

Clinical evaluation of a dressing with poly absorbent fibres and a silver matrix for managing chronic wounds at risk of infection: a non comparative trial

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Objective: To assess the efficacy, safety and acceptability of a new silver poly absorbent dressing (UrgoCleanAg) in the local management of exudative chronic wounds at risk of infection, with inflammatory signs suggesting heavy bacterial load.

Method: This prospective, multicentre, non-comparative clinical trial was conducted in French hospital wards (dermatology and vascular medicine) or specialised private-practice physicians. Patients were considered at high-risk of infection when presenting with at least three of five selected inflammatory clinical signs, suggesting a heavy bacterial load (pain between two dressing changes, erythema, oedema, malodorous wound and presence of a heavy exudate). They were treated for a maximum period of four weeks, and followed by the physician on a weekly basis, including a clinical examination, area tracings and photographs. The primary efficacy criterion of the trial was the relative wound surface area reduction at the end of the four weeks of treatment. Acceptability was documented by the nursing staff at each dressing change between the weekly evaluations.

Results: We recruited 37 patients with chronic wounds. Wound surface area, mostly covered by sloughy tissue, was reduced by 32.5%

at the end of the treatment (median value), while the clinical score (maximum value of 5, based on inflammatory clinical signs) decreased from 4.0 to 2.0. Effective debridement properties were documented (62.5% relative reduction of sloughy tissue at week 4; 58.8% of debrided wounds at week 4) and improvement of the periwound skin status was noted (healthy for 28.6% of the patients at week 4 versus 2.7% at baseline). In addition, the tested wound dressing presented a good safety profile associated to a high level of acceptability, noted by both patients and nursing staff.

Conclusion: These clinical data support that the tested dressing is a credible therapeutic alternative for the management of chronic wounds at risk of infection with inflammatory signs suggesting heavy bacterial load.

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silver dressing • venous leg ulcers • clinical trial • risk of infection • inflammatory signs

Leg ulceration is a common problem, with an estimated prevalence of 1% to 2% in the adult population.¹ Despite recent advances in wound care, appropriate local and holistic management and effective compression therapy, around 50% of venous leg ulcers (VLUs) still remain unhealed after 24 weeks.² The refractory nature and the high recurrence of these chronic wounds often cause pain and suffering to patients, affecting their quality of life and also representing a significant financial burden on health-care systems.³

Moreover, these chronic wounds are also more susceptible to microbial invasion. Serious complications become prevalent including delayed

healing, cellulitis, enlargement of wound size, debilitating pain, and deeper wound infection causing systemic illness.⁴ It is well documented that the longer a leg ulcer remains unhealed, the more aerobic and anaerobic organisms grow.⁵ A high bioburden can in turn be responsible for a chronic inflammatory response, an increased risk of cellular dysfunction, biochemistry imbalance and disruption of the normal wound healing sequence.⁶ The presence of slough and devitalised tissue, accumulated during the inflammatory phase, provides an ideal environment for further attachment and proliferation of microbes, and for subsequent biofilm formation.⁷

Antimicrobial dressings, such as silver dressings, help to reduce the bioburden and the inflammatory response within the wound. They can be used as a barrier to prevent further contamination by external microorganisms.⁸ Recent systematic reviews and meta-analyses have confirmed the beneficial effects of silver dressings when used appropriately.⁸⁻¹⁰ The international consensus on the appropriate use of silver dressings in wounds, published in 2012, highlights that

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'silver dressings should be used in the context of an accepted standard wound care that involves the holistic management of the patient, the wound and wound bed preparation'.⁸ It recommends that 'the dressing should be chosen on the basis of patient and wound need, e.g. level of exudate and wound bed condition'.⁸

The dressing pad evaluated in this clinical trial is made of cohesive poly absorbent fibres impregnated with a silver lipido-colloid matrix (the TLC-Ag healing matrix). The poly absorbent fibres were recently found to be effective with autolytic debridement properties in a randomised controlled trial (RCT).¹¹ The TLC-Ag healing matrix has been established in its efficacy in the management of chronic wounds presenting with a risk of infection as demonstrated through previous randomised controlled trials.¹²⁻¹³ The purpose of this non-comparative clinical trial was to evaluate the performance (efficacy and safety) of the dressing, on the healing process of chronic wounds presenting a high-risk of infection.

