An observational study of the use of a soft silicone silver dressing on a variety of wound types

Routine use of this dressing in a specialist wound care centre eradicated clinical signs of localised infection in most cases. Healing progression was generally reported as good and there was a reduction in the level of pain intensity

localised wound infection; pain; healing; patient acceptability

Acute and chronic wounds offer pathogenic microorganisms the opportunity to flourish in an attractive environment of devitalised tissue.[1,2] While all wounds contain microorganisms, the majority are not infected. However, immediate clinical intervention is required when interactions between the microorganisms and host can disrupt the wound healing process or result in local detrimental effects.

Nearly all leg ulcers are colonised with microorganisms (by *Pseudomonas aeruginosa* in approximately 20% of cases), which may lead to local or systemic wound infection.[3-6]

According to the European Wound Management Association (EWMA) position document, wounds with signs of colonisation, such as increasing malodour, pain or exudate, can be treated with topical antimicrobial dressings to prevent the development of overt infection.[7]

Infection by multidrug-resistant bacteria, such as meticillin-resistant *Staphylococcus aureus* (MRSA), is a major complicating factor in patients with chronic leg ulcers[8,9] and burns.[10] Additionally, the risk of soft tissue infection, such as cellulitis, is increased in patients with chronic wounds.[11]

Use of systemic antibiotics is higher in patients with leg ulcers compared with age- and gender-matched patients with other diseases.[2] Limiting the use of systemic antibiotics in this group will minimise the evolution of resistant strains of bacteria.[12]

Silver, in its ionic form, has a broad spectrum of antimicrobial activity.[13-18] In addition, laboratory studies have found that it is effective against biofilms,[18] which are thought to play a part in infection in chronic wounds.[19] Laboratory studies[20] and clinical evaluations involving patients with acute and chronic wounds have found silver to be effective in managing bacterial burden.[14,21,22]

Mepilex Ag (Mölnlycke Health Care, Gothenburg, Sweden) is an absorbent polyurethane foam dressing that contains silver sulphate. By combining the antimicrobial efficacy of silver with the adhesive properties of Safetac soft silicone technology, the dressing can manage wounds at risk of infection and facilitate atraumatic dressing removal.[23-26]

Mepilex Ag is indicated for leg ulcers, diabetic foot ulcers, pressure ulcers and surgical wounds with low to moderate exudate levels that are at risk of infection. Positive healing responses and minimal dressing-related pain have been observed in case studies and small clinical evaluations of Mepilex Ag in the treatment of acute and chronic wounds including arterial leg ulcers, mixed aetiology leg ulcers, burns, diabetic foot ulcers, pressure ulcers and traumatic wounds.[27,28]

This observational study aimed to evaluate the effect of Mepilex Ag on clinical signs of local wound infection, wound-related pain and the progression towards healing, and to measure patient acceptance of the dressing, when used on various wound types.

Method

This was a single-centred, open, non-randomised, prospective study. Newly presenting in- and outpatients attending a specialist wound care clinic with various wound types were enrolled into the study over a three-month period. To be included, they had to have wounds with signs of local infection requiring topical antimicrobial therapy only, based on the clinical judgement of a single investigator (FM). Patients with infected wounds that the investigator thought required antibiotics were excluded. To prevent antibiotic resistance, the clinic's protocol encourages clinicians to use their clinical judgement when prescribing antibiotics, and to restrict their use to wounds with clear and overt signs of infection. Therefore, patients whose wounds showed signs of mild localised erythema, warmth and oedema, as well as those with increasing malodour, pain or exudate, were considered to meet the above inclusion criterion. Where these symptoms were more

F. Meuleneire, RN, Tissue Viability Nurse Specialist, Wound Care Centre, Zottegem, Belgium.
Email: Frans.Meuleneire@telenet.be

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Fig 1. Wound types included in the study

