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Treatment of 52 patients with a self-adhesive siliconised superabsorbent dressing: a multicentre observational study

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Treatment of 52 patients with a self-adhesive siliconised superabsorbent dressing: a multicentre observational study

Objective: To provide 'in use' clinical data to support exudate management in patients with moderately to highly exuding wounds with bordered superabsorbent wound dressing with a silicone adhesive interface.
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: The primary aim of this study was to evaluate the clinical objective in relation to exudate handling (moderate to high) with a superabsorbent silicone border dressing (Zetuvit Plus Silicone Border; SAP silicone border dressing; designated RespoSorb Silicone Border in some countries). The SAP border dressing had met the clinical objectives relating to exudate management, affirmed by the health professionals with a yes response in 94% of cases. Additionally, the health professionals rated the handling of exudate as excellent/good (78%) and most (80%) reported that they would use the SAP silicone border dressing again. Allied to this was the fact that the SAP silicone border dressing improved the wound edge and periwound skin conditions (29% and 36% of patients, respectively). Regarding dressing retention, the SAP silicone border dressing retained its position in 72% of patients. For wear time, the largest proportion of dressing changes, both pre-study and during the evaluation period, was every third day (45% and 44%, respectively). But there was a shift to extended wear time with use of the SAP silicone border dressing with 72% of patients' dressing changes being every third day or longer.
Conclusion: The SAP silicone border dressing was successful in managing wound exudate in moderately to highly exuding wounds and consequently this had a beneficial impact on the wound edge and periwound skin. Overall, there was a positive effect on wound bed preparation and in turn the healing response was progressive. This study has shown that the SAP silicone border dressing successfully controlled exudate and provided positive benefits when used in the treatment of patients with moderately to highly exuding wounds.
Declaration of interest: This study was supported by Paul Hartmann Ltd.

exudate management • silicone border • superabsorbent • wound dressing • Zetuvit Plus Silicone Border

In normal wound healing a well-established series of events has been identified;[1] however, a breakdown in part of this process leads to hard-to-heal wounds.[2–4] The exudate from these wounds can be excessive and lead to maceration of the wound/periwound skin, exacerbating wound chronicity and/or leading to infection.[5,6] Exudate leakage may occur through or around the dressing, soiling the patient's clothes, causing malodour, and having social and psychological effects on the patient.[7]

Exudate management

Management of excess exudate is a key factor in treatment of a patient with an acute/hard-to-heal wound.[8] A variety of wound dressings have been developed to be used on wounds of different aetiologies that produce moderate-to-high levels of exudate.[8,9] Some of these dressings, such as foams, have a reasonably high level of fluid absorption, but little or no retention capabilities, so cannot be used under compression.[10] The newer dressings, containing superabsorbent polymer (SAP), are more able to cope with higher levels of exudate and have proved successful clinically, some being able to be used under compression bandaging.[11–13]

Wound/skin protection

Protection of the wound, made up of developing tissue and cells[14,15] and periwound skin, is a vitally important factor in aiding healing. Periwound skin is vulnerable, due in part to the underlying pathologies that may have contributed to the cause of the wound in the first place.[16,17] The periwound skin also provides an anchor point for adherent wound dressings.[18] This can be problematic: if the adhesive used is too aggressive then the adhesive tack of the dressing overwhelms the structure of the skin and causes removal of cells leading to damage to the wound/periwound, also inflicting further pain and suffering on the patient[18,19] and increasing costs.[20] In order to overcome this problem, some dressings have been developed with adhesives that do not have such an aggressive adhesive tack,

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thereby reducing or eliminating the skin damage completely.[21] Specifically, silicone as an adhesive on wound dressings has been shown to be effective in reducing damage to periwound skin and has many clinical benefits over the more traditional dressings.[13,22,23]

Aim

This study evaluates a new self-adhesive superabsorbent dressing with silicone interface (Zetuvit Plus Silicone Border, SAP silicone border dressing; Paul Hartmann Ltd.) in the management and treatment of wounds with moderately to highly exuding wounds.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
• Aged ≥18 years old • Patient with any wounds that have moderate-to-high levels of wound exudate in need of management • Signed consent form	• Aged <18 years old • Patients with known allergy/ hypersensitivity to any of the components of the dressing • 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

Methods

Product

We evaluated a SAP silicone border dressing for the treatment of acute and hard-to-heal wounds with moderate-to-high levels of wound exudate of different types such as pressure ulcers (PU), diabetic foot ulcers (DFU), venous leg ulcers (VLU) and arterial ulcers.

