

An observational study of a superabsorbent polymer dressing evaluated by clinicians and patients

Simon Barrett,¹ Lead TVN; Rosie Callaghan,² TVN;

Paul Chadwick,³ PhD MSc (res) BSc (hons) FCPM, National Clinical Director at the College of Podiatry;

Sam Haycocks,⁴ FFPM RCPS (Glasg), Advanced Podiatrist; *Mark Rippon,⁵ Visiting Clinical Research Fellow, Huddersfield University, Medical Marketing Consultant Daneriver Consultancy Ltd;

Jackie Stephen-Haynes,⁶ Professor and Consultant Nurse in Tissue Viability;

Sue Simm,⁷ Clinical Development Manager

Corresponding author email: markrippon@btconnect.com

1 Humber NHS Foundation Trust, The Grange Hessle, 11 Hull Road, Hessle, HU13 9LZ. **2** Worcestershire Health & Care Trust. **3** College of Podiatry, Quartz House, Mill Street, London **4** Salford Royal (NHS) Foundation Trust, UK. **5** Holmes Chapel. **6** Birmingham City University and Worcestershire Health & Care Trust. **7** Hartmann UK.

An observational study of a superabsorbent polymer dressing evaluated by clinicians and patients

Objective: This open, non-comparative, multi-centre investigation examines the use of a new superabsorbent polymer (SAP) wound dressing used for exudate management (in medium-to-high exuding wounds) in a patient population with a variety of wound types. The primary objective of this study was to evaluate the fluid management capabilities of the dressing.

Method: Both acute and chronic wounds with moderate-to-high exudate production levels were assessed (over a period of two weeks) as requiring exudate management, with a SAP dressing, Zetuvit Plus*, as part of their normal treatment regimen. Clinicians recorded a subjective assessment of exudate management and its impact on periwound skin conditions. In addition, wound bed preparation, healing trajectory and pain level reduction were monitored to give an insight into the clinical implications of using this dressing. Data was also collected from clinicians and patients on clinical performance of the dressing.

Results: The SAP dressing achieved ratings of 'very good'/'good' (83% and 13%, respectively) in relation to its wound exudate handling properties. The dressing supported improved wound healing, reduced

damage to and enhanced the status of the periwound skin. Pain levels were reduced and, as a consequence, patient reported outcomes were improved. Patients commented that the exudate handling capabilities of the dressing, its conformability and comfort allowed them to resume a semblance of normality in their life. All participating clinicians indicated that they would continue to use the SAP dressing. A sub-population cost analysis has highlighted that, when compared to alternative (historical) exudate management treatments, the SAP dressing was less expensive. The cost reduction arises from data that shows product use and frequency of dressing change (that impacts on nurse time) are both reduced. For the 10 patients evaluated, total costs were £2,491 and £1,312 before and during use, respectively; a saving of £1,179.00 (47%).

Conclusion: The SAP dressing was well tolerated and shown to be effective in the management of moderate-to-high exudate. Consequently, the dressing supported improved healing, and reduced damage to periwound skin, leading to lower pain levels. Overall, both the patients and clinicians rated the SAP highly.

Declaration of interest: This study was supported by funding from Hartmann.

chronic wounds • exudate management • superabsorbent wound dressings • Zetuvit Plus

Wound exudate is an important component of the wound healing response, and has implications in both acute and chronic wound healing.¹ In acute wounds, wound exudate is at its highest level during the inflammatory phase and contains many components that aid healing.^{2,3} However, in chronic wounds, exudate contains components that are deleterious and which compromise the healing response, such as high levels of matrix metalloproteinase (MMP) which may degrade tissue.⁴⁻⁸

Therefore, the management of wound exudate is an important aspect of wound care, particularly chronic

wound care (Table 1). Effective wound exudate control is needed to minimise the aspects of a patients' Quality of Life (QoL) negatively affected when this control is inadequate.⁹ Some of the negative effects on QoL include periwound skin damage and elevated pain.¹⁰ A number of wound dressings that have been developed to effectively manage wound exudate have been shown to reduce the time-to-healing, frequency of dressing changes and nursing time.¹¹ Effective fluid handling is an important property of an 'ideal dressing'.¹² An advantage of a dressing with high fluid absorbency and fluid retention is to allow these dressings to remain in place for extended periods of time; this reduces the number of times the patients have to 'suffer' dressing changes.¹³

Superabsorbent polymer wound dressings have been developed with the aim of providing extra fluid-handling capacity compared with standard dressings, such as foam dressings.^{14,15} These superabsorbent dressings are designed to be used on wounds of varying aetiologies that produce moderate-to-high volumes of wound exudate.¹⁶ Benefits of effective exudate absorption by superabsorbent dressings include reducing the risk of exudate leakage and skin maceration.¹⁷ In recent years, there has been an increase in the number of wound dressings containing a

Simon Barrett,¹ Lead TVN; **Rosie Callaghan,**² TVN; **Paul Chadwick,**³ PhD MSc (res) BSc (hons) FCPM, National Clinical Director at the College of Podiatry; **Sam Haycocks,**⁴ FFPM RCPS (Glasg), Advanced Podiatrist; **Mark Rippon,**⁵ Visiting Clinical Research Fellow, Huddersfield University, Medical Marketing Consultant Daneriver Consultancy Ltd; **Jackie Stephen-Haynes,**⁶ Professor and Consultant Nurse in Tissue Viability; **Sue Simm,**⁷ Clinical Development Manager

Corresponding author email: markrippon@btconnect.com

1 Humber NHS Foundation Trust, The Grange Hessle, 11 Hull Road, Hessle, HU13 9LZ. **2** Worcestershire Health & Care Trust. **3** College of Podiatry, Quartz House, Mill Street, London **4** Salford Royal (NHS) Foundation Trust, UK. **5** Holmes Chapel. **6** Birmingham City University and Worcestershire Health & Care Trust. **7** Hartmann UK.

superabsorbent polymer (SAP) in order to take advantage of their superior fluid absorbing capabilities.^{14,18} Depending on the physical and chemical design of the polymer, the fluid-handling capacity of SAP can vary substantially and, in combination with other materials (e.g., cellulose), can modify the polymer's characteristics.¹⁴ SAPs have also been shown to have additional properties that enhance wound healing. These properties include reducing wound bioburden,¹⁹⁻²² and the modulation of protein-degrading enzyme (proteinases) and reactive oxygen species (ROS).^{17,20,23} Elevated levels of proteinases and ROS in the ulcer wound environment are potentially damaging to wound and periwound tissues if they are not effectively controlled.^{24,25} The removal and sequestering of excessive amounts of wound exudate supports wound healing by preventing tissue damage caused by elevated levels of these tissue-destroying components.¹⁶

A new superabsorbent polymer (SAP) dressing, Zetuvit Plus* is used on severely exuding wounds. It is a combined absorbent dressing pad which consists of four layers of different materials.

