dressing. Patients note the dressing as being very comfortable, that they were able to tolerate the dressing well and noted the benefits on their QoL. Clinicians noted the dressing's superior exudate absorbency and general exudate management characteristics, retention qualities and good conformability.

A total of 258 wear time assessments were used to

calculate the mean number of days between dressing changes. The redistribution of wear time data into the three wear time assessment groups indicates that 58.1% of dressing changes fall into the <4 day wear time group, 30.6% into the 4–5 days and the remaining 11.2% into the >5 days wear time group. Although a significant proportion of the wounds had dressing changes every third day, almost 50% of wounds were dressed every second day or daily, which probably reflects the moderate and high levels of wound exudate produced by the wounds. Use of this superabsorbent wound dressing in the treatment of these wounds resulted in a mean number of days between dressing changes of almost four days and reflects the exudate management capabilities of the dressing and the improving status of these wounds during its use.

Limitations

In this study, there was no rigid standard protocol applied to the study methodology as would have been seen in a controlled trial. The patients included in the study were chosen based on clinical decisions and the appropriateness of the dressing in terms of managing moderate to high exudate levels. This led to there being a bias in the wound types assigned to the treatment group and, because of this, the patient population contained a larger proportion of hard-to-heal wounds that required more complex wound care.

The study was designed as a 'real life' setting study to reflect the actual care that patients receive as part of the regular clinical routine, and to reflect the day-to-day clinical experience of patients and clinicians that pose significant healthcare challenges but which results in a heterogeneous study population.

Conclusion

The superabsorbent wound dressing achieved the clinical objective relating to wound exudate management in all the assessments undertaken in this study, thus underlining the effective fluid handling capabilities of the dressing. In addition, the silicone interface allowed for undisturbed healing as evidenced by little or no adherence of the dressing to underlying tissue and no damage to the periwound skin. Patient experience was enhanced in that there was little pain associated with the wound or at dressing change throughout the study and its flexibility/conformability allowed for greater comfort and patient satisfaction aligned with increased QoL. Overall the superabsorbent wound dressing (with the addition of the silicone interface) showed that, based on this analysis, it may be superior to other superabsorbent polymer dressings or silicone wound dressings but further comparative studies are needed to confirm these early findings. In effect, the superabsorbent wound dressing conforms to the criteria of an ideal wound dressing for exudate management as laid down in the WUWHS consensus document.[28]

Further research could investigate a wider variety of different wound types and compare with other dressings (including superabsorbent polymers). Additionally, further investigation could be conducted in terms of the propensity of extending the evaluation period up to when a healing response can be identified (6–12 weeks). Also, increasing the wear time of the dressing could be considered in order to investigate whether a reduction in labour and resource costs can be achieved. Additionally, extended wear time will prevent the disturbance of the wound and potentially lead to a better/quicker healing response. **JWC**

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Reflective questions

- What causes excessive levels of wound exudate?
- Why is wound exudate management so important?
- What effects do poor exudate management have on the patient?
- In what instances would you use an SAP dressing over a foam dressing?

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