Management of chronic wounds with an innovative absorbent wound dressing

- **Objective:** To evaluate the efficacy and tolerability of an innovative absorbent wound dressing (UrgoClean; Laboratoires Urgo) in the local management of venous leg ulcers and pressure ulcers, during the sloughy stage of the healing process.
- **Method:** A pilot, prospective, non-controlled open-label clinical trial held in 21 investigating centres. Adult patients, presenting with either a venous leg ulcer (VLU) or a category III/IV pressure ulcer (PU) with more than 50% of the surface area covered with sloughy tissue, a duration of less than 24 months, and no clinical signs of infection were included in the study. Patients were followed over a 6-week period with weekly visits, which included a physical examination, wound-area tracings and photographs by the investigating physician. Evaluations by the nursing staff and by the patients were made at each dressing change.
- **Results:** Fifty patients with either a VLU (n=35) or a PU (n=15) were recruited. At baseline, mean wound surface area was 11.9 ± 11.3 cm^2 and 12.5 ± 10.7 cm^2, with a mean duration of 8.3 ± 6.4 months and 2.9 ± 3.0 months in the VLU and PU groups, respectively. Wounds in both groups were covered with more than 70% sloughy tissue, and the peri-lesional skin was considered to be healthy in 19 patients. By 6 weeks, mean wound surface area reduction in the VLU and PU groups was 23.7% and 29.2%, respectively, with full healing in 6 patients. All treated wounds were considered to be debrided by week 3 (< 40% slough for all wounds) and the median relative decrease of the sloughy tissue, at week 6, in the VLU and PU groups was 75% and 89%, respectively. Dressing acceptability was documented as being very good for both patients and nursing staff, particularly conformability and ease of use, with no residue left on the wound bed at dressing removal and the dressing also remained in one piece. Seven local adverse events were deemed to be potentially related to the trial dressing.
- **Conclusion:** The results suggest that the dressing promoted the healing process of chronic wounds, showing itself to be a credible therapeutic alternative for the sloughy stage of the wound-healing process. It also demonstrated good tolerance and acceptability.
- **Declaration of interest:** This study was sponsored by a grant from Laboratoires Urgo pharmaceutical company. S. Bohbot and O. Tacca are employees of Laboratoires Urgo. S. Meaume has received monetary compensation as a speaker for Laboratoires Urgo. Data management and statistical analyses were conducted by Vertical (Paris, France).

chronic wound; sloughy tissue; multicentre clinical trial; UrgoClean

The healing process of chronic wounds evolves in different phases, which can be juxtaposed, leading to epithelialisation. The first phase is represented by debridement of the wound, which can be mechanical, surgical, enzymatic or autolytic.[1] The method depends on the condition of the wound bed, resources, knowledge, and patient and clinician treatment goals.[2]

This phase is necessary because it facilitates the latter stages of healing by removing the sloughy tissue, which causes hypoxia to the wound area, inhibits the development of granulation tissue and slows re-epithelialisation.[3] Removal of devitalised tissue is, therefore, considered to be the first step in wound bed preparation of the chronic wound.[4]

Non-selective debridement will effectively remove dead tissue, but may harm the viable tissue and can be painful in the sensate patient.[5] Selective autolytic debridement is simple, safe and practical, and can represent a first line treatment. By releasing endogenous proteolytic enzymes and activating phagocytes, necrotic tissue and slough are digested and separated from healthy tissue;[4,6] this process may take weeks and is facilitated by the use of moisture-retentive dressings.

A variety of dressings are used to aid autolytic debridement; hydrogels and hydrocolloids donate moisture to the wound,[7] while alginates and Hydrofiber absorb moisture from the wound bed.[8] Alginate fibres may promote autolytic debridement, as they are active during the sloughy stage of the

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healing process, absorbing any exudate and fibrinonecrotic debris present on the wound bed.[9–11] Hydrofiber is another type of absorbent dressing (based on carboxymethylcellulose), which also has various studies documenting its exudate management and wound cleansing properties.[12–14]

The primary drawback of existing autolytic dressings, such as alginates and Hydrofiber, is the lack of cohesivity, which means that intact removal from the wound bed is not always possible. However, recently, a highly cohesive dressing composed of hydro-desloughing fibres coated with a soft-adherent lipido-colloid layer, known to promote the healing process,[15–17] has been specifically developed for the desloughing phase of the healing process for chronic wounds (UrgoClean; Laboratoires Urgo).