- Soft, non-woven wound contact layer
- Thin cellulose diffusion layer (quickly passes exudate into the absorbent core)
- Superabsorbent core made of cellulose fibres blended with SAP (to quickly absorb and retain wound exudate)
- Green, hydrophobic outer layer, water repellent and air-permeable (to protect clothing and bedding and against contamination).

The dressing can also be applied under compression therapy.

Aim

Our aim was to investigate the ability of a new superabsorbent polymer (SAP) dressing, to manage exudate, in medium-to-high exuding wounds, of various aetiologies.

Methods

Ethics approval

Formal ethical approval was deemed not to be required as the SAP dressing was a CE-marked product being used according to the manufacturer's instructions, and patients were not being treated outside of their normal regimen. The investigation was performed in accordance with the Declaration of Helsinki²⁶ and applicable regulatory requirements. Patient participation was voluntary, all were provided with patient information and were asked to sign an informed consent form, to allow further use of data in educational or commercial settings. All patients had the right to refuse to enter the study.

Study design

The study was designed as an open, non-comparative, multi-centre investigation. Inpatients and/or out-

Table 1. Implications of poor exudate management

Clinical consequence	Subsequent clinical implication on the patient
Wound exudate leakage and staining leading to soiled clothing, furniture, etc	Need for frequent dressing changes and/or having to wash clothes, etc
Malodour from the wound or leaked exudate	Issues leading to potential embarrassment of the patient, carer/family, possibly leading to isolation
Periwound skin damage	Skin maceration or excoriation that may lead to localised infection and other implications outlined in this column
Discomfort/pain resulting from 1-3 above	Quality of life issues for the patient
Excessive levels of chronic wound exudate containing detrimental biological factors such as matrix metalloproteinases (MMPs)	Tissue destruction which may also lead to discomfort/pain and, ultimately, delayed healing
Note: the majority of the above complications relating to poor exudate management will lead to an increase in costs	

Table 2. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Older than 18 years-of-age	Known allergy/hypersensitivity to any of the components in the dressing
Signed consent form	Patients who will have difficulty following the protocol
Patient with any wounds that have moderate-to-high levels of wound exudate in need of management	Severe underlying disease judged by the investigator to interfere with treatment

patients were included.

Study endpoints

The primary objective of this study related to the exudate management capabilities of the SAP dressing and its impact on the periwound skin, in terms of damage that might be caused by wound exudate. Specifically, the study was aimed at wounds with moderate-to-high levels of exudate, in addition, the type and viscosity of the wound exudate varied, covering the wide range of exudate challenges seen in the clinic. Additional objectives included an evaluation of the dressing's ability to promote wound bed preparation and wound progression. Dressing performance when used in the treatment of a range of wounds and conditions was also assessed.

Patients inclusion and exclusion

Inclusion and exclusion criteria are outlined in Table 2. Patients included in the study were selected by the clinical investigator(s) according to whether their wound had moderately-to-highly exudate and in need of an appropriate wound dressing to manage the exudate.

Test procedure and dressing evaluation

Each patient was treated according to the local clinical routine and evaluated during a treatment period of two weeks, or for a minimum of four dressing changes. All dressings were applied according to the manufacturer's instructions and the patients'

*Designated RespoSorb Super in other countries.

Table 3. Patient population characteristics

	Patient number	Age mean±standard deviation	Wound duration
Male	18	74.71±15.47 years	Between weeks and years
Female	32	78.00±14.78 years	
Total number of separate wound assessments—312			

individual clinical requirements.

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

At each subsequent dressing change a subjective wound assessment was undertaken and the following variables were evaluated and recorded on designated evaluation forms developed for the study:

- Level of exudate within the wound ('high', 'moderate' or 'low'), exudate description ('clear', 'yellow/green', 'brown/bloody', 'other') and viscosity ('high', 'moderate' or 'low') and the need for its management
- Associated with the exudate management, the reason for any dressing changes ('scheduled change', 'leakage', 'strikerthrough', 'reached maximum exudate handling capacity', 'wound observation' or 'failure of fixation')
- The impact of any exudate on the condition of periwound skin ('healthy', 'eczematous', 'excoriated', 'dry', 'inflamed', 'macerated', 'hyper-hydrated')
- Healing parameters related to wound size (length and width) and appearance of wound bed (% re-epithelialisation, % granulation, % necrosis, % slough)
- Level of bacterial contamination of wound ('infected', 'critically colonised')
- Level of pain before and after dressing application, using a visual analogue scale (VAS)
- Adverse events (AE) relating to, for example, the wound ('inflammation', 'infection'), significant deterioration of the surrounding skin ('inflammation', 'infection', 'significant deterioration', 'eczema', 'erysipelas', 'erosion', 'irritation', 'maceration', 'blistering', 'ulceration') or any other deleterious effects that might be harmful to the patient.

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 clinician perspectives. Both clinician and patient views were recorded.

Wound healing progression was assessed by calculating the wound area at each assessment point. In order to more easily 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 '1').

Treatment cost analysis

A sub-population of 10 patients were randomly identified. A retrospective interrogation of patient case notes was undertaken for the identification and recording of treatments over a two week period immediately before and then for a two week period during treatment with the SAP dressing.

Costs were assigned to each treatment using:

- Wound care products: Wound Care Handbook 2017–2018²⁷ (a guide to product selection)
- Nurse time: via Royal College of nursing NHS Payscales 2017–2018, valid from 1st April²⁸
- Pharmaceuticals: Dermatology Handbook 2017–2018.²⁹

Calculations were undertaken to show:

- Total cost of treatments per patient
- Difference in cost of treatment
- Total savings over ten patients.

Statistics

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) or trendlines, using an XL software package, where appropriate.

Duration of study:

The duration of the study, to allow for recruitment of 50 patients, was to be six months (or less if patient enrolment was concluded before this). These evaluations were undertaken in accordance with routine dressing changes on a clinical requirement basis. The patient was to be evaluated over a period of two weeks, or a minimum of four dressing changes.

Results

Epidemiology

We recruited 50 patients/wounds and 312 individual assessments comprised the data. The patient population characteristics are summarised in Table 3. A variety of wounds were evaluated with the majority chronic:

- Venous leg ulcers (VLUs) 29%
- Pressure ulcers (PUs) 22%
- Diabetic foot ulcers (DFUs) 8%.