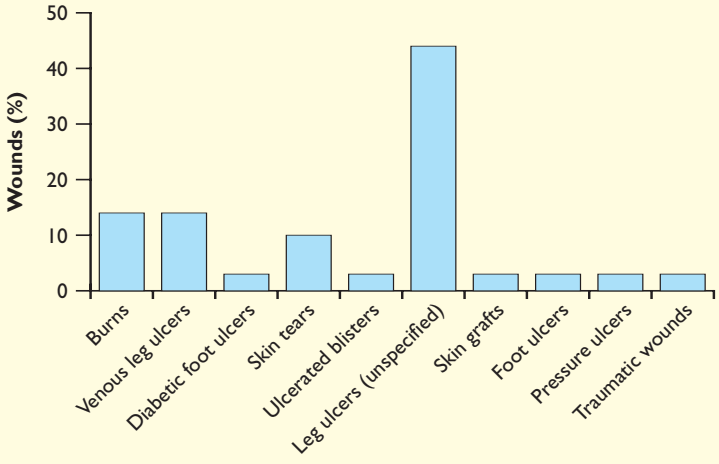

Table 1. Inclusion and exclusion criteria

Inclusion criteria
Patients aged 18 years and over
Patients with a localised wound infection requiring topical antimicrobial therapy only
Signed informed consent
Exclusion criteria
Patients with a wound infection requiring systemic antibiotics
Patients with known allergy/hypersensitivity to any of the test dressing's components
Patients who would have had difficulty following the study protocol
Patients with severe underlying disease judged by the investigator to interfere with the treatment (eg, HIV/Aids, cancer, poorly controlled diabetes)
Patient undergoing treatment with therapies that may interfere with healing, such as corticosteroids and immunosuppressants

marked, and accompanied for example by the discharge of pus, antibiotics were considered to be required. The full inclusion and exclusion criteria are given in Table 1.

It was agreed by local clinical governance before starting the study that, as this was a CE-marked product that was used in accordance with its instructions for use, ethics committee approval was not required.

Baseline demographic data (age, gender, medical history) and the wound history were recorded at the first consultation.

Appropriate sizes of the test dressing were applied to the wounds. Dressings were changed when judged necessary by the investigator, but at least once weekly.

The study protocol stipulated that each patient should be followed for four weeks or until the wound healed, whichever occurred first. However, the dressing could be used for longer if the investigator preferred. Equally, the investigator could discontinue the dressing at any point during the study.

At the first consultation and subsequent dressing changes, the clinical signs of local wound infection were assessed to monitor its progress and determine whether antibiotics were needed. For the purposes of the study, the healing response was monitored at each dressing change via a qualitative visual assessment, with the single investigator classifying the wounds as:

- Healed: complete re-epithelialisation
- Almost healed: more than 90% re-epithelialisation
- Minimal lesions: no re-epithelialisation but the wound was smaller than at baseline
- Healing slowly: little sign of progression to healing.

Patients rated pain severity immediately before and during each dressing change using a validated visual analogue scale (VAS) ranging from zero (no pain) to 10 (worst pain ever).[29]

The wounds were photographed at each dressing change as a record of the healing progression.

At the final dressing change, patients were asked to take dressing comfort, the healing progression and the level of persistent pain and pain experienced at dressing change into consideration and rate the dressing's overall performance as 'excellent', 'very good', 'good', 'bad' or 'very bad'. Similarly, the investigator gave an overall rating of the dressing based on the progression towards healing, resolution of wound infection, patient comfort, and handling, using the same scales as above.

Statistical evaluation

Descriptive statistics (median, minimum, maximum) and a Mann-Whitney U test were used to compare pain severity scores measured at baseline with those recorded at the first dressing change (first visit) and last dressing change (final visit).

Results

Thirty patients (male, n=9; female, n=21) with a median age of 74 years (range 29–91) and one wound each met the inclusion criteria. Twenty-seven patients completed the study and three were withdrawn (after 15, 21 and 35 days respectively) because their wounds were not healing. However, data collected from these three patients were included in the analysis.