Study type and patients

This study was an 'open-labelled noncomparative study', and 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. Patients were recruited into the study from eight clinical centres. Patient participation was voluntary and they were required to complete patient consent forms to allow further use of data in educational or commercial settings. All patients had the right to refuse to enter the study. The evaluation period was for a minimum of two weeks or at least three dressing changes.

Inclusion and exclusion criteria for the study are identified in Table 1.

Terms of study/ethics approval

Each clinical centre followed their local ethical requirements to gain approval to be allowed to undertake this study. All patients signed a consent form and could decide whether they wanted to be included or not. The investigation was performed in accordance with the ethical rules of the Declaration of Helsinki and applicable regulatory requirements.

Objectives

The primary objective of the evaluation was the effectiveness of SAP silicone border dressing in the management of moderately to highly exuding wounds.

Secondary objectives were:

- Damage reduction to the wound edge/periwound skin and wound bed preparation as an indication of exudate management (e.g., maceration/excoriation)
- Wound area as an indication of healing
- The physical handling attributes of the dressing (e.g., dressing application/removal, conformability, comfort)
- Clinical effectiveness of SAP silicone border dressing when used under compression
- Pain scored at and between dressing changes.

An overall appraisal will be undertaken after the patients have completed the study.

Dressing evaluation

Patients were assessed at baseline (initial assessment) and again at subsequent dressing changes. At baseline, the following information was collected: patient's characteristics and status of the wound (wound bed, periwound skin condition, exudate levels). Previous wound treatment history, medical and surgical history and concomitant medications (including antibiotics) were also recorded.

At each subsequent dressing change a subjective and semi-quantitative wound assessment was undertaken and the following variables were evaluated and recorded on designated evaluation forms developed for the study used by all the investigations centres:

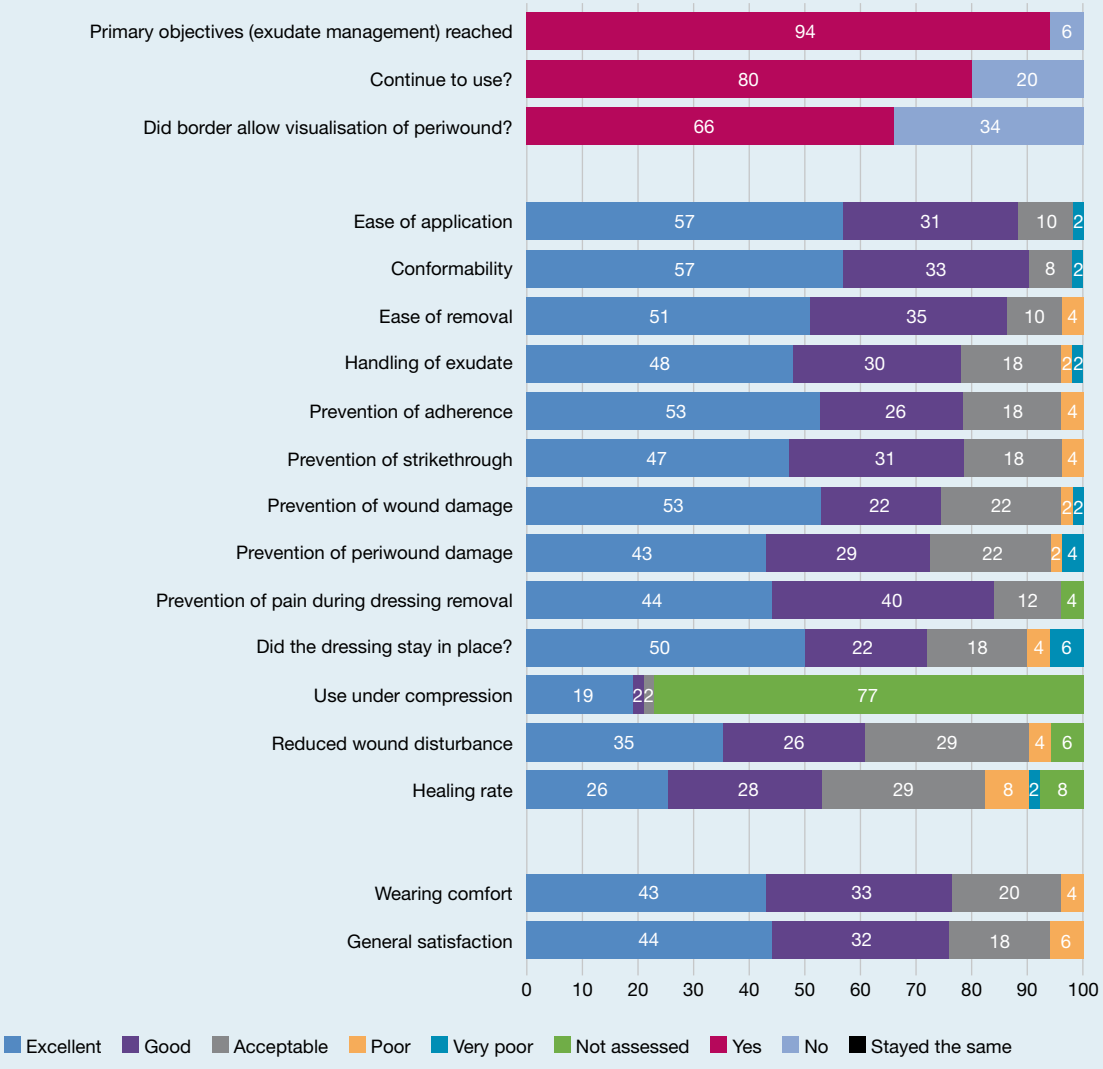
- Exudate management—assessment of exudate management was evaluated as 'poor', 'adequate', 'good' or 'very good'
- Impact of exudate management on wound edge and periwound skin—skin condition (including localised