The aim of this pilot study, therefore, was to evaluate the efficacy, safety and acceptability of this new dressing for chronic wounds, such as venous leg ulcers (VLUs) and pressure ulcers (PUs), at the debridement phase of the healing process.

Method

This open-label pilot study included both hospitalised patients and outpatients presenting with either a VLU (ankle brachial pressure index [ABPI] >0.8) or PU at the sloughy stage of the healing process, through 21 active investigating centres (hospital dermatology units, vascular rehabilitation departments, or geriatric wards). The following criteria were established at baseline:

- ≥18 years of age
- Exuding wounds (moderate to heavy exudate)
- Surface area 4–70cm^2, covered with more than 50% sloughy tissue and no dark necrotic plaque
- Duration of less than 24 months
- Non-cancerous
- No clinical signs of infection.

Sloughy tissue was defined as wet yellow-brown fibrinous tissue present in the wound bed. Patients in the VLU group had to wear a compression bandage system with the trial dressing.

Patients with a known allergy to carboxymethylcellulose, being treated with a high dose of steroids or immunosuppressant therapy, or presenting with a progressive neoplastic lesion treated by radiotherapy or chemotherapy were excluded from participation.

Recruited patients were followed for a maximum period of 6 weeks, or until full healing occurred, with fully healing defined as complete epithelialisation, without exudate. Weekly evaluation, including a clinical examination, wound-area tracing of the treated wound and photographs, was undertaken by the investigating physician.

Evaluations by the nursing staff (either hospital-based, or community-based if outpatients) and by the patients, were made at every dressing change. These subjective dressing assessments were done on a 4-point scale for the parameters ease of application, ease of removal, pain on removal, conformability to the wound bed, and bleeding on removal.

Interventions

The UrgoClean dressing (Laboratoires Urgo) is a non-woven pad of highly absorbent and cohesive polyacrylate fibres (polyacrylate polymers form the envelope of the fibre with an acrylic core at the centre). This pad is coated with a soft-adherent lipido-colloid layer designed to be in contact with the wound bed and the surrounding skin. This dressing is specific to the management of sloughy or exuding wounds.

Local treatments by the nursing staff were conducted exclusively with saline solution. The dressing was applied directly to the wound bed and the wound dressing-change frequency was directed by the investigating physician, dependent on wound condition and exudate volume.

The investigators were asked to use compression bandage therapy for patients in the VLU group and an adequate pressure relief system for patients in the PU group; the nature of these systems was left to the choice of the investigator.

Endpoints

The primary endpoint of the study was the reduction in the wound surface area after 6 weeks treatment. The relative area evolution, expressed as a percentage, was calculated from the wound-area tracings made during the weekly evaluations (under standardised procedure).

Secondary endpoints included the clinical evolution of the wounds (represented by the percentage of sloughy and granulating tissue covering the study wound), local tolerance of the dressing (occurrence of local adverse events documented by the investigating physician during the weekly visits) and the acceptability of the dressing by the patients and the nursing staff.

Wound areas were centrally measured from the tracings by a Parisian clinical research organisation, independent from the sponsor. To evaluate wound changes over time, relative wound-area regression compared with baseline was calculated, with the same method applied to evaluate changes to sloughy and granulation tissue present in the wound bed.

Statistical analysis

All enrolled patients were included in the efficacy and safety analysis, which was conducted separately for both VLU and PU populations.

Scale variables were summarised by their mean, standard deviation, median and range. The last observation carried forward (LOCF) was used to compensate for missing data, when necessary. Other analyses and dressing performance evaluations were only descriptive and no statistical tests were used.