The levels, type and viscosity of exudate for each wound, at each time point, represent a wide range of exudate types. In particular, a high proportion of the wounds were rated in the 'high' (35%) or 'moderate' (59%) range.

Past treatments

Before inclusion in this study, a wide variety of wound dressings were being used to manage wounds. Foams

(24%), antimicrobials (21%), alginates (13%) and gels (13%) were the four most common dressing categories used.

Exudate management

Clinicians rated the SAP dressing fluid management capabilities as ‘very good’ (83%) or ‘good’ (13%) in managing all the different levels and types of exudate seen. All the clinicians participating in the study recorded that they would continue to use the SAP dressing (Fig 1).

Reasons for dressing changes

Fig 2 shows the total number of dressing-related observations when clinicians performed a dressing change. The main clinical observation noted was ‘dressing changes’ as part of the scheduled treatment regimen followed by the observation of ‘dressing strikethrough’ (72.0% and 12.4%, respectively). After further discussion with the investigators it was clarified that, in general, strikethrough was recorded even when only a small amount of exudate was apparent on the surface of the dressing. Generally, this level of strikethrough would have been disregarded as clinically irrelevant but was still captured in this study. Closer examination of the data showed that many assessments had multiple observations. For example, one patient, during a scheduled dressing change, had additional observations of ‘wound observation’, ‘exudate handling’ and ‘leakage’. Results of an analysis to assess whether a dressing change was scheduled or unscheduled, show that over 95% of changes were scheduled, with only 4.5% being unscheduled. The main reason for an unscheduled dressing change was associated with ‘wound observation’ (possibly due to clinicians wanting to monitor more frequently than the schedule indicated), followed by issues with ‘exudate handling’ and ‘strikethrough’. Despite this, all of the clinicians indicated that the wear time could have been lengthened as the dressing did not appear to have reached its full absorbance capacity.

The median frequency of dressing change was three days, (range: 1.5–11 days) (Table 4). Dressing change frequencies were highest between 2 and 4 days. The dressing change frequency of previously used treatments was recorded at the start of the study and showed the percentage of patients that had their dressings changed several times a day (6%), twice daily (4%), once daily (47%), every second day (18%) and every third day (20%) (Table 4, note some patients’ previous dressing change frequencies were not recorded).

In terms of periwound skin conditions during the course of the evaluation period, there was a significant increase in the number of patients identified with healthy skin (5% rising to 28%). There were also significant decreases in patients exhibiting excoriation (28% to 20%), to 16%) and maceration (26% to 9%) (Fig 3). There were 11% of patients who recorded having

Fig 1. Assessment of clinician’s experience with the use of the dressing

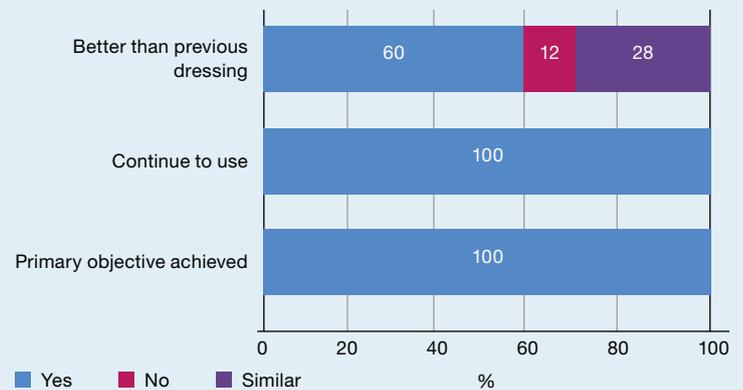


Fig 2. Proportion of dressing-related observations noted at dressing changes during study duration

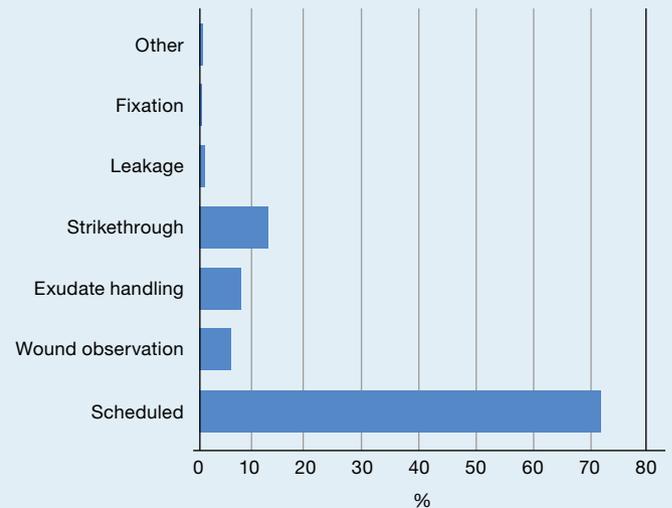


Fig 3. Changes in periwound skin condition

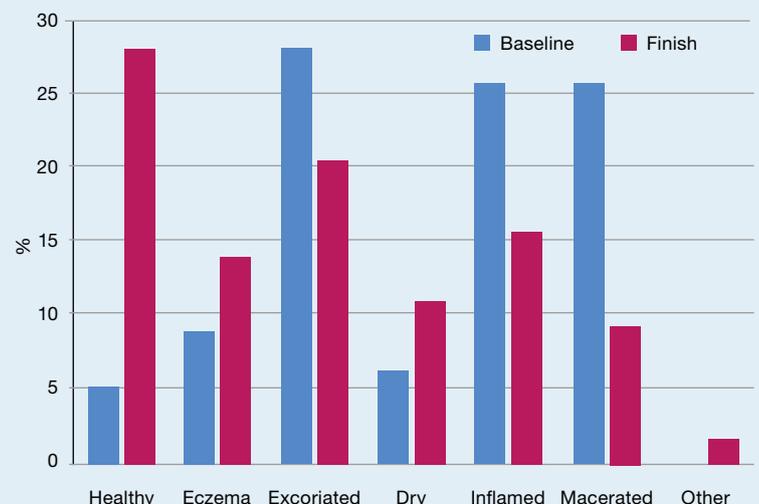


Table 4. Frequency of dressing change

	Before inclusion* (%)	During study (%)
Several times a day	6	0
Twice a day	4	0
Once a day	48	8
Once a every 2 days	18	36
Once a every 3 days	20	42
Once a every 4 days	0	4
Once a every 5 days	0	4
Weekly	0	2
Other	0	2

