Clinical evaluation of polyabsorbent TLC-NOSF dressings on chronic wounds: a prospective, observational, multicentre study of 1140 patients

Objective: The superior wound healing properties and cost-effectiveness of TLC-NOSF dressings in the local treatment of chronic wounds have already been demonstrated by several randomised controlled trials (RCTs) at a high quality level. Therefore, this study aimed to evaluate the efficacy and safety of new TLC-NOSF dressings with polyabsorbent fibres in an unselected population of patients under real-life conditions.
Method: A large, prospective, multicentre, observational study with two polyabsorbent TLC-NOSF dressings (UrgoStart Plus Pad and UrgoStart Plus Border, Laboratoires Urgo, France) was conducted in Germany between July 2017 and December 2018. Main outcomes included wound healing rate, clinical assessment of wound healing progression, local tolerability and acceptance of dressings.
Results: A total of 1140 patients with chronic wounds of various aetiologies (leg ulcers, diabetic foot ulcers, pressure ulcers, etc.) were treated with the investigated dressings in 130 centres, for a mean duration of 56±34 days. By the final visit, 48.5% of wounds had healed and 44.8% had improved. Similar results were reported regardless of wound aetiology or regardless of proportions of sloughy and granulation tissue at the start of treatment. According to the subgroup analysis by wound duration, the sooner the TLC-NOSF treatment was initiated, the better the clinical outcomes for all types of wounds. The dressings were very well tolerated and accepted by the patients.
Conclusion: These results are consistent with those from RCTs conducted on TLC-NOSF dressings. They complete the evidence on the good healing properties and safety profile of these dressings, especially in non-selected patients treated in current practice, and regardless of the characteristics of wounds and patients. They support the use of the dressings as a first-line intervention and until wound healing in the management of chronic wounds, in association with appropriate standard of care.
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chronic wounds • foot ulcers • leg ulcers • pressure ulcers • observational study • TLC-NOSF dressing

Chronic wounds are defined as wounds that do not progress through the healing process in a timely manner.[1] Some wounds, such as leg ulcers (LU), diabetic foot ulcers (DFU) and pressure ulcers (PU), present chronic features from the outset, while others initially start as acute and become chronic after several weeks of stagnation due to the patient's general condition or inappropriate care. These wounds are often resistant to treatment and may last for several months or years.[1] Some of their common shared features include prolonged or excessive inflammation, deleterious degradation/synthesis ratio of the extracellular matrix (ECM) and impaired neovascularisation which, altogether, subsequently impair the wound healing process.[2] It is estimated that 1–2% of the population in developed countries will suffer from a chronic wound in their lifetime;[1] but the prevalence of these wounds is also estimated to be growing at a rate of 12% per year as a result of population ageing and increasing incidence of comorbid conditions, such as diabetes and vascular disease.[3] In association with these chronic wounds, patients experience pain, decreased quality of life (QoL) and high levels of complications, such as repetitive wound infection episodes and prolonged hospital stays.[4–10] In order to optimise the colossal expenses relating to the treatment of these wounds and to ensure the best possible patient care, health societies and health authorities regularly update their recommendations, based on the analysis of all the robust clinical evidence available.[11–13]

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In 2019, the National Institute for Health and Care Excellence (NICE) stated in its medical technologies guidance that:

> *'clinical and economic evidence supports the case for adpoting UrgoStart dressings to treat DFUs and venous LUs in the NHS.'*[11]

The same year, the International Working Group on the Diabetic Foot (IWGDF) guidance also recommended considering the use of these dressings in non-infected, neuroischaemic DFUs in order to enhance the wound healing process.[12] These dressings benefit from the technology lipidocolloid with nano oligo saccharide factor (TLC-NOSF), a lipidocolloid matrix containing sucrose octasulfate potassium salt. The potassium salt of sulfated oligosaccharides is known to have many biological activities, such as inhibition of matrix metalloproteases (MMPs), interaction with growth factors and restoring biological functions.[14,15] The healing enhancer properties of the TLC-NOSF dressings have been established in the management of chronic wounds in high quality clinical studies with low risk of bias, while their cost-effectiveness has been demonstrated from different health economic perspectives.[11,16,17] In the management of LUs of venous or mixed origin, the double-blind, randomised controlled trial (RCT) 'CHALLENGE' (187 patients, 45 centres) demonstrated significant improvements in early wound healing (p=0.002) and in patients' QoL with TLC-NOSF dressings compared with non-interactive dressings.[18,19] The 'Wound Healing Active Treatment' (WHAT) RCT (117 patients, 27 centres) established superior wound area reduction (p=0.006) and better healing rates (p=0.029) with TLC-NOSF dressing compared with another MMP-inhibitor dressing.[20] In the management of neuroischaemic DFUs, the European double-blind RCT 'EXPLORER' (240 patients, 43 centres) demonstrated that a significantly higher wound closure rate (p=0.002) and a shorter time-to-closure (p=0.029) were achieved with the TLC-NOSF dressing compared with a non-interactive dressing.[21,22] Evidence of reduced healing times for LUs, DFUs and PUs treated with the TLC-NOSF dressings were also reported in current practice, with a pooled analysis of the data from eight observational studies with 10,220 patients conducted in France and in Germany.[23] The good healing rates reported in these observational studies were also consistent with the results of the RCTs and other interventional clinical trials conducted with the dressings.[14,24,25] In all the studies, the authors reported good tolerance and good acceptability of the evaluated dressings by both the patients and health professionals.[16–25]

The range of TLC-NOSF dressings, which includes contact layers and adhesive or non-adhesive foam dressings, has expanded with new wound dressings formed of a pad of polyabsorbent fibres coated with the TLC-NOSF healing matrix. These polyabsorbent fibres suit the needs of wounds in the granulation stage of wound healing as well as wounds at the debridement stage. The clinical efficacy and safety profile of the new TLC-NOSF dressings have been already evaluated in two interventional, prospective, single-arm clinical trials, both conducted in hospital departments and private practice of specialised physicians.[26] The clinical results showed the investigated dressings to be an effective, safe and simple treatment for the local management of chronic wounds at the different stages of healing and until wound closure.

Thus, it was the intention of this study to investigate the performance of the pad and border version of the polyabsorbent TLC-NOSF dressings, which had yet to be assessed in an observational study, on a large unselected cohort of patients with chronic wounds, treated under real-life conditions.

Methods

Study design and patients

This study was a prospective, observational, multicentre study conducted with general practitioners, medical practitioners, internists, surgeons, dermatologists and other specialists, located across Germany, to ensure a representative cohort of patients and physicians.

Any patient with an exuding chronic wound that the health professional had decided to treat with one of the two evaluated dressings was eligible. In the case of patients presenting with multiple eligible wounds, the wound considered by the physician as the most suitable to be assessed was selected for the study. Patients were followed up in an outpatient setting or during home visits for a maximum duration of 12 weeks, with a maximum of four documented visits. All decisions regarding diagnosis and therapy were made by the treating physician and the therapeutic procedure was not influenced by the study. Clinical best practices was assumed, for example with compression for venous leg ulcers (VLU) or offloading for DFUs, and some differences in care protocols were expected between clinical settings. The participating physicians could discontinue the use of the evaluated dressing and the patient's participation in the study at any point of the follow-up.

Study wound dressing

Both evaluated wound dressings (UrgoStart Plus Pad and UrgoStart Plus Border, Laboratoires URGO, France) contain a sterile, non-woven pad of cohesive polyabsorbent fibres coated with a soft, adherent healing matrix impregnated with nano-oligosaccharide factor (NOSF, sucrose octasulfate). UrgoStart Plus Border also includes a superabsorbent layer and a vapour permeable waterproof outer film with silicone adhesive on the edges to provide superior absorption capacity and easier application. According to the manufacturer's instructions, it is recommended changing the dressings every one to two days during the wound desloughing stage. Thereafter, the dressing should be changed as

often as required, depending on the exudate volume and clinical status of the wound, and at least once a week.

Outcomes and assessments

At the initial visit, the relevant demographic information and medical history of the patient were recording, along with the wound characteristics (aetiology, wound duration, wound area, wound bed tissue, exudate level, condition of the periwound skin), and previous and current wound treatment (including previously used dressings, current antibiotic treatment and local wound care). The health professionals assessment of the first application of the evaluated dressings (ease of application and conformability) was also documented. At the interim visits, investigators documented wound characteristics, wound healing progression and the occurrence of adverse events. Outcomes related to the final assessment visit included:

- Treatment and evaluation duration (in days)
- Overall wound healing progression ('wound healed', 'greatly improved', 'slightly improved', 'unchanged', 'slightly deteriorating' or 'greatly deteriorating')
- Relative reduction of wound area (in %)
- Reduction of the percentage of sloughy tissue on the wound bed
- Change in the exudate level ('increased', 'unchanged', 'decreased')
- Change in the periwound skin condition ('improved', 'unchanged', 'deteriorating')
- Frequency of dressing changes and acceptability of the dressing (usefulness, pain at dressing change and patient's acceptance)
- Overall opinion of the health professional on the performances of the evaluated dressings ('better', 'identical' or 'worse') compared with their previous experience with adhesive foams or polyacrylate dressings, in terms of time to reach wound closure, deshloughing capacities, absorption capacities, ease of dressing application, handling, adhesiveness of the border edges, conformability, patients' acceptance and pain management.

Throughout the study period, the occurrence of adverse events were documented and the local tolerance of the dressings was assessed by the physicians at the final visit according to the following definitions: 'very good' (no local adverse event related to the device during the observation period), 'good' (not more than one temporary event of mild or moderate intensity) and 'poor' (more than one event or at least one severe temporary event or one persistent event).

Data management

An electronic data entry system with a standardised electronic case report form (eCRF) was used in this clinical study. All the physicians received specific access codes to enable them to enter their data. The electronic system performed automatic checks for data completeness and inconsistent data. The data management and quality assurance of the study were carried out by an independent contract research organisation (INPADS GmbH, Bad Dürkheim, Germany) in accordance with the recommendations on planning, conducting and analysing of post-marketing surveillance studies of the Federal Institute for Drugs and Medical Devices/Paul Ehrlich Institute (BfArM/PEI, 2010). The patients included in the study were informed about the processing of their personal and health data by their participating health professionals, and gave their explicit and written consent for the processing of their data in the study.

Statistical analysis

The estimation of the cohort size required for this observational study was based on the literature and on experience from previous observational studies, in order to allow a pragmatic evaluation of the dressing's performance in a sufficiently diverse cohort of patients and health professionals.[23]

The statistical analyses were performed according to the statistical analysis plan, by an independent contract research organisation (INPADS), using SAS 9.1.3 for windows (Statistical Analysis System, SAS Institute, US). The biometric analyses and dressing performance evaluations were merely descriptive, and no statistical tests were used. Values were reported as mean±standard deviation (SD); median and interquartile range (IQR) or count and percentage. Efficiency and safety analyses included all patients for whom the initial visit and the final visit were documented. Missing values were not replaced. Data of VLUs, arterial LUs and LUs of mixed origin were pooled into a 'LUs' group. All other aetiologies, other than LUs, DFUs and PUs, were grouped into an 'other wounds' group. Post-hoc analyses were performed according to a post-hoc analysis plan in order to determine the performance of the dressing, depending on wound duration and wound bed tissue proportion at the start of treatment. Wounds were considered to be in 'debridement stage' when the wound bed was covered by <50% granulation tissue, and in 'granulation stage' when the wound bed was covered by ≥50% granulation tissue.

Ethical approval