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Fig 1. Trial profile

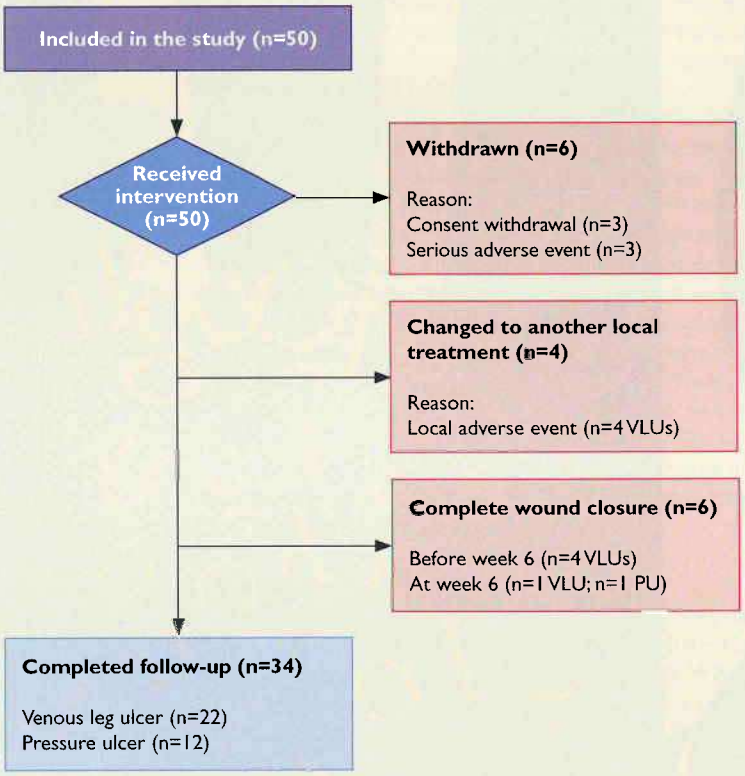

Table 1. Patients' characteristics at baseline

	Venous leg ulcer (VLU)	Pressure ulcer (PU)
No. of patients (n)	35	15
Gender (female/male)	23/12 (66%/34%)	8/7 (53%/47%)
Age (years)*	71.3±16.8 (27.2–98.5)	78.8±9.0 (56 ; 88.3)
BMI (kg/m²)*	28.2±5.6 (19.6–44.6)	23.6±6.9 (15.6–36.6)
Main histories (n)†		
• Hypertension	20 (57%)	12 (80%)
• CV disease	9 (26%)	7 (47%)
• Allergy	2 (5.7%)	1 (6.7%)
• Diabetes	4 (14%)	10 (67%)
• Other	20 (57%)	13 (87%)
Venous history (n)		
• Deep vein thrombosis	12 (34%)	—
• Stripping	9 (26%)	—
• Sclerotherapy	4 (11%)	—
• Familial history	14 (40%)	—
Patient status (n)‡		
• Outpatient	32 (91%)	0 (0.0%)
• Hospitalised	2 (5.7%)	15 (100%)

* Results presented as mean±SD (range);
† Several answers possible (total could be greater than 100%);
‡ Not specified in one VLU patient

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Ethics

The study was conducted in accordance with European good clinical practice recommendations, current French regulations and the principles of the declaration of Helsinski. All included patient received detailed information on the study's conduct and gave their written consent prior to the initiation of treatment with the tested dressing. For confused patients, the decision for participation in this clinical trial was given by a legally-acceptable representative or family member, who was present at the initiation of the study.

Study protocol and documentation were submitted and approved by the Paris Medical Ethics Committee, and by the French Health Authorities (AFSSAPS; registration number 2008-A00269-46).

Results

Fifty patients were enrolled through 21 French investigating centres; 35 VLUs were recruited from 15 centres and 15 PUs (category III/IV from the European Pressure Ulcer Advisory Panel [EPUAP] classification), located on either the pelvis or heels, from six other centres.