Table 2. Patient and wound characteristics of patients included in the study

	Number of patients	Age, mean±SD years	Wound duration, mean±SD days	Wound size, mean±SD cm²
Male	31	65.8±13.8	812.6±1598.1	44.1±99.2
Female	21	77.3±13.8	827.1±1887.0	128.3±490.0
Total	52	70.6±14.8	818.6±1704.9	77.1±313.6

Total number of separate clinical wound assessments made was 246; SD—standard deviation

Fig 1. Overall dressing assessment. There were 10 clinical investigators who took part in this study. Overall dressing assessment questionnaires were completed for 51/52 (98%) patients.



tissue damage trauma) was assessed using the following parameters: wound edge (maceration, dehydration, undermining, thickened/rolled edges, contracting/healing, healthy); periwound skin (healthy, eczema, excoriation, dry, inflamed, maceration, hyper-hydration)

- Healing progression—assessed by measuring wound area (width x length). Health professionals also made a subjective assessment ('excellent', 'good', 'adequate', 'poor') of overall healing response of the wound since the previous assessment
- Pain—pain before and after dressing application was assessed using a 10cm visual analogue scale (VAS)
- Level of wound bacterial contamination—the clinicians used their clinical experience for the detection of wound odour, determination of critical colonisation and signs of infection itself to assess this as a level of overall infection
- Clinical effectiveness under compression—assessment of exudate management evaluated in the group of patients undergoing compression therapy
- Dressing assessment—an overall dressing assessment (including physical attributes of dressing (see Fig 1)

At the end of each patient evaluation a summary assessment form was completed by the nurse or senior clinical investigator identifying whether the clinical objectives had been reached and providing an overall evaluation of dressing performance from both patient and health professional perspectives. Both health professional and patient views were recorded.

Wound healing progression was assessed by calculating the wound area at each assessment point. In order to compare the wound area data from all patients, the data was normalised and the change in wound area was calculated against the patient's own baseline (i.e., the baseline wound area is expressed as 100%).

All clinical centres followed a detailed study protocol and used a standard study Evaluation Form. The SAP silicone border dressings were applied according to the manufacturer's instructions and the patients' individual clinical requirements. Retention or the use of ancillaries was not prescribed as part of the protocol; their use was entirely down to the treating health professionals.