The various wound types are given in Fig 1. Before

recruitment into the study, they had been treated with dressings including alginates, hydrocolloids, hydrogels, foams, paraffin gauze and silver, as well as topical antimicrobial preparations such as povidone-iodine and silver sulphadiazine.

At the first consultation, the median wound duration was 45 days (range 2–300).

The median treatment period was 36 days (range 9–91) and the median number of dressings used was four (range 2–9) per patient.

All wounds exhibited clinical signs of local infection, as defined above, at baseline. By the end of the study period, these clinical signs had been eradicated in 27/30 (90%) wounds. However, one of these 27 patients developed overt clinical signs of infection during the study period, as judged by the investigator, on day 7. He was given systemic antibiotics (ciprofloxacin), and the signs subsided within three days. Data from this patient were included in the analysis, even though antibiotic usage was an exclusion criteria, as the study was designed to reflect the 'real-life' clinical situation. No other patients received antibiotics during the study period.

Regarding the healing response, 16 wounds (53%) healed, eight (27%) almost healed, two (7%) were only minimal lesions and one (3%) was healing slowly.

The pain severity reported at the baseline consultation (before the dressing was first used) was significantly higher than at the first and final visits. Median pain severity scores before the dressing changes were 6.5 (range 0–9) at baseline, 4 (range 0–9) at the first visit ($p<0.0001$) and 0 (range 0–8) at the final visit ($p<0.0001$). Median pain severity scores at dressing removal were 6 (range 0–9) at baseline, 3 (range 0–7) at the first visit ($p<0.0001$) and 0 (range 0–8) at the final visit ($p<0.0001$) (Table 2).

The investigator's and patients' overall evaluations reported at the final visit show that the majority rated the dressing as 'excellent' (67% and 64% respectively) or 'very good' (10% and 18% respectively (Figs 2 and 3). Additionally, some patients indicated that the dressing allowed them to sleep better because they were 'pain free', while some whose wounds appeared not to be progressing towards healing still wanted to continue using it.

No dressing-related adverse events were recorded.

Discussion

This study set out to evaluate the resolution of clinical signs of local wound infection, the severity of wound-related pain and healing progression in wounds treated with Mepilex Ag, and to assess patient acceptability of the dressing. The sample size was relatively small, but as it comprised a cross-section of patients with a variety of wounds, the clinical data obtained reflects 'real-life' situations.

The results showed that, following use of the dress-

Table 2. Statistical analyses of wound-related pain severity scores (measured by visual analogue scale) before and during dressing changes

	Median	Range (min.–max.)	p value
Pain severity before dressing change			
Baseline	6.5	0–9	–
First dressing change	4	0–9	<0.0001*
Final dressing change	0	0–8	<0.0001†
Pain severity during dressing change			
Baseline	6	0–9	–
First dressing change	3	0–7	<0.0001*
Final dressing change	0	0–8	<0.0001†

* Baseline versus first dressing change
† Baseline versus final dressing change

Fig 2. Summary of the investigator's overall evaluations of the dressing at the final visit

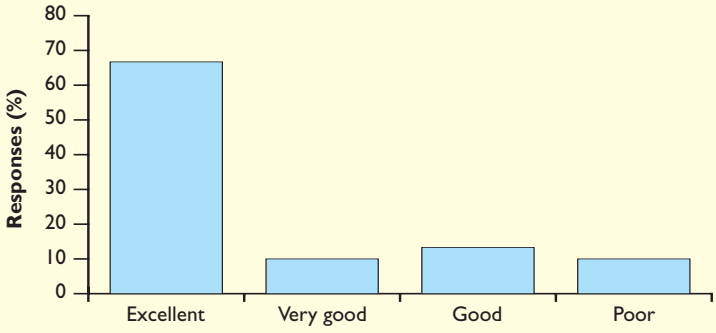

Fig 3. Summary of the patients' overall evaluations of the dressing at the final visit