As noted in the trial profile (Fig 1), 44 patients (88%) were treated up to week 6, or to full healing, with the tested dressing; the remaining patients (n=6; 12%) discontinued the local treatment with the tested product: six patients withdrew from the study with no possible follow-up (three consent withdrawals, three serious adverse events) and four patients in the VLU group switched to another local treatment, following the occurrence of a local adverse event (AE).

The median duration of treatment was similar in both groups (41 and 42 days, respectively). All included PU patients and 34 VLU patients were used for the efficacy analysis (one patient in the VLU group was excluded because only the baseline wound area was available). Patients' baseline characteristics are presented in Table 1.

Patients were predominantly female, especially in the VLU group. They were older in the PU group and mean BMI was higher for VLU patients. All PU patients and two VLU subjects were hospitalised patients and almost all patients had concomitant diseases, with diabetes present in 4 and 10 patients in the VLU and PU groups, respectively.

The main wound characteristics are summarised in Table 2. The mean wound duration was 8.3±6.4 months for VLUs and 2.9±3.0 months for

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PUs. Wounds had been present for more than 6 months in 20 VLU cases (57%) and two PU cases (13%). The mean wound area was 11.9±11.3cm² and 12.5±10.7cm² for the VLU and PU groups, respectively. Mean percentage of the wound area covered with sloughy tissue was greater than 70% at baseline for all patients and, with the exception of one VLU patient, no dark necrotic tissue was present on the wound bed at baseline.

Of the VLUs, nearly 70% were recurrent and in 32 cases (91%), the patients' ABPI was documented as having a value 0.8–1.2. In association with the tested dressing, 32 VLUs (91%) were treated with a compression bandage system; of these, 69% (n=22) used a monolayer bandage and 31% (n=10) used a multi-layer system. Simple gauze was most frequently used as a secondary dressing in the VLU group. For PUs, other types of secondary dressings were applied (absorbent dressings, such as foams or absorbent gauzes).

The PUs were located on the heels in seven cases (47%) and in the sacral area for eight patients (53%). The majority of patients (n=12; 80%) were incontinent with only six (40%) not suffering from confusion; for these confused patients, data regarding the patient evaluation of the product (such as pain on dressing removal) were recorded as missing or undocumented. Two patients were totally bedridden. A Norton score was available for 10 patients (67%), with a mean value of 11.4±3.6, and with adequate off-loading in 80% (n=12) of cases.

Primary endpoint — efficacy

The surface area evolution of the treated wounds was documented by the physicians at the inclusion and during all follow-ups, on a weekly basis. After a mean time of treatment of 37.1±9.3 days in the VLU group and 37.8±11.8 days in the PU group, the mean surface area reduction was 23.7±53.4% and 29.2±72.5% in each group, respectively.

The mean reduction in surface area over the 6-week treatment period is reported in Fig 2. In total, five VLUs and one PU were noted as healed by week 6.

Secondary objectives

At each clinical assessment, the percentage of sloughy tissue covering the wound bed was estimated by the investigating physician. After 6 weeks treatment, the relative decrease of sloughy tissue (median value) was approximately 75% and 89% vs baseline in the VLU and PU groups, respectively (Fig 3).

In addition to the other secondary evaluation criteria, condition of the surrounding skin was documented by the physician, and was considered by the investigators to be improved by the end of the 6-week follow-up. Healthy surrounding skin was recorded in 64% and 75% of VLU and PU patients, respectively, compared with 37% and 40% at baseline.