Data presentation and statistical analysis

Statistical analyses were performed on all subjects who completed the study. Only descriptive statistical analyses were undertaken on the relevant data including mean, standard deviations (SD) using an XL software package, where appropriate.

Results

Epidemiological study information

Study evaluation books were completed for all patients. We recruited 54 patients into the study, but two patients were excluded from the analysis (one patient did not attend the clinical assessments and one did not meet the inclusion criteria. This only came to light when the data analysis was being performed). There were two patients who had wounds on bilateral lower limbs and in these only one wound was used for assessment. A total of 52 wounds are included in this study, VLUs and DFUs made up the largest contingent (40% and 29%, respectively), along with PUs (8%) and malignant wounds (8%). The mean wound duration before inclusion in the study was 818.6 (± 1704.9) days and the mean starting wound size was 77.1 cm² (± 313.6 cm²; Table 2). The most used dressings before the study were foams, superabsorbents and antimicrobials (26%, 25% and 20%, respectively). Dressing changes before enrolment were every third day in 45 % of patients, daily in 26% or in some patients several times a day. There were 12 patients enrolled in the study receiving compression as part of their treatment.

Overall results

Upon conclusion of the study, the health professionals completed an overall assessment form (for each patient) that rated several different measurement parameters that were evaluated throughout the study (Fig 1). This assessment provided an overview assessment of the clinical performance of the dressing.

Fig 1 shows levels (>75%) of excellent/good assessments from health professionals in several areas, and a number related to exudate management (e.g., handling of exudate, prevention of adherence). This was reflected in a near-100% assessment for the achievement of the study's primary objective of exudate handling.

Objectives

Health professionals rated the dressing as having achieved the study's primary objective of effective exudate management in 94% (47/50) of patients (Fig 1). Handling of wound exudate and prevention of exudate strikethrough were both rated highly (78%; 39/50).

Fig 2. Examples of exudate management. A 67-year-old male with a leg ulcer. Comorbidities include type 2 diabetes. The wound area was 95% covered with necrotic tissue/slough and produced moderate levels of exudate. A patient with highly exuding wounds showing before the dressing was removed, with indications of exudate maintained within the superabsorbent core of the dressing and after removal, both dressings showing a significant amount of exudate, clearly seen retained within the dressing

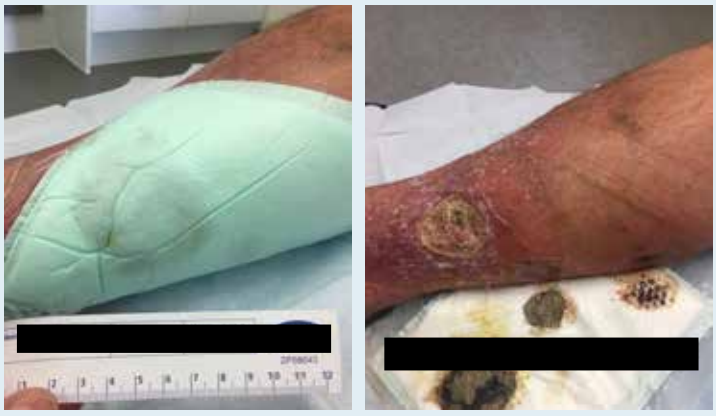


Fig 3. Wound edge and periwound skin improvements at day 0 initial presentation (**a**) and day 7 (**b**). A 67-year-old male with a venous leg ulcer of 6 months' duration before inclusion into the study, 70% of wound area covered with slough and 30% granulation tissue (**a**). Despite high levels of wound exudate production, skin improvements were seen over the course of study (**b**)