*Data not available for two patients before the study

Fig 4. Percentage wound area reduction from baseline to finish of evaluation. Dotted line—trendline. Mean±standard deviation

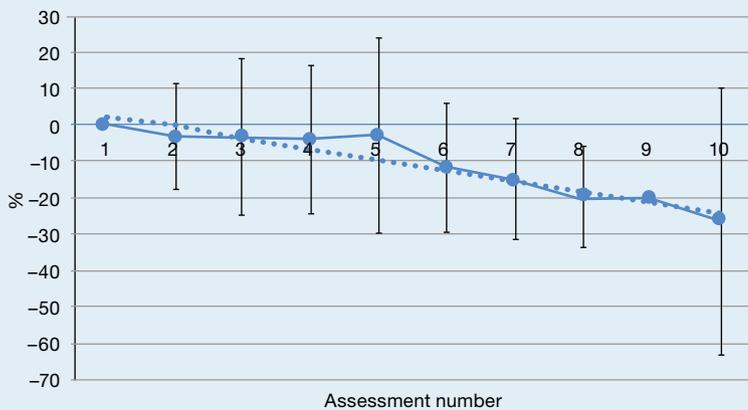
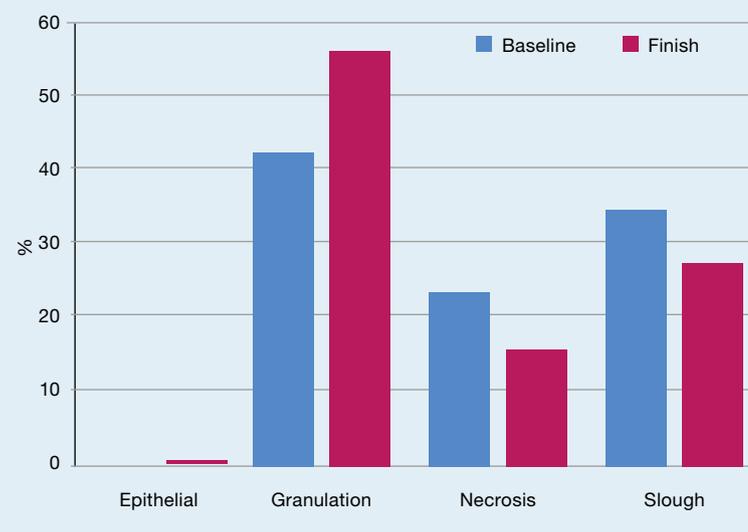


Fig 5. Wound bed changes during evaluation period



‘dry’ skin at the end of the study compared with 6% at the beginning. This increase in the proportion of patients with dry skin may be attributable to wound progression and/or improved dressing exudate management as the periwound skin dries. Overall, the periwound skin

conditions ‘improved’ in 54% of patients, ‘stayed the same’ in 42% of patients, and ‘deteriorated’ in only 4% of patients, over the course of the observation period. At the start of the study 8% of patients had healthy periwound skin and this proportion increased to 36% by the end of the study (Fig 3).

Analysis of the data relating to infection showed that 40.6%, 28.4% and 34.2% of wound assessments noted wound odour, infection or critical colonisation, respectively (assessments evaluated subjectively). Alongside this data, nearly half of the wounds presented with some kind of infection related signs: redness (23.2%) and oedema (14.9%) or friable tissue (10.2%). The high levels of bacterial burden may be responsible for the high levels of exudate seen in many of the wounds. As a consequence of these indications of infection/critical colonisation a variety of topical antimicrobial agents, such as Flamazine, Metrotop, Metronidazole and honey, were used in conjunction with the SAP dressing in attempt to treat these infections. The results show, in the time period evaluated, the infection parameters recorded in majority of the wounds remained the same, but odour and infection parameters were eliminated in 22% and 10% of patients, respectively. Interestingly, laboratory data has indicated that the SAP dressing is effective in absorbing bacteria and chemicals (thiols) associated with producing odour in chronic wounds.³⁰

Wound healing progression

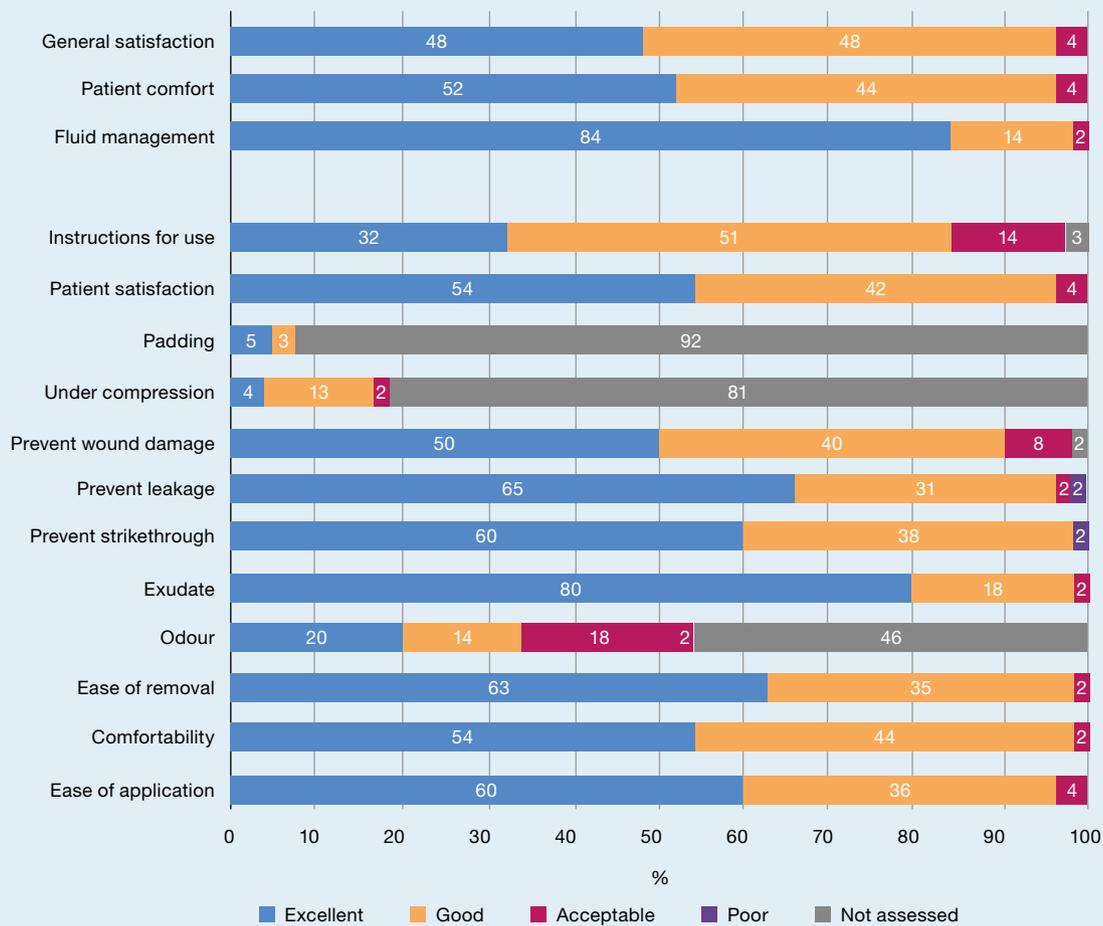
Overall, there was a trajectory of healing with a trend towards a reduction in wound size of about 25% (Fig 4).