Table 2. Wound characteristics at baseline

	VLUs (n=35)	PUs (n=15)
Wound duration (months)		
• Mean ± SD	8.3 ± 6.4	2.9 ± 3.0
• Median (range)	7 (0.2–22)	2 (0.5–12)
• <3 months	12 (34%)	12 (80%)
• 3–6 months	3 (8.6%)	1 (6.7%)
• >6 months	20 (57%)	2 (13%)
Surrounding skin (n)		
• Healthy	13 (37%)	6 (40%)
• Erythematous	17 (49%)	4 (27%)
• Oedema	5 (14%)	0 (0.0%)
• Irritation	1 (2.9%)	0 (0.0%)
• Eczema	2 (5.7%)	1 (6.7%)
• Maceration	2 (5.7%)	3 (20%)
• Other	3 (8.6%)	2 (13%)
Wound area (cm²)		
• Mean ± SD	11.9 ± 11.3	12.5 ± 10.7
• Median (range)	9.3 (0.7–62.5)	7.6 (3.4–44.8)
Colourimetric aspect (%)		
Sloughy tissue		
• Mean ± SD	73.9 ± 17.7	74.5 ± 16.9
• Median (range)	80 (20–89)	70 (50–100)
Granulation tissue		
• Mean ± SD	23.8 ± 15.6	25.5 ± 16.9
• Median (range)	20 (0–50)	30 (0–50)
Dark necrotic tissue		
• Mean ± SD	2.3 ± 13.5	0.0 ± 0.0
• Median (range)	0 (0–80)	0 (0–0)
VLU recurrence (n)	24 (69%)	—
VLU aetiology (n)		
• Venous	18 (51%)	—
• Post-thrombotic	11 (31%)	—
• Mixed	6 (17%)	—

The investigating physicians documented the local tolerance at each monitored evaluation over the total follow-up period, based on the occurrence of local AEs. Seven AEs were reported as probably or certainly related to the tested dressing (three peri-wound eczema, one erythema, one pain, one over-granulation and one newly formed ulcer). Their occurrence led to the discontinuation of treatment in four of the cases (two eczema, one pain and one erythema).

This clinical trial amassed 796 local treatments documented by the investigating nursing teams and private nurses, who performed the dressing changes between medical evaluations, with a mean dressing change frequency of 3 days in the VLU and PU groups (median value of 3 days for the VLU group and 2 days for the PU group). The nursing staff documented the acceptability of the trial dressing at every dressing change throughout the trial duration. Table 3 presents the elements for each of the evaluated parameters. Regardless of the treatment group, the tested dressing was considered to be very easy to apply and remove with very good conformability to the wound bed throughout the hundreds of treatments performed. Painless dressing removal was also widely noted at the time of dressing change.

Fig 2. Mean surface area reduction for VLU and PU groups over the 6-week period

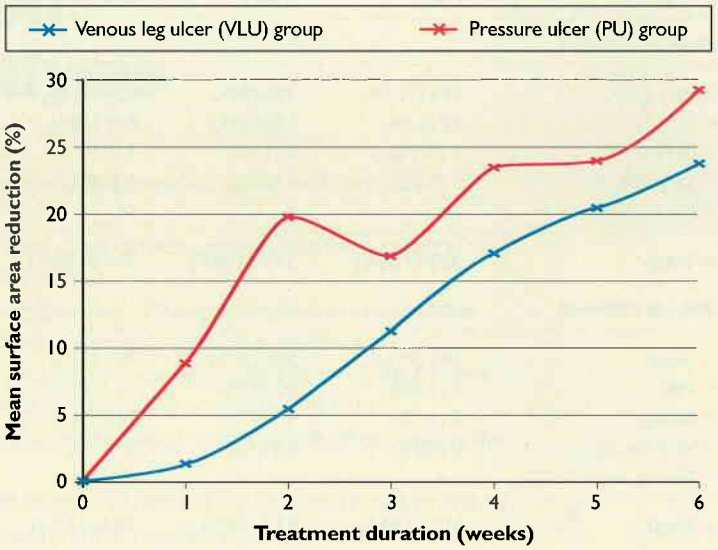
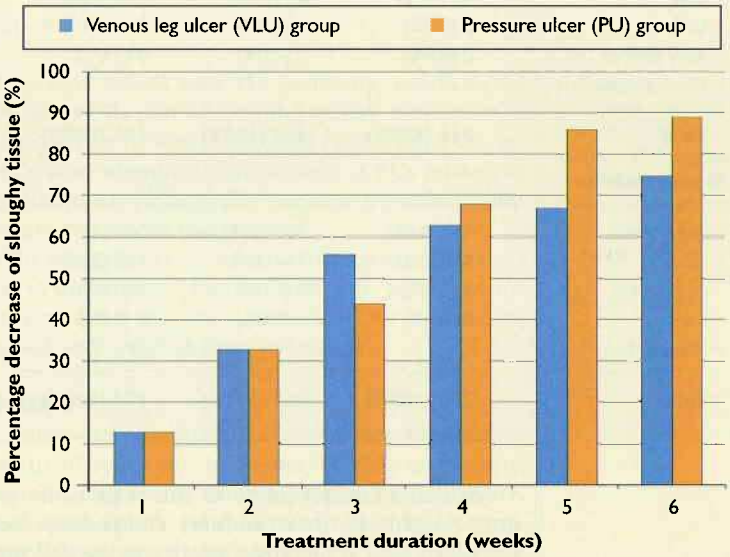