Material and methods

Study design

This prospective multicentre non-controlled clinical trial was conducted in France. From May to October 2013, the participating clinicians enrolled both hospitalised and ambulatory patients from 17 active investigating centres (including dermatology and vascular medicine hospital wards, private physicians, angiologists and dermatologists).

Patients

The eligible patients were adult patients (≥ 18 years old) with an exuding chronic wound at risk of infection. Risk of infection was considered high when at least three of the five inflammatory clinical signs were present: pain between dressing changes, periwound erythema, local oedema, malodour and presence of heavy exudate. The wound was required to be leg ulcer of venous or mixed origin, with an ankle-brachial pressure index (ABPI) between 0.7 and 1.3 or stage III or IV pressure ulcer (PU) (according to the European Pressure Ulcer Advisory Panel Classification).¹⁴ The ulcer surface area had to be covered by more than 50% of sloughy tissue without dark necrotic plaque, and to range between 3–50 cm². The ulcer duration had to be longer than one month and less than 36 months. During the study, patients with leg ulcers had to adhere to wearing their compression therapy system.

Patients were excluded if they had a known hypersensitivity to any component of the evaluation dressing, were being treated with high-dose steroids or immunosuppressant therapy. They were also excluded if presenting with an ulcer requiring a surgical treatment, a progressive neoplastic lesion treated by radiotherapy or chemotherapy, a malignant wound, a clinically infected wound or an erysipelas of the lower limb requiring systemic antibiotics, or had a history of a deep venous thrombosis within the previous three months.

Endpoints

The primary end-point of this study was the relative wound area reduction after 4 weeks of treatment. All the acetate tracings were centrally measured by experienced operators using digital software (Universal Desktop Ruler).

Secondary objectives were to assess:

- Percentage of wounds with a favourable outcome, defined as a relative wound area reduction of at least 40% after the 4-week treatment period
- The decrease of the clinical score, based on the presence of the five inflammatory clinical signs,
- Desloughing properties of the dressing through the clinical assessment of the wound bed condition (sloughy tissue, granulation tissue) and the percentage of debrided wounds, defined in this trial as in ^{11,15} as a wound bed covered for more than 70% of its surface in granulation tissue at the last available assessment
- Condition of the periwound skin: healthy or not healthy (including erythematous, oedematous, irritated, eczematous or macerated skin)
- The safety profile (local tolerance, adverse events and adverse device effects)
- Global Performance Score (GPS) of the silver dressing
- Dressing change frequency
- Acceptability of the silver dressing.