This wound area reduction correlates with data showing positive changes in the levels of devitalised tissue and healthy granulation tissue in the wound bed. During the evaluation period there is a decrease in the level of necrosis (23.3% to 15.6%) and slough (34.4% to 27.4%) in the wound bed and a corresponding increase in healthy granulation tissue (42.3% to 55.7%) (Fig 5). Closer inspection of the data demonstrated that, in many cases, levels of granulation tissue remained stable (for the period of the study) indicating that the environment provided by the SAP dressing was beneficial for maintenance of the wound bed.

Overall dressing assessment

In the overall dressing assessment summary sheets, the majority of responses, in particular performance with regard to exudate management, rated the SAP dressing as ‘excellent’ or ‘good’ in over 95% of respondents. The dressing’s performance and the dressing use experience were all rated highly as either ‘excellent’ or ‘good’ in all but 2–3 parameters. In these cases, odour control and under compression, only a few assessments were made n=26 and n=9 respectively, however, a significant proportion of respondents (>65%) provided ‘excellent’ or ‘good’ ratings. It is noteworthy that the patients’ ratings for ‘wear comfort’ and ‘general satisfaction’ were both ‘excellent’/‘good’, within the 90–100% range (Fig 6).

Fig 6. Questionnaire responses on dressing performance and dressing use experiences



SAP dressing use with ancillary products

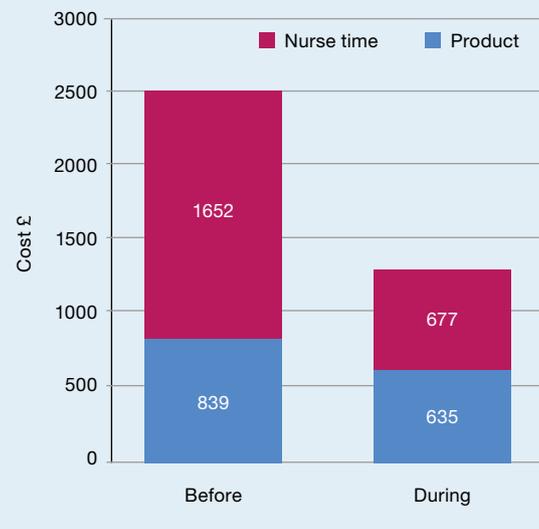
In several of the patients, the SAP dressing was used successfully with ancillary products that were part of the overall treatment of the patient’s wound and other comorbidities. Several wounds showed indications of critical colonisation (34.2%) and/or infection (28.4%), and the SAP dressing was used in conjunction with topical antimicrobial agents to reduce bacterial burden. In addition, some patients were prescribed steroid creams to reduce skin conditions that had a component of local inflammatory response, such as eczema. The SAP dressing was used under compression to treat patients with a VLU, with no adverse effects, or reduction in effectiveness of the compression reported.

Patient benefits

Benefits reported by patients included: exudate management capabilities; the wound area was kept dry; no resultant soiling of clothes or footwear; and less pain during dressing removal (because of no adhesion of the dressing to the surface of the wound).

Wound pain ‘at dressing change’ and ‘between dressing change’ was assessed using a validated VAS at the beginning and end of the study. At dressing

Fig 7. Costs before and during treatment with the superabsorbent polymer dressing



change, pain levels were reported to be the same or reduced in 56% and 38% of patients, respectively. In two patients (4%) pain at dressing change was noted

Fig 1. A 62-year-old female with bilateral leg oedema and chronic leg ulceration of 10 months' duration. The status of the left leg wound at presentation (**a** and **b**). The superabsorbent polymer dressing after removal one week before the start of treatment and with exudate absorption and retention within the dressing (**c**). The dressing was retained to the position of the wound (**d**). Healing of the wound on the right leg one week after the start of treatment (**e** and **f**)



to have increased. Between dressing changes, pain levels remained the same or reduced in 60% and 32%, respectively. An increase in wound pain between dressing change was observed in 8% of patients. Generally, patients with high initial pain levels showed a reduction, while those starting with

low levels of pain tended to stay the same (data not shown).

Cost comparison analysis

In this sub-population analysis, 10 patients were drawn ad hoc from the study. This cohort included three males and seven females, aged (mean±standard deviation) 77±2.6 and 76±16.0 years, respectively. The wounds were VLU (n=4), PU (n=2), arterial (n=1), chest wound (n=1), 'wet legs' (n=1) and surgical (n=1). Using the patient case notes, data relating to the management of exudate were collected two weeks before and two weeks during the use of SAP dressing. From this, data cost were assigned relating to the products (sources in 1 and 2 of the methods section)^{27,29} and nurse time (source in 3 of methods section).²⁸

The mean costs per patient were, before enrolment in the study, £84.00±19.40 for products used and £150.20±82.60 for nurse time. The costs during the study were £63.50±33.10 for products used and £67.80±£12.10 for nurse time.

For the 10 patients evaluated, total costs were £2,491 and £1,312 before and during use, respectively, a saving of £1,179.00 (47%) (Fig 7). The greatest saving can be seen in nurse time and this relates, for the most part, to the fact that mean frequency of dressing changes was, before enrolment in the study six times per week which reduced to 2.7 times per week during the study.

Case series

A 62-year-old female, with bilateral leg oedema and chronic leg ulceration of 10 months' duration. The patient also had diabetes and an irregular heartbeat. Fig 1a and 1b show the status of the left leg wound at presentation. The wounds on the right and left leg measured 24cm² and 22cm² respectively. They had previously been treated with Aquacel, Kliniderm, Actifast under Ksoft, Klite, dressings had been changed daily. Leakage of wound fluid had led to excoriation and skin ulceration. Background and dressing change pain levels were moderately high (each at VAS 5). At this time point the wounds showed a 50:50 granulation tissue slough ratio.