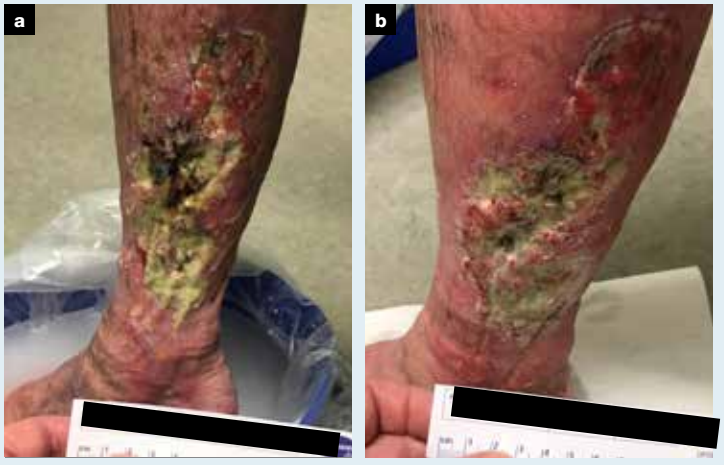


Fig 5. An example of healing progression. A diabetic foot ulcer in a 36-year-old male (**a** and **b**). patient had wound for 3 months before enrolment into study (a). Wound presented with 90% granulation tissue and 10% slough which improved to 100% granulation tissue at the end of the study period (**b**). Wound edge and periwound skin condition was good at the end of the study period (**b**)

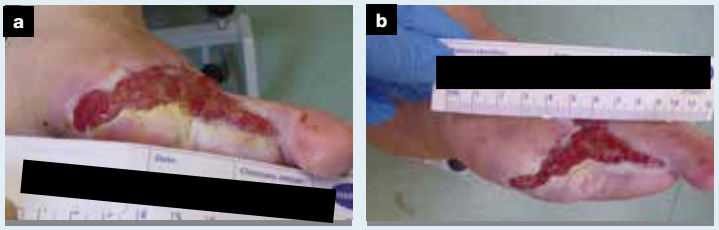


Fig 4. Mean wound area change over course of study. Wound area relative to starting area ± standard deviation

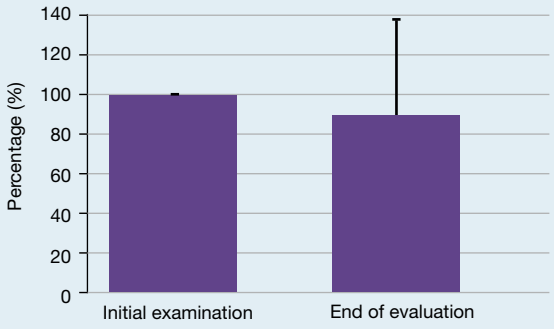


Fig 2 illustrates the successful management of wound exudate in two patients with photographs of how SAP silicone border dressing successfully managed exudate in two patients with wounds exhibiting moderate-to-high levels of exudate. Of the 12 patients who received the SAP silicone border dressing under compression, health professionals assessed that, for a majority of the patients, the dressing was rated as 'excellent' in terms of clinical effectiveness at exudate management (Fig 1).

A subset of secondary objectives relate to the intimate contact between the dressing and the wound/periwound and the effect of the dressing upon them. Health professionals felt that the dressing performed well (i.e., rated performance as excellent/good) in reducing wound disturbance (61%), preventing dressing adherence (79%) and in the prevention of wound and periwound skin tissue damage (75% and 72%, respectively).

Additionally, data collected from the day-to-day clinical assessments showed that conditions in the periwound skin demonstrated improvements, stayed the same or deteriorated in 36%, 50% and 14%, respectively. At the wound edge, skin condition improved, stayed the same or deteriorated in 29%, 60% and 11%, respectively.

Fig 3 is an example of a patient who presented with a large and eroded wound, with damage to the wound edge and periwound skin. Over time the wound healed and the damage to the wound edge and periwound skin was significantly reduced.

Healing progression/wound bed preparation

Fig 1 indicates that the wound healing rate over the course of the 14-day study was scored by health professionals as excellent/good in 54% of patients. Healing progression was assessed for each assessment point for all patients and the change in wound area for each patient was calculated relative to the initial wound area. Fig 4 shows the mean change in wound area at the end of the study for all patients relative to the starting wound area. Wound area decreased for all patients by approximately 18% by the end of the study compared with the starting area.

Improvements in wound bed accompanied the reduction in overall wound area. A subjective evaluation of the change in the proportion of devitalised tissues and granulation tissue within the wound bed found an increase in the level of granulation tissue over the course of the evaluation period (63% to 69%). There was a corresponding decrease in the wound area covered by devitalised tissue (slough) (36% to 26%). Figs 5 and 6 show a series of clinical pictures that exemplify a) the healing rate and b) development of the wound bed in wounds treated with SAP silicone border dressing.