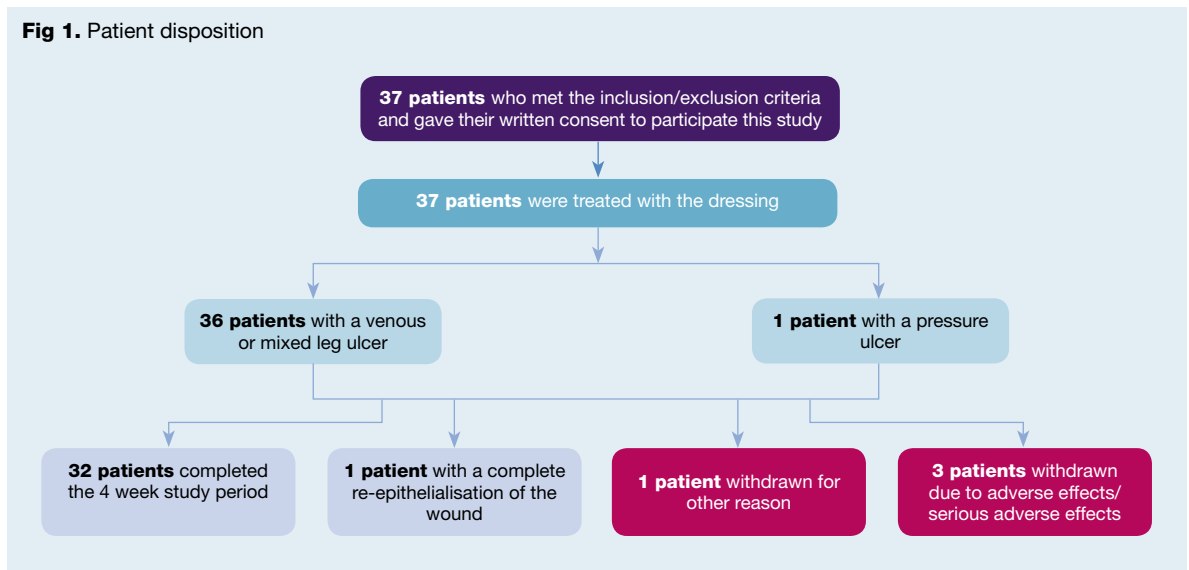
Data collection

All the included patients gave their written consent before their participation in the trial, after they had received full written information about study objectives and conduct. An ABPI measurement was performed (Dopplex D900, Huntleigh Healthcare, Cardiff, UK) and all the inclusion and exclusion criteria validated at the inclusion visit. Basic demographic information, relevant medical history of the patient and characteristics of the target ulcer (location, duration, clinical assessment using a colorimetric scale) were recorded. Wound area tracing and a photograph were taken by the physician before the initiation of the treatment. Patients were evaluated during a maximum treatment period of 4 weeks or until wound healing (defined as complete epithelialisation) occurred if earlier.

Weekly evaluation undertaken included clinical examination with local tolerance assessment, wound-area tracing and photographs of the treated wound based on a standard procedure. Thus, a total of 5 clinical evaluations were conducted over the 4-week treatment period (Day 0/W1/W2/W3 and week 4). At the last clinical evaluation the overall performance of the dressing was evaluated by the investigating physician using the Global Performance Score (GPS), on a 0–36 scale. The higher the score, the better the dressing performance considered. This subjective GPS was calculated on the basis of nine parameters:

- Efficacy
- Safety
- Preservation of granulation tissue
- Pain during dressing removal

Fig 1. Patient disposition



- Management of exudate
- Handling, conformability of the dressing,
- Patient comfort and acceptability of the dressing.

For each parameter using the following qualitative scale of five scores was using: 4–very good, 3–good, 2–fair, 1–poor, 0–very poor.

Dressings were applied according to the manufacturer’s instructions. Dressing changes were documented both by the hospital-based nursing staff at each of the weekly visits scheduled in the protocol, and by the community-based nurses for the care provided between two protocol-scheduled visits. Dressing acceptability was assessed by the nursing staff and by the patients. Ease of application, conformability to the wound bed, ease of removal, and dressing adherence were rated based on a 4-level scale. Patient pain levels were rated using a 100mm visual analogue scale. This scale was considered appropriate to distinguish between absence of pain (score=0), minor pain (scores <30mm), moderate pain (scores between 30 and 50mm) and marked pain (beyond 50mm).¹⁶

Study dressing and intervention

The study dressing, poly absorbent TLC-Ag dressing (UrgoClean Ag; Laboratoires URGO, Chenôve, France), is a sterile, non-woven pad made of cohesive poly-absorbent fibres, coated with a soft-adherent lipido-colloid mass containing 3.5% silver sulphate (Technology Lipido-Colloid Silver: TLC-Ag) designed to be in contact with the wound bed and the surrounding skin. The dressing (10x10cm) was either applied by the investigating physicians, hospital or community nurses, as per the trial protocol.

Saline solution was the recommended cleansing solution to be used during the trial period. Dressing changes were performed according to the judgment of the investigator, depending on the level of exudate and the clinical status of the wound. Leg ulcers were treated with appropriate compression therapy, as recommended

by French Healthcare Authorities.¹⁷ The compression system chosen (single- or multi-layer bandages) was based on a full patient assessment, patient compliance and clinician preference.

Statistical analysis

The statistical analyses of this trial were conducted by an institution (Altizem, Nanterre, France), independent from the company supporting the trial dressing (Laboratoires URGO), according to a previously approved statistical analysis plan. Study data were entered (double-entry) into a SAS database (version 9.1.3). Analyses and dressing performance evaluations were only descriptive and no statistical tests were used. Continuous data were described by sample size, mean value, standard deviation, median and range. Categorical data were described in terms of number of patients and percentage. All the patients for whom at least one follow-up area wound tracing was available were introduced in the efficacy analysis and all the patients who received at least two dressing applications were taken into account in the tolerance and acceptability analyses, Intention-To-Treat basis (ITT). The last observation carried forward (LOCF) was used to compensate for missing data, when necessary (one patient withdrawn before treatment week four).