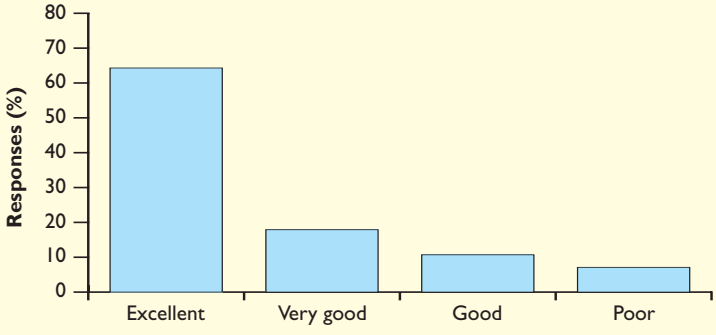

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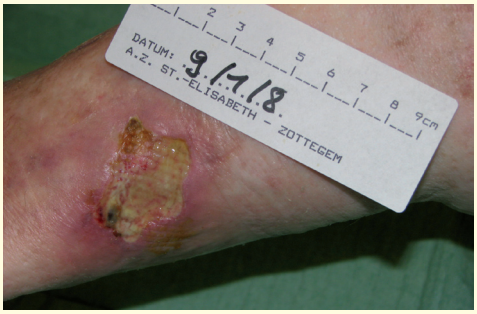
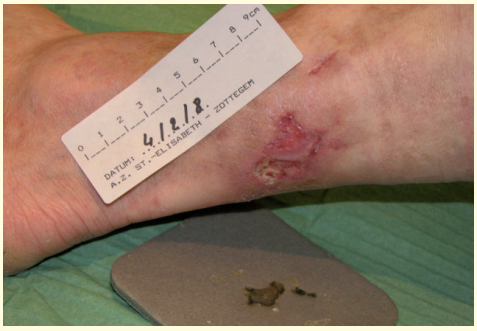
Fig 4. Case study 1

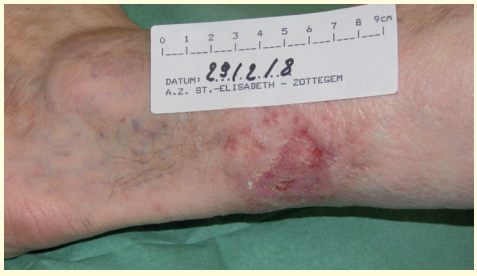
Patient history: 68-year-old male with history of arrhythmia (pacemaker fitted). No ongoing medication
Wound history: 3.5-month-old ulcer with signs of local infection on the lower left leg with vasculitis (very painful)
Results: wound healed completely
Investigator's evaluation: overall excellent experience with the dressing
Patient's comments: overall excellent experience with the dressing: once treatment started, there was a real difference and the wound healed quickly with fewer pain sensations