Wound bed preparation

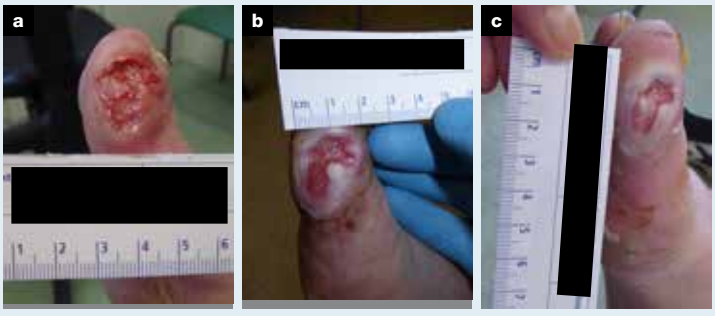
In this study a subjective evaluation of the levels of necrosis, slough and granulation tissue of the wounds at baseline compared with that assessed at completion of the study showed a trend to increase in the percentage of the wound area covered with granulation tissue (63% wound area coverage to 69%), and a corresponding decrease in the proportion of the wound bed covered with slough (36% to 26%).

Fig 6 presents a sequence of pictures that demonstrates the development of granulation tissue in the wound bed.

Physical attributes of SAP silicone border dressing

The physical attributes of the dressing were rated overall in the final clinical assessment and the results show that ease of application, ease of removal and conformability were rated excellent/good in 88%, 86% and 90% of patients, respectively (Fig 1). Allied to this was the fact that the prevention of pain during dressing removal was rated as excellent/good in 84% of patients and 12% rated prevention of pain as being 'acceptable' (4% of patients had no assessment of pain prevention) (Fig 1). Importantly, the ability for the dressing to remain in place was rated as excellent/good in 72% of patients and dressing retention was assessed as 'acceptable' in 18% of patients (Fig 1). In only 10% of patients was dressing rated as poor/very poor for dressing retention.

Fig 6. Wound bed preparation. Day 0 initial presentation (**a**), day 6 (**b**) and day 12 (**c**). A 70-year-old male with a diabetic wound who presented with an ulcer on the right big toe. Wound area at the start of the 14-day evaluation was measured at 4.4 cm² and the wound bed showed 50% coverage with slough and 50% granulation tissue (**a**). Over the course of the evaluation treatment with the SAP silicone border dressing the slough was completely debrided resulting in a wound bed of 100% healthy granulation tissue. Clinicians assessed a 60% reduction in wound area over the course of 14 days

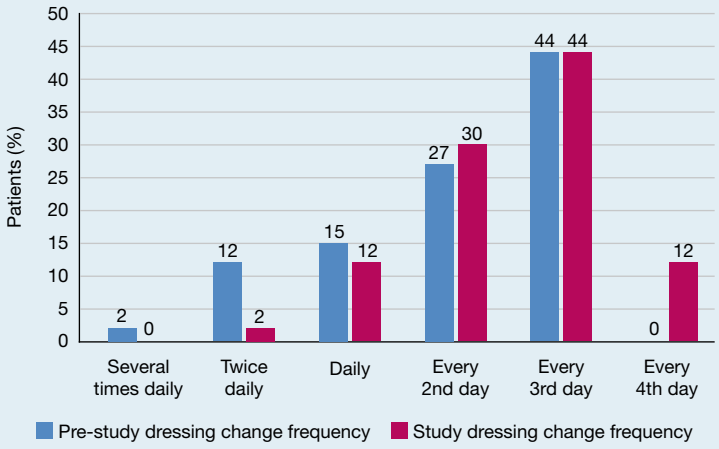


Dressing wear time

An assessment of the retention of the SAP silicone border dressing at each dressing change was undertaken throughout the study and the results showed that the dressings were assessed as being retained fully or partly in place in 86% and 7% of cases, respectively.

Fig 7 demonstrates the mean frequency of dressing change pre-study compared with during the evaluation period as assessed at the conclusion of the study. There appeared to be a shift to longer wear times during the study. For example, 12% of patients during the evaluation showed a mean frequency of dressing change of every 4th day compared with no patients in the pre-study period. During the evaluation period, when the total number of dressing changes over the course of the evaluation period were examined, the frequency of the number of days between dressing change (grouped) was <4 days (70.2%), 4–5 days (21.1%) and >5 days (8.7%).