The required sample size for this clinical trial was estimated based on the data available in the literature ,concerning the local treatment of chronic wounds.^{12,15,18} It appeared that a total number of 35 patients (i.e. several hundred dressing changes) was deemed to be sufficient to provide relevant and acceptable clinical data to determine the primary and secondary endpoints.

Ethics approval

This clinical investigation was conducted in accordance with Good Clinical Practice (GCP), with the principles laid down in the Declaration of Helsinki and with

French law Huriet-Serusclet relative to the protection of persons. The authorisation to conduct this clinical trial (RCB ID No.2011-A00141-40) from the French Healthcare Authorities (ANSM) and the approval of the French Ethics Committee CPP Est I (No. 2013/08) were obtained in April 2013.

Results

Baseline characteristics of patients and leg ulcers

A total of 37 patients were enrolled into this clinical trial, 36 with a VLU and one with a stage III PU located on the heel. The mean treatment period was of 28.8±4.0 days per patient (median value: 29 days).

As illustrated in the patient flow chart (Fig 1), 86.5% of the population (32/37 patients) were followed-up until week four. There were four patients (10.8%) who discontinued prematurely for other reasons than complete healing of their wound, which occurred in one patient (2.7%) during the course of the four week treatment. As only one patient was suffering from a PU among the 37 patients included in the study, it was agreed with the coordinator of the study and the statistician to analyse the documented parameters in the global cohort. All the patients included in the study had a clinical evaluation follow-up and received at least two dressing applications, allowing the ITT analysis (efficacy, safety and tolerance), to be performed on 37 patients.

The baseline patients and wound characteristics are presented in Table 2. Included patients were mostly outpatients (91.9%) and predominantly female (54.1%), with a mean age of 77.8±14.0 years and an average body mass index (BMI) of 27.9±6.1 kg/m². There were seven patients with diabetes (18.9%), the mean duration of the disease being 11.3 years. Half of the patients (18 of the 36) had a previous history of deep vein thrombosis or venous surgery with a mean ABPI value of 1.02±0.11, testifying the venous aetiology of the treated leg ulcers. Compression therapy was documented present for 77.8% of the cases (with 55.6% of single layer bandage, the others with multilayer compression systems) and the most common previous local treatment applied were alginates (21.6%) and contact layers (16.2%).

The included leg ulcers were recurrent in 52.8% of the cases, present for seven months on average, and considered as stagnating or worsening in 78.4% of the cases. At baseline, the mean wound surface area was 13.5±14.6 cm² with 68.2±16.4% of the wound bed covered by sloughy tissue (mean value). The other part of the wound bed was covered by granulation tissue (31.8±14.4%), without any dark necrotic tissue.

The most commonly reported inflammatory clinical signs suggesting a wound at risk of infection were the presence of a high level of exudate (97.3%), a perilesional erythema (86.5%) and pain between two dressing changes (83.8%). Oedema and malodorous wounds were respectively reported in 73.0% and 64.9% of the cases. Based on these five clinical signs, the mean clinical score value was 4.1±0.7 at baseline.