After removal one week before the start of treatment, exudate absorption and retention can be seen within the SAP dressing (Fig 1c). The dressing was retained to the position of the wound (Fig 1d). Figs 1e and 1f demonstrate good healing of the wound on the right leg one week after the start of treatment. Within the periwound area there was reduced maceration/excoriation. Overall, there was excellent exudate absorbency by the dressing and the pain levels were reduced as a VAS of 4 was now reported.

A 79-year-old male, ulceration to medial malleolus of 5 years duration. At enrolment the wound size was 20cm² (Fig 2a and b) Previously treated with Silvercel, Kliniderm and Actifast under K1/K2 every second day. The wound was critically colonised, there was high levels of oedema and severe excoriation of periwound

skin. The background wound pain was moderate (VAS 3) that increased at dressing change (VAS 7). After two weeks the patient's wounds were healing well (Fig 2c and d) and the periwound skin was showing reduced erythema, excoriation and maceration. The dressing had good exudate absorbency and no strikethrough. The pain levels according to the VAS remained unchanged.

Patient 3, a 94-year-old with chronic leg ulceration of three years duration. Comorbidities include atrial fibrillation, osteoporosis and inflammatory bowel disease. The wound size at enrolment was 16.5cm². It had previously been treated with Urgotul Silver, Kliniderm, Actifast under KSoft, Klite, changed every third day. At presentation, there was 50:50 granulation tissue slough ratio, periwound tissue was eczematous, dry and inflamed with areas of excoriation (Fig 3a). After one week, wound healing was progressing (Fig 3b), the periwound skin maceration and excoriation were reduced and there was a decrease in wound exudate located on the wound bed surface and periwound skin. Figure 3c shows the wound contact side of a SAP dressing; the wound exudate is contained within a small area mirroring the shape of the wound. Figure 3d shows the outer facing side of the dressing with very little indication of exudate strikethrough.

Discussion

In this study, three patients presented with so-called 'wet legs'. This problem occurs if the volume of interstitial fluid in the limb exceeds its capacity to retain it. This may be complicated if there is a breach in skin integrity or an infection, and which can result in gross swelling, blistering and leakage of interstitial fluid onto the skin.³¹ The symptoms arising from 'wet legs' can have a significant impact on a patient's QoL; excessive exudate levels that are inadequately managed can lead to problems including malodour, reduced mobility and soiling of clothes, footwear, bedding and furniture.²⁷ Reduced mobility and the potential embarrassment these symptoms can cause to the patient can lead to social isolation.^{31,32} Anecdotal evidence has indicated that some patients have been treated with nappies as there was no alternative treatment for managing the extremely high levels of exudate. For 'wet legs', a dressing needs to absorb and retain exudate, so that fluid does not leak back onto the skin.³³ Therefore, superabsorbent dressings that have a greater absorption capacity than foam dressings should be used on these types of wet wounds.¹⁸ The data from this study shows that the SAP dressing was very effective in managing such wounds.

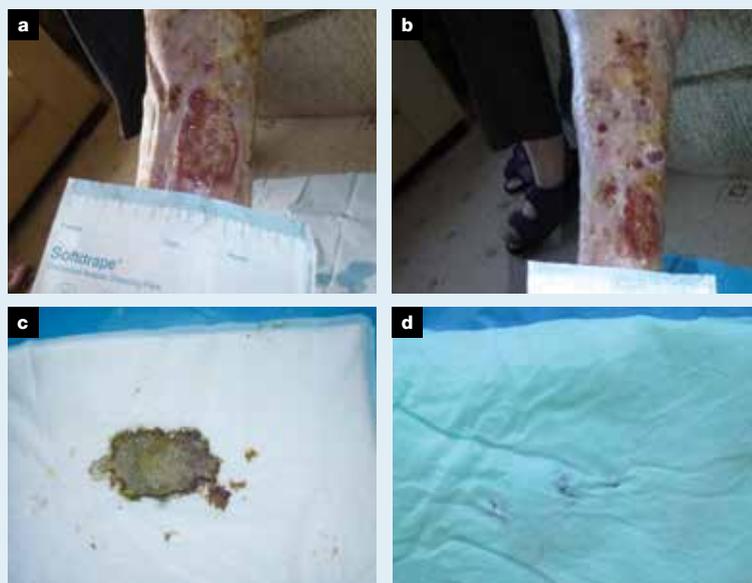
We observed little effect of the antibacterial measures taken on the signs of wound infection. The limited impact on wound infection in this study is not surprising. Biofilms have been shown to be prevalent in many chronic wounds³⁴ and are notoriously difficult to eradicate,^{35,36} particularly within two weeks.

According to our data, a number of patients were being treated with foams to manage moderate-to-high

Fig 2. A 79-year-old male, ulceration to medial malleolus of five years' duration shows the status at presentation (a and b). The periwound skin was excoriated and macerated, and the wounds produced significant levels of exudate. After two weeks (c and d) the wounds are healing well, and the periwound skin is showing reduced erythema, excoriation and maceration



Fig 3. A 94-year-old with chronic leg ulceration of three years' duration. At enrolment, a 50:50 granulation tissue slough ratio, the periwound tissue was eczematous, dry and inflamed with areas of excoriation (a). After one week, healing progressed, the periwound skin maceration and excoriation, and wound exudate on the wound bed surface and periwound skin were reduced. The wound contact side of the dressing (c) and the outer facing side of the dressing (d) show good retention with little exudate strikethrough



wound exudate. This appears contrary to current recommendations in that a recent best practice statement document, 'Effective Exudate Management'⁹ which suggests caution in the use of foam dressings, stating that in a study on moderate-to-heavily exuding VLU's Schulze et al.³³ found maceration at 20% of dressing changes. This has led to their withdrawal from some dressing formularies.³⁷ Furthermore, the document recommends that a highly exuding wound will require a superabsorbent dressing or NPWT.⁹

It is likely that the beneficial healing environment provided by the SAP dressing was due partly to the removal/sequestration of damaging components, such as MMPs by the dressing. This sequestration has been confirmed by laboratory studies.³⁸ Overall, the healing response seen with the dressing was comparable to the healing responses seen in other similar studies.³⁹⁻⁴¹ Our data was also supported by the findings that the dressing achieved its primary objective in 100% of the assessments and that the SAP dressing was better than or similar to previously used dressings.⁴²

As regards dressing changes, our data suggests that the frequency of dressing changes, when the wounds were treated with the SAP dressing, was reduced, when compared with dressing change frequency before the study. Furthermore, the calculated wear time is slightly longer than the standard practice relating to the use of SAP-containing wound dressings on moderate-to-high exudate levels.⁴³

It is noteworthy that some of the wound exudates were rated as 'high' viscosity. This is often true in terms of infected wounds,⁴⁴ of which a high number were included in this study. This SAP wound dressing can absorb wound exudate of varying viscosities, which offers clear clinical benefits. It is also interesting to note that, in one patient, the SAP dressing effectively absorbed post-debridement blood.