Fig 3. Relative decrease of the sloughy tissue over time



Discussion

Biofilm, matrix metalloproteinases (MMPs) on the wound bed and senescent cells at the wound edge irreversibly change the physiology of wound healing and contribute to a pathologic, chronic inflammatory environment.[5] The process of debridement activates cellular activity by removing senescent fibroblasts cells from the wound bed and non-migratory epithelial cells from the wound edge,[2] and, by also removing MMPs from the wound bed, may improve the availability of growth factors, and thus promote healing.

In chronic wounds, as removal of debris is part of a continuous process, debridement must be done without injuring viable tissue.[4] Autolytic debridement is, therefore, often chosen as first-line treatment, as it represents the natural and most selective form of debridement, sparing healthy tissue, managing wound exudate and providing a moist environment.[1]

This open, prospective and non-controlled pilot study was conducted to document the ability of a new wound dressing (UrgoClean) to deslough exuding chronic wounds and to measure its healing potential, over a 6-week treatment period. These chronic wounds were evaluated on a weekly basis by the investigating physician, and included a clinical examination, wound-area tracings and photographs; each dressing change was documented by the health professionals throughout the whole treatment period.

Over the treatment period, wound evolution was favourable in terms of wound size reduction. Local management of the treated wounds with the dressing achieved a median wound area reduction of 23% and 29% in the VLU and PU groups, respectively, when combined with compression therapy or adequate off-loading.

This could be considered as a poor outcome when compared to other clinical studies undertaken with similar wound types. However, the most probable explanation for this is that the treated wounds were widely covered with sloughy tissue at baseline, which is known to slow the re-epithelialisation.[3] A sloughy wound cannot, therefore, be expected to have the same rate of healing as a clean granulating wound, even when there is little knowledge of healing outcomes related to the condition of the wound bed in sloughy chronic wounds.

Additionally, the trial population and the treated wounds, selected by hospital investigating centres, met many parameters of poor prognosis regarding the healing process (mean duration >6 months and mean size >10cm^2, at baseline, for the VLU group). In addition, there was also chronic impairment to the peri-wound skin, especially in the VLU group.