At baseline, the periwound skin was generally poor,

Table 1. Patient and ulcer characteristics at baseline

	n (%) or mean ± standard deviation	Median value (min–max)
Patient characteristics		
	n = 37	
Outpatient / hospitalised	34 (91.9%) / 3 (8.1%)	
Gender (female/male)	20 (54.1%) / 17 (45.9%)	
Age (years)	77.8 ± 14.0	82.0 (34–93)
Weight (kg)	78.7 ± 21.5	72.0 (46–150)
Height (cm)	167.1 ± 8.6	165.0 (148–186)
Body mass index (kg/m ²)	27.9 ± 6.1	28.0 (19–48)
Patient history and associated diseases		
High blood pressure	25 (67.6%)	
Heart disease	13 (35.1%)	
Diabetes	7 (18.9%)	
History of allergy	5 (13.5%)	
Other disorders	31 (83.8%)	
Venous history and evaluation*		
Deep vein thrombosis (DVT)	7 (19.4%)	
Venous surgery	11 (30.6%)	
Family history of venous disease	20 (55.6%)	
Ankle-brachial pressure index	1.02 ± 0.11	1.0 (0.82–1.30)
Target ulcer characteristics		
Location (right / left lower limb)*	14 (38.9) / 22 (61.1)	
Recurrence*	19 (52.8%)	
Ulcer duration (months)	7.4 ± 7.0	6 (1–28)
Surface area (cm ²)	13.5 ± 14.6	8.1 (2.2–65.4)
Sloughy tissue (%) on the wound bed	68.2 ± 16.4	70 (50–100)
Granulation tissue (%) on the wound bed	31.8 ± 14.4	30 (1–50)
Periwound skin condition		
Healthy	1 (2.7%)	
Erythematous	32 (86.5%)	
Oedematous	27 (73.0%)	
Irritated by the dressing	3 (8.1%)	
Eczematous	3 (8.1%)	
Macerated	13 (35.1%)	

* Data given for n=36 venous leg ulcers

with only one patient having healthy periwound skin. Out of the 37 patients, 32 displayed erythema (86.5%), 27 oedema (73.0%), 13 maceration (35.1%), 3 eczema and irritation (8.1%).

Primary end-point: wound area reduction

After the four-week treatment period with the trial dressing and the associated compression therapy system, the median wound surface area reduction was 32.5% [interquartile range: 53.7–2.5] compared with baseline. Additionally, 45% of the treated ulcers decreased their surface area by 40% or more versus baseline and one leg ulcer healed during the trial period. The median closure rate was 8.3 mm² per day (8.6±29.2 mean value) and the median absolute wound

Table 2. Clinical signs and clinical score at baseline and at week 4

	At baseline	At week 4
Clinical signs (n) %	n=37	n=30
Pain between two dressing changes	31 (83.8)	18 (60.0)
Perilesional erythema	32 (86.5)	21 (70.0)
Oedema	27 (73.0)	11 (36.7)
Malodorous wound	24 (64.9)	12 (40.0)
High level of exudate	36 (97.3)	9 (30.0)
Clinical score (mean ± sd)	4.1 ± 0.7	2.4 ± 1.1
median (min–max)	4 (3–5)	2 (1–5)

area reduction was 2.56 cm² (2.74±8.34 mean value) after the treatment period.

Clinical signs of infection

During the four weeks of treatment, no local infection occurred. Considering the decrease of the five clinical signs which compose the clinical score, each of them decreased, in a variable manner, as shown in the Table 3; and after the treatment period, the median clinical score value decreased from 4.0 to 2.0 (4.1±0.7 to 2.4±1.1, mean value).

Changes of the wound bed status

After the four-week treatment, 20 of the 37 wounds (54.1%) were considered debrided (as defined by less than 30% of sloughy tissue covering the wound bed). The relative reduction of sloughy tissue was of 62.5% (median value) versus baseline (Fig 2) with only 20% of the wound surface area still covered by sloughy tissue (median value) versus 70% at baseline.

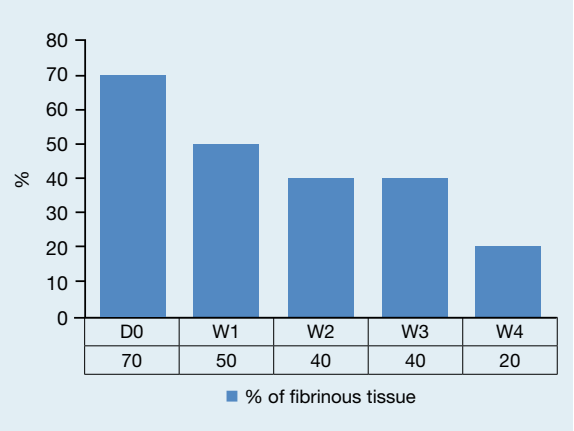
Changes of the periwound skin condition

An improvement in the condition of the periwound skin was observed throughout the investigation period. The number of patients with healthy periwound skin increased from one patient at baseline (2.7%) to 10 patients at the final visit (27.0%), while the percentage of poor periwound skin condition decreased for each of the followed parameters: oedema (73.0% at baseline to 31.4% at final visit), erythema (86.5% to 62.9%), maceration (35.1% to 14.3%) and only one case of irritation and eczema (out of the three initial ones) were still displayed at the final visit.