At the start of the study, a variety of periwound skin conditions (eczema, excoriation, maceration) were present. These conditions can generally be attributed to the presence and intimate contact of wound exudate with the periwound skin.⁴⁵ Chronic wound exudate contains many components, such as MMPs, elastases, and ROS, which are likely to cause damage to the integument.^{19,46,47} Our periwound skin data compares favourably with the results of another study which looked at a superabsorbent dressing in a similar patient population.³⁹ The treatment period in the study reported by Cutting was over four weeks and not two weeks, as here.³⁹ The improvement of periwound skin seen in this study has implications for wound healing as it has been demonstrated (in VLU's) that the integrity and status of periwound skin is an important determinant towards supporting healing.⁴⁸

Conclusion

The SAP dressing achieved the primary objective relating to wound exudate management in all of the assessments undertaken in this study and underlines the fluid handling capabilities of the dressing. In doing so it supported healing, reduced damage to periwound skin and increased positive patient-reported outcomes. Overall, the dressing was rated highly by clinicians and patients. In particular, many patients commented how comfortable the dressings were to wear, and that they found they were able to resume a semblance of normality in their life.

The sub-population cost analysis has highlighted that, when compared with alternative (historical) exudate management treatments, the SAP dressing was less expensive. The reduction in costs arises from data that shows product use and frequency of dressing change (that impacts on nurse time) are both reduced when using the dressing. **JWC**

References

- 1 Chamanga E. Effectively managing wound exudate. *Br J Community Nurs* 2015; Suppl Wound Care:S8, S10. <https://doi.org/10.12968/bjcn.2015.20.Sup9.S8>
- 2 Spear M. Wound exudate: the good, the bad, and the ugly. *Plast Surg Nurs* 2012;32(2):77-79. <https://doi.org/10.1097/PSN.0b013e318256d638>
- 3 Power G, Moore Z, O'Connor T. Measurement of pH, exudate composition and temperature in wound healing: a systematic review. *J Wound Care* 2017; 26(7):381-397. <https://doi.org/10.12968/jowc.2017.26.7.381>
- 4 Serra R, Buffone G, Falcone D et al. Chronic venous leg ulcers are associated with high levels of metalloproteinases-9 and neutrophil gelatinase-associated lipocalin. *Wound Repair Regen* 2013; 21(3):395-401. <https://doi.org/10.1111/wrr.12035>
- 5 Amato B, Coretti G, Compagna R et al. Role of matrix metalloproteinases in non-healing venous ulcers. *Int Wound J* 2015; 12(6):641-645. <https://doi.org/10.1111/iwj.12181>
- 6 Junka A, Wojtowicz W, Ząbek A et al. Metabolic profiles of exudates

- from chronic leg ulcerations. *J Pharm Biomed Anal* 2017; 137:13-22. <https://doi.org/10.1016/j.jpba.2017.01.018>
- 7 Humbert P, Courderot-Masuyer C, Robin S et al. Exudates absorption and proteases trapping in venous leg ulcers. *J Wound Care* 2017; 26(6):346-348. <https://doi.org/10.12968/jowc.2017.26.6.346>
- 8 Moor AN, Vachon DJ, Gould LJ. Proteolytic activity in wound fluids and tissues derived from chronic venous leg ulcers. *Wound Repair Regen* 2009; 17(6):832-839. <https://doi.org/10.1111/j.1524-475X.2009.00547.x>
- 9 Wounds UK. (2013) Wounds UK Best Practice Statement. Effective exudate management. <http://www.wounds-uk.com/best-practice-statements/best-practice-statement-effective-exudate-management>
- 10 Santos VL, Oliveira AS, Amaral AF et al. Quality of life in patients with chronic wounds: magnitude of changes and predictive factors. *Rev Esc Enferm USP* 2017; 51(0):e03250. <https://doi.org/10.1590/s1980-220x2016049603250>
- 11 Dabiri G, Damstetter E, Phillips T. Choosing a wound dressing based on common wound characteristics. *Adv Wound Care (New Rochelle)* 2016; 5(1):32-41. <https://doi.org/10.1089/wound.2014.0586>
- 12 Sood A, Granick MS, Tomaselli NL. Wound dressings and comparative effectiveness data. *Adv Wound Care (New Rochelle)* 2014; 3(8):511-529. <https://doi.org/10.1089/wound.2012.0401>
- 13 Landriscina A, Rosen J, Friedman AJ. Systematic approach to wound dressings. *J Drugs Dermatol* 2015; 14(7):740-744
- 14 Cutting KF, Westgate SJ. Super-absorbent dressings: how do they perform in vitro? *Br J Nurs* 2012;21 Sup20:S14-S19. <https://doi.org/10.12968/bjcn.2012.21.Sup20.S14>
- 15 Browning P, White RJ, Rowell T. Comparative evaluation of the

Reflective questions

- What specific physiological impacts does a SAP dressing have on wound healing
- Outline two consequences of poor exudate management
- What are the advantages and disadvantages of the different dressing types in managing exudate.