Table 3. Dressing acceptability

	PUs	VLUs	Total
Ease of removal			
• Very easy	194 (93.7%)	435 (76%)	629 (81%)
• Easy	12 (5.8%)	130 (23%)	142 (18%)
• Difficult	1 (0.5%)	6 (1.1%)	7 (0.9%)
• Very difficult	0 (0.0%)	0 (0.0%)	0 (0.0%)
• Missing data	—	—	18
• **Total**	**207 (100%)**	**571 (100%)**	**796 (100%)**
Pain at removal			
• None	193 (95%)	508 (90%)	701 (91%)
• Mild	7 (3.4%)	50 (8.9%)	57 (7.4%)
• Strong	3 (1.5%)	4 (0.7%)	7 (0.9%)
• Very strong	0 (0.0%)	2 (0.4%)	2 (0.3%)
• Missing data	—	—	29
• **Total**	**203 (100%)**	**564 (100%)**	**767 (100%)**
Ease of application			
• Very easy	174 (81%)	496 (86%)	670 (84%)
• Easy	40 (19%)	83 (14%)	123 (15%)
• Difficult	2 (0.9%)	1 (0.2%)	3 (0.4%)
• Very difficult	0 (0.0%)	0 (0.0%)	0 (0.0%)
• Missing data	—	—	—
• **Total**	**216 (100%)**	**580 (100%)**	**796 (100%)**
Conformability			
• Very good	133 (64%)	465 (82%)	598 (77%)
• Good	69 (33%)	99 (18%)	168 (22%)
• Acceptable	6 (2.9%)	0 (0.0%)	6 (0.8%)
• Poor	0 (0.0%)	0 (0.0%)	0 (0.0%)
• Missing data	—	—	24
• **Total**	**208 (100%)**	**564 (100%)**	**772 (100%)**

Without a control group in this pilot study, it is only possible to make indirect comparisons with published data in literature, relative to the desloughing capacities of autolytic dressings. As data are limited, the comparisons have to remain circumspect; however, performance of the tested dressing regarding reduction of surface area seems to be at least similar to those reported in clinical literature when considering the use of fibre dressings.[9,18] Limová observed a non-significant 29% and 33% reduction in surface area for VLUs treated with calcium alginate dressings over a 6-week period,[9] while Wild found a 43% and 18% reduction in surface area for VLUs, with baseline surface area of 5.49±8.92cm^2 and 6.30±9.93cm^2, respectively, treated with a cellulose dressing and Hydrofiber dressing over a 4-week period.[18]

Even though the clinical evaluation made by the investigating physician can be considered as subjective, it was shown that mean visual estimations of fibrin percentage within the wound bed, and wound debridement were considered to be as reliable as computerised planimetry and consequently, a valid technique for daily practice.[19]

Dressing acceptability was documented as 'very good' by health professionals (removal and application 'very easy'/'easy'. due to the micro-adherence with excellent conformability of the dressing) and was well accepted by the patients; these favourable outcomes were observed in both VLU and PU groups. Additionally, the dressing was noted to have high tensile strength, with a one-piece removal and no residue left in the wound bed, which can be considered a drawback with some autolytic dressings.[9]

Mean dressing-change frequency was 2–3 days in both groups, with no documented maceration, which seems to differ from others debridement strategies; from 1–2 days for some autolytic dressings,[10,11] to daily (or even twice daily) for enzymatic dressings.[2,20]

Following a median treatment duration with Urgo-Clean, similar in both groups (42 and 41 days in VLU and PU groups, respectively), no unexpected local AEs were documented in this study. However, seven AEs did occur and were considered as possibly related to the tested dressing, which resulted in four premature discontinuations. This low incidence of local adverse events suggests the dressing was well tolerated. In addition, improvement of the surrounding skin condition was documented during the trial, possibly as a result of the lipidocolloid layer on the tested dressing, which has been previously documented in a French survey concerning VLUs and compression therapy concordance,[21] and in clinical evaluations.[16,22]

There is insufficient evidence to promote the use of one debriding agent over another on the basis of effectiveness alone.[23] Therefore, the choice of debriding process will take into account important variables, such as the number of dressing changes required, nursing time, tolerance (notably pain and surrounding skin condition) and the cost of treatment.[23]

Conclusion

In conclusion, it can be considered that this pilot study has documented good performance for this new dressing, regarding its desloughing properties and its protection of the surrounding skin, with a high level of acceptability by both patients (pain-free dressing change) and nursing staff (ease of application and removal, change frequency).

It is reasonable, therefore, to conclude that the dressing seems to represent a benefit at this specific stage of the healing process. However, it remains necessary to consolidate these encouraging preliminary results, with clinical data provided from a randomised controlled trial. ■