Local tolerance (safety)

Throughout the four weeks of treatment, only one local adverse event (pain), considered to be possibly related to the treatment, was reported by the investigating physician and the patient was withdrawn from the trial. In addition to this event, four other local adverse events (one pain, two new lesions due to the compression system, and one necrotic angiodermatitis) were recorded in four other patients, as non-related to the dressing. Of these non-related events, two were responsible for the patient being withdrawn from this trial.

Fig 2. Relative reduction of sloughy tissue overtime (median value)



Investigator, nurse and patients evaluations

During this trial, the mean dressing changes per week was 3.3±1.5 (3.1 as median value) and for a number of ulcers, weekly dressing changes were observed. The study dressing has always been used as a primary dressing, while gauze and absorbent dressing have been used as secondary dressings in respectively 74.2% and 15.0% of the cases. In total, 180 clinical evaluations were performed by the investigating physicians during this trial, and 440 dressing changes were documented by the nursing staff. The acceptability parameters (Table 4) revealed a high level of acceptance for both patients and nurses: very easy to apply and to remove, being painless without

Table 3. Characteristics at application and removal of the dressing

Ease of dressing application	Very easy	89.5%
	Easy	9.7%
	Difficult	0.8%
	Very difficult	–
Conformability during dressing application	Very good	60.9%
	Good	36.5%
	Poor	2.3%
	Very poor	0.3%
Ease of removal	Very easy	72.8%
	Easy	24.0%
	Difficult	3.2%
	Very difficult	0%
Dressing adherence upon removal	None	56.4%
	Minor	30.3%
	Moderate	11.5%
	Marked	1.8%
Pain during dressing removal	None	47.6%
	Minor	26.4%
	Moderate	17.9%
	Marked	8.1%

substantial dressing adherence. At the final visit, the GPS of the tested dressing was rated by the trial investigators at 30 (median value) on its 0–36 scale; all the nine items documented to calculate this GPS had at least a value of 3 ('good') on its 4 point-scale (Fig 3).

Discussion

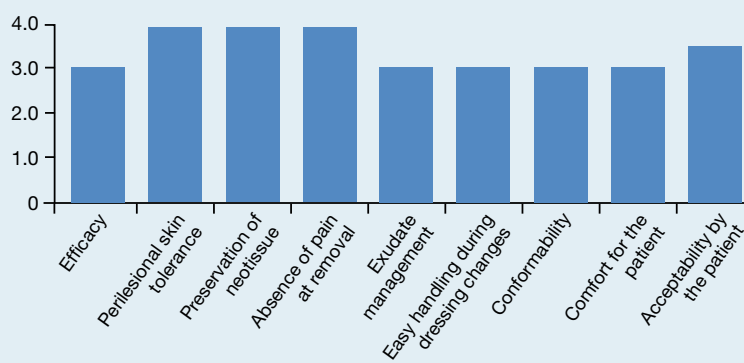
The significant autolytic debridement properties of the poly-absorbent fibres¹¹ and the significant efficacy on the healing process of the TLC-Ag healing matrix on the decrease of clinical signs of infection have been previously demonstrated compared to relevant control group in randomised controlled trials.^{12–13} This open prospective study is the first to document the performance of a dressing combining these properties in the local management of exuding chronic wounds presenting inflammatory clinical signs suggesting a heavy bacterial load.

Results showed that after 4 weeks of treatment with this new dressing and an appropriate compression therapy, the wound surface area has been reduced by 32.5% compared with baseline. This result is consistent with those documented in the previous clinical trials (RCTs and open trial) assessing other dressings with a TLC-Ag healing matrix in the same indication and during which equivalent regressions (33.4%, 29.1% and 32.4%) were reported after four weeks of treatment.^{12,13,18} This wound evolution seemed to be favourable regarding the poor prognosis parameters of the treated wounds at baseline (ulcer duration >6 months, 53% of recurrent ulcers, surface area >10 cm², 70% of sloughy tissue and a poor periwound skin condition in 97% of the cases).