- functional properties of superabsorbent dressings and their effect on exudate management. *J Wound Care* 2016; 25(8):452–462. <https://doi.org/10.12968/jowc.2016.25.8.452>
- 16** Wiegand C, Tittelbach J, Hipler UC, Elsner P. Clinical efficacy of dressings for treatment of heavily exuding chronic wounds. *Chronic Wound Care Manage Res* 2015; 2:101–111. <https://doi.org/10.2147/CWCMR.S60315>
- 17** Wiegand C, White RJ. Binding and inhibition of protease enzymes, including MMPs, by a superabsorbent dressing in vitro. *J Wound Care* 2013; 22(5):221–229. <https://doi.org/10.12968/jowc.2013.22.5.221>
- 18** Ousey K, Atkin L, White R. Superabsorbent wound dressings: a literature review. *Wounds UK* 2013; 9(3):52–60.
- 19** Eming S, Smola H, Hartmann B et al. The inhibition of matrix metalloproteinase activity in chronic wounds by a polyacrylate superabsorbent. *Biomaterials* 2008; 29(19):2932–2940. <https://doi.org/10.1016/j.biomaterials.2008.03.029>
- 20** Wiegand C, Abel M, Ruth P, Hipler UC. Superabsorbent polymer-containing wound dressings have a beneficial effect on wound healing by reducing PMN elastase concentration and inhibiting microbial growth. *J Mater Sci Mater Med* 2011; 22(11):2583–2590. <https://doi.org/10.1007/s10856-011-4423-3>
- 21** Wiegand C, Abel M, Muldoon J, Ruth P, Hipler UC. SAP-containing dressings exhibit sustained antimicrobial effects over 7 days in vitro. *J Wound Care* 2013 Mar; 22(3):120–127. <https://doi.org/10.12968/jowc.2013.22.3.120>
- 22** Larkö E, Persson A, Blom K. Effect of superabsorbent dressings in a 3D acellular tissue model of *Pseudomonas aeruginosa* biofilm. *J Wound Care* 2015; 24(5):204–210. <https://doi.org/10.12968/jowc.2015.24.5.204>
- 23** Wiegand C, Hipler UC. A superabsorbent polymer-containing wound dressing efficiently sequesters MMPs and inhibits collagenase activity in vitro. *J Mater Sci Mater Med* 2013; 24(10):2473–2478. <https://doi.org/10.1007/s10856-013-4990-6>
- 24** Wlasczek M, Scharffetter-Kochanek K. Oxidative stress in chronic venous leg ulcers. *Wound Repair Regen* 2005; 13(5):452–461. <https://doi.org/10.1111/j.1067-1927.2005.00065.x>
- 25** Chen WY, Rogers AA. Recent insights into the causes of chronic leg ulceration in venous diseases and implications on other types of chronic wounds. *Wound Repair Regen* 2007; 15(4):434–449. <https://doi.org/10.1111/j.1524-475X.2007.00250.x>
- 26** World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA* 2013; 310(20):2191–2194. <https://doi.org/10.1001/jama.2013.281053>
- 27** Cowan T. (ed) *Wound Care Handbook 2017–2018* (10th edn). MA Healthcare Ltd, 2017
- 28** Royal College of Nursing (RCN) NHS pay scales 2017–18 <https://www.rcn.org.uk/employment-and-pay/nhs-pay-scales-2017-18> (accessed 30 January 2018)
- 29** Van Onselen J (ed) *Dermatology Handbook 2017–2018* (6th edn). MA Healthcare Ltd, 2017
- 30** Laboratory report (on file) Perfectus PB065-002-V1 Daresbury Laboratories, SciTec Daresbury, Keckwick Lane, Cheshire, WA4 4AD
- 31** Whayman N. The causes and treatment of wet weeping legs. *Wound Essentials* 2015; 10(1):30–34.
- 32** Managing BP. 'wet legs' in patients with chronic oedema. In: *Skills for Practice: Management of Chronic Oedema in the Community*. Wounds UK, London, 2006; pp 20–23
- 33** Schulze HJ, Lane C, Charles H et al. Evaluating a superabsorbent hydroxypropyl polymer dressing for exuding venous leg ulcers. *J Wound Care* 2001; 10(1):511–8. <https://doi.org/10.12968/jowc.2001.10.1.26038>
- 34** Omar A, Wright JB, Schultz G et al. Microbial biofilms and chronic wounds. *Microorganisms* 2017; 5(1):pii:E9. <https://doi.org/10.3390/microorganisms5010009>
- 35** Bianchi T, Wolcott RD, Peghetti A et al. Recommendations for the management of biofilm: a consensus document. *J Wound Care* 2016; 25(6):305–317. <https://doi.org/10.12968/jowc.2016.25.6.305>
- 36** Snyder RJ, Bohn G, Hanft J et al. Wound biofilm: current perspectives and strategies on biofilm disruption and treatments. *Wounds* 2017; 29(6):S1–S17
- 37** White R, Gardner S, Cutting K. What is the current status of foam dressings? *Wounds UK* 2012; 8(3):21–24.
- 38** Internal Laboratory report Ref. 685020 and 685020 (data on file), Clinic for skin diseases Erfurter Str. 35, 07743 Jena Klinik für Hautkrankheiten
- 39** Cutting KF. Managing wound exudate using a super-absorbent polymer dressing: a 53-patient clinical evaluation. *J Wound Care* 2009; 18(5):200–205. <https://doi.org/10.12968/jowc.2009.18.5.42174>
- 40** Verral D, Coulborn A, Bree-Aslan C. Evaluating a super absorbent dressing (Flivasorb) in highly exuding wounds. *Br J Nurs* 2010; 19(7):449–453. <https://doi.org/10.12968/bjon.2010.19.7.47447>
- 41** Goto T, Tamai N, Nakagami G et al. Can wound exudate from venous leg ulcers measure wound pain status?: a pilot study. *PLoS ONE* 2016; 11(12):e0167478. <https://doi.org/10.1371/journal.pone.0167478>
- 42** Data on File, Hartmann internal report
- 43** Morris C. Flivasorb® and the management of exudate. *Wounds UK* 2009; 5(2):63–66.
- 44** Vowden P, Bond E, Meuleneire F. Managing high viscosity exudate. *Wounds International* 2015; 6(1). http://www.woundsinternational.com/media/other-resources/_1155/files/viscous-exudate-wint.pdf
- 45** Whitehead F, Giampieri S, Graham T, Grocott P. Identifying, managing and preventing skin maceration: a rapid review of the clinical evidence. *J Wound Care* 2017; 26(4):159–165. <https://doi.org/10.12968/jowc.2017.26.4.159>
- 46** Rayment EA, Upton Z. Finding the culprit: a review of the influences of proteases on the chronic wound environment. *Int J Low Extrem Wounds* 2009; 8(1):19–27. <https://doi.org/10.1177/1534734609331596>
- 47** Patel S, Maheshwari A, Chandra A. Biomarkers for wound healing and their evaluation. *J Wound Care* 2016; 25(1):46–55. <https://doi.org/10.12968/jowc.2016.25.1.46>
- 48** Hunter SM, Langemo D, Thompson P et al. Observations of periwound skin protection in venous ulcers: a comparison of treatments. *Adv Skin Wound Care* 2013; 26(2):62–66. <https://doi.org/10.1097/01.ASW.0000426714.57540.c4>