09/01/2008: first application of dressing



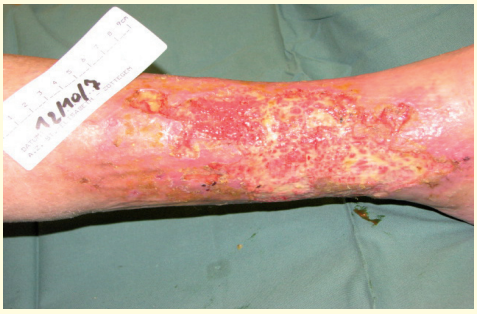
04/02/2008: second application

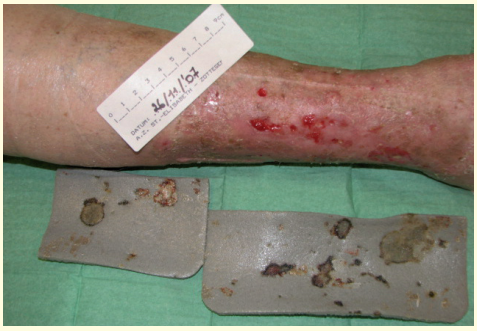


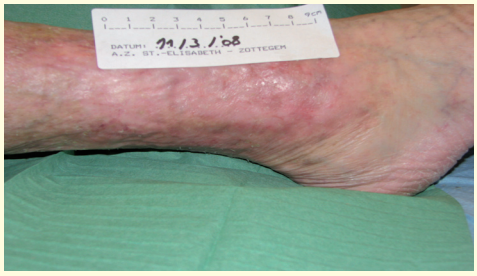
29/02/2008: final application

Fig 5. Case study 2

Patient history: 74-year-old female receiving medication for a thyroid condition. No major surgical interventions
Wound history: venous leg ulcer to the lower right leg (painful with signs of local infection). The wound started with superficial necrosis and known venous hypertension
Results: most of the wound healed, leaving only a minor wound consisting of several smaller lesions
Investigator's evaluation: An overall excellent experience with the dressing, with the patient being discharged after only one week of treatment


12/10/2007: first application of the dressing


26/11/2007: final application of the dressing



11/03/2008: follow-up

ing, clinical signs of local infection were eliminated and healing progressed well in almost 90% of the wounds. Only three patients (10%) discontinued the dressing, in all cases due to poor healing responses. These patients had comorbidities (CREST syndrome [limited scleroderma], venous hypertension, hypothyroidism) that may have affected the therapeutic response to the dressing.

Data generated from this observational study compare well with those for other silver dressings in

terms of antimicrobial efficacy and healing rates.[30-32]

They are also consistent with laboratory data demonstrating that the dressing has a rapid (within 30 minutes) and persistent antimicrobial activity (up to seven days) against a wide range of pathogens that might be present in colonised or infected wounds.[28]

Silver is thought to initiate a wound-healing response above and beyond that of eradicating bacterial infection.[33,34] While this study was unable to clarify this, virtually all of the wounds demonstrated a positive healing response. This warrants further investigation.

Pain is a significant problem for many patients with acute and chronic wounds. Infection increases the severity of wound-related pain,[35] especially in patients with burn injuries.[36] Further pain can be caused by trauma to the wound and surrounding skin during dressing removal.[37] This highlights the need for an effective antimicrobial dressing that takes account of the enhanced pain perception in patients with localised wound infection.

In the present study, there were statistically significant reductions in pain levels between baseline versus both the first and final dressing change. This indicates that the dressing rapidly reduced pain levels, improving patients' quality of life.

Other studies have had similar results. For example, a recent comparative study involving paediatric patients (n=38) with a variety of wound types found that Safetac technology (Mepilex Border Lite) significantly (p=0.001) reduced pain before and during dressing change, compared with baseline, when wounds were treated with a various types of dressing.[38]

In another study, a survey of over 3000 patients with various wound types that had been treated with a variety of dressings at baseline showed a significant (p<0.01) reduction in pain following use of Safetac dressings.[26] The benefits of Safetac have been demonstrated in clinical evaluations (randomised controlled trials, observational studies, case studies and surveys).[26,39-41]

Patients mostly rated the dressing as excellent/very good, and were complimentary about the ensuing pain reduction and, in some cases, the fact that healing finally resulted in hospital discharge.

Figs 4 and 5 present photographs and brief clinical summaries of examples of wounds treated with the test dressing in which localised infection was resolved and healing achieved.

It is important to stress that the results of this study are non-comparative, are obtained from a relatively small patient population, are based on subjective assessments and include one patient who was given systemic antibiotics. Nevertheless, they do provide an insight into the efficacy and safety of the dressing in a 'real-life' clinical setting.

Larger and comparative studies are needed, which should focus on specific wound types, such as diabetic foot ulcers.

Conclusion

These results show that Mepilex Ag can be used to treat a variety of types of wound at risk of overt clinical signs of infection. They also demonstrate the benefits of using atraumatic dressings on patients with heightened pain sensitivity in the wound and/or surrounding skin, due to local wound infection. ■

Declaration of interest

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