Sloughy tissue is known to adversely affect and slow re-epithelialisation while favouring bacterial proliferation,^{19–21} hence guidelines recommend regular and frequent debridement.^{22–25} In this trial, despite the fact that the wound bed of the included ulcers was covered in 70% of sloughy tissue at baseline, more than 50% of the treated wounds were debrided by the end of the treatment period. The reduction of the sloughy tissue covering the wound bed from 70% to 20% also supports the desloughing capacity of the poly-absorbent fibres of the dressing, as it was already demonstrated in previous trials assessing dressings with the same fibres.^{11,15} This autolytic debridement asset could be a part of a multifaceted treatment strategy to maintain a healthy wound bed in chronic wounds and to keep the bacterial bioburden at a tolerable level, as recommended by some authors.²⁶

High bacterial bioburden is recognised to irreversibly change the physiology of wound healing and contribute to a pathologic chronic inflammatory environment.²⁷ However, the effects of bacteria in a wound are often described as a continuum that extends from the most benign to the most serious forms, depending on the wound bioburden, including contamination, colonisation, critical colonisation and wound infection.^{5,6,28} Here, as in several other clinical

Fig 3. The Global Performance Score of the dressing as rated at the end of the 4-week treatment (median values).



trials,^{12,13,18,29} wounds were considered to be at high-risk of infection when they met at least three of the five selected clinical signs. Despite the high clinical score at baseline (on average 4/5), no local infection occurred during the course of the four-week treatment. The clinical score decreased from 4 at baseline to 2 at the final visit, and all the signs were sensitive to the tested dressing, supporting the antimicrobial properties of the dressing. Recognition and management of wounds at risk of developing a wound infection is a topic of intense debate,³⁰ as there is no generally accepted definition for these wounds, also referred to as wounds at risk (W.A.R) or wounds at risk of infection.³¹ Because of this lack of clear definition, many wounds are classified as being 'potentially at risk of infection', even if they present less clinical signs than the '3 out of 5' expected in this trial. In some clinical trials, only one to three clinical signs among the five to ten proposed were judged sufficient to consider a wound at risk and then to initiate the use of silver dressings.^{32–34} In a recent French survey considering 794 patients presenting chronic or acute wounds in the community,³⁵ general practitioners and specialists had prescribed silver dressings when 3.8 clinical signs among a list of ten were present (mean value). More recently, a new classification (W.A.R. Classification) has been proposed for the wounds presenting a risk of infection, based on the presence of endogenous and exogenous factors which could increase the risk of infection.³¹ Therefore, while the use of silver dressings has been found to be safe and supportive of healing in wounds at high-risk of infection or with clinical signs suggesting a local infection,^{8,36–38} a consensus on a more precise definition and classification of the wounds at risk would be useful to allow further comparison of the antimicrobial dressing efficacy.

In this trial, improvement of the periwound skin was noted at the end of the treatment period (27% considered healthy versus less than 3% at baseline) and only one local adverse event possibly related to the tested dressing occurred during the trial. Hundreds

of dressing change evaluations have documented an easy to use and well tolerated dressing, with a one-piece and painless removal and no adherence on the wound bed. A high level of acceptability of the new silver dressing was also documented from clinician and patient perspectives.

Limitations

The main limitations of this study were its non-comparative design and its relative small sample size. Considering the positive outcomes of this trial and the consistency of these results with those of previous randomised controlled trials, it would be interesting to further investigate the performance of this dressing within a larger cohort study.

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Conclusion

This trial was carried out on 37 patients with chronic wounds. The promotion of the wound healing process was shown, through the wound surface area reduction, the rapid decrease of the inflammatory signs and of the sloughy tissue, a good safety profile and a high acceptability. The results of this clinical trial corroborate the findings of previous clinical trials on TLC-Ag healing matrix dressings^{12–13} and on poly-absorbent fibres dressings^{11,15} suggesting that this new dressing provides a real clinical benefit for chronic wounds at risk of infection presenting inflammatory clinical signs and can be considered as a promising new therapeutic option for the management of such chronic wounds when used in the context of accepted standard of wound care. **JWC**

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