Fig 7. Mean frequency of dressing change pre- and during evaluation



Discussion

The inclusion criteria of this study included that the wounds would be moderately (68%) or highly (32%) exuding wounds. Managing these wounds requires the use of dressings appropriate for the level of exudate, based upon proven clinical evidence that supports their use.[24] The World Union of Wound Healing Societies (WUWHS) consensus document on wound exudate and its management has recently provided useful guidance on the types of dressings to be used to meet these challenges.[8] Alginates, carboxymethylcellulose (CMC) dressings, foams and SAP dressings have been identified as being the primary dressings for use in moderately to highly exuding wounds.[8]

However, some of these dressings have drawbacks and may not be appropriate for all these wounds. For example, the British National Formulary indicates that foam dressings may struggle to absorb and retain wound exudate under compression,[25] allowing leakage of exudate resulting in maceration.[26] SAP dressings have several positive aspects for exudate management, some of which include absorbing and retaining large volumes of exudate,[12,27–30] sequestering and retaining damaging components of hard-to-heal wound exudate, such as matrix-metalloproteinases,[31,32] and providing an optimal moist healing environment, aiding healing progression[28,31,33,34] and providing extra patient comfort.[12,27,29,33,34]

The clinicians rated the study dressing highly in terms of exudate management (94% agreement that dressing achieved clinical objective) and this translated to a significant proportion stating that they would continue to use the SAP silicone border dressing. Several patients who had circumferential wounds (VLUs) that produced high levels of exudate required several dressing changes per day and the SAP silicone border dressing successfully managed the exudate, resulting in a reduction in wound dressing change frequency. This provides significant patient benefits, including that it reduces periwound skin problems,[35] promotes wound progression,[6] reduces the risk of infection[36] and has a positive psychological impact for the patient.[37] The beneficial use of SAP silicone border dressing in the management of moderately to highly exuding wounds reflects comparable clinical evaluations for similar SAP dressings.[12,13]

Wound edge and periwound skin condition

The wound edge and periwound skin are important aspects of promoting wound progression.[38] Many wounds have been shown to be surrounded by problematic or unhealthy skin.[39] Wound skin protection was a key component in this evaluation and both wound edge and periwound skin condition were assessed as part of the evaluation of the dressing's ability to protect skin.

The wound edge is important for the healing process[40–42] as it is the tissue that is directly adjacent to the wound and is a major source of the epidermal cells necessary for wound closure.[43] During acute wound healing, the proliferative phase of healing results in the formation of new granulation tissue at the site of the wound and wound contraction begins (facilitated by special fibroblasts, myofibroblasts) while at the same time epidermal cells proliferate and migrate from the wound edge.[44–46] In hard-to-heal wounds, where the underlying physiology and the presence of wound biofilms can play a role in delaying healing, physical barriers to healing include thickened and rolled wound edges, which delay re-epithelialisation.[47,48] In addition, maceration at the wound edge, caused by poor management of wound exudate, interferes with the healing process and further delays healing.[24,49]

The periwound skin is an area of skin up to 4cm beyond the wound and which includes the wound edge.[18,50] The periwound skin has been shown to be important for the healing of VLUs and damage to this tissue may lead to a delay in healing[16] and must be viewed as just as important as the wound itself when considering the optimal route to treating the wound.[51]

Maceration is a frequent problem in this area.[50] In this study the periwound skin was assessed as the area of skin beyond the wound edge, particularly to the region of skin adjacent to the wound that is beneath the dressing that extends beyond the wound area. A dressing unable to absorb and/or retain wound exudate (i.e., fail to provide effective exudate management) leads to exudate coming into contact with the periwound skin, leading to periwound skin maceration/excoriation and the potential for increasing the wound size through further tissue damage, prolonging healing. The extended tissue damage may also lead to localised tissue infection.[5] Therefore, it is important to choose the most appropriate wound dressing in order to minimise damage to the wound edge and periwound skin.[52] Wound dressing choice decisions should be based upon, amongst other considerations, evidence that dressings prevent damage to periwound skin.[53–56] Initial assessment of the patients enrolled into this study showed that the wound edge and periwound skin exhibited several skin conditions—including maceration, excoriation and inflammation—all suggestive of poor exudate management before inclusion into the study. Approximately one-third of patients showed improved wound edge and periwound skin condition (as measured by reductions in the level of exudate-related skin conditions), suggesting that good exudate management resulted in an improvement localised skin condition.

Wound progression

The results from this study show a trend towards a reduction in wound area of approximately 20% over the 14 days of the study. This effect of the dressing is particularly noteworthy since the effects were seen after only 14 days of wound treatment with the study dressing and a number of the hard-to-heal wounds had been present for many months (and years) before inclusion into the study; these latter wounds are likely to have entered into a stalled or static phenotype where a 'kick-start' to healing was required[57,58] and are less likely to heal.[59] It is possible that one mechanism responsible for enabling the beneficial impact on healing is the effective management of wound exudate and the removal/sequestering of the damaging components contained within hard-to-heal wound exudate (e.g., proteolytic enzymes).[60,61] This mechanism has been proposed for other SAP-based wound dressings[12] and compares favourably with that seen in other treatment studies of wounds of similar dimensions.[62–64]

Reflective questions

- What are the benefits of a combined silicone and superabsorbent wound dressing?
- In what wound types would this dressing be used and not used?
- Would a silicone dressing be useful in patients who suffer from high levels of pain at dressing change and if so why?

Wound bed preparation

A prerequisite for healing to occur is the physical removal of devitalised tissue, which is a key step in wound bed preparation. Effective wound bed preparation promotes the development of healthy granulation within the wound bed which then allows effective healing progression (including re-epithelialisation).[4,65] The fluid-absorbing properties of SAP dressings has been suggested to aid in the autolytic debriding properties of these dressings[12] and the results presented here confirm the wound bed-preparing properties of SAP dressings.

Dressing retention/wear time

The wear time of a wound dressing is governed by a number of factors, including those related to the patient, the characteristics of the wound and the properties of the dressing itself.[66] Wound inspection and adherence to protocol can also affect the wear time of the dressing.[67] Minimising the number of dressing changes aids in the undisturbed healing of wounds.[66] In this current study, clinicians rated the SAP silicone border dressing as excellent/good in 72% of patients and acceptable in an additional 18% of patients. In the remaining 10% of patients, where clinicians rated the dressing as poor or very poor, a number of clinicians reported anecdotally that they thought the hot weather and the increase in patients' sweating played a role in the dressing's limited performance

The results from this study show that the majority of dressing changes occurred every third day with a shift to longer wear times during the evaluation period compared with the pre-study period. Consequently, there is the potential for leaving the SAP silicone border dressing in place for longer periods of time than is currently being practiced. This would not only benefit the patient but would be also aid clinicians and, ultimately, the service provider (in the form or reduced healthcare costs). Most reasons for changing a patient's dressing are related to the need to inspect the wound or because of adherence to care plans, rather than being related to dressing performance.[67] For clinicians to take advantage of improvements in dressing performance will require there to be confidence in dressing performance that is driven by evidence.

Physical dressing characteristics and performance

The frequent use of wound dressing, particularly traditional wound dressings and some adhesive dressings, can result in damage to wound edge and periwound skin.[22,68] The SAP silicone border dressing was rated highly for the prevention of adherence to tissue, prevention of periwound damage and reduced wound disturbance. These characteristics of the dressing, together with the dressing's ease of application and removal, are dressing characteristics that are important to both patient and healthcare team. Although pain levels were generally low in patients enrolled in this study, the use of the SAP silicone border

dressing did not adversely affect pain levels for patients and ensured that the levels of comfort reported by the patients was generally high.

Limitations

A short duration is highlighted as a limitation of the study. However, some (off-protocol) extended use by the heath professional indicated that more beneficial outcomes might arise from prolonging the time that the dressing was used.

Conclusion

The primary objective of this study was to investigate the exudate-handling characteristics of the SAP silicone border dressing in patients with moderately to highly exuding wounds. The results determined that this dressing was successful in this respect and consequently this had a beneficial impact on the wound edge and periwound skin, reducing detrimental skin conditions and enabling the development of healthier tissue in these areas. Both clinicians and patients were positive in their responses to the use of the SAP silicone border dressing in the treatment of these patients and the management of excessive wound exudate. **JW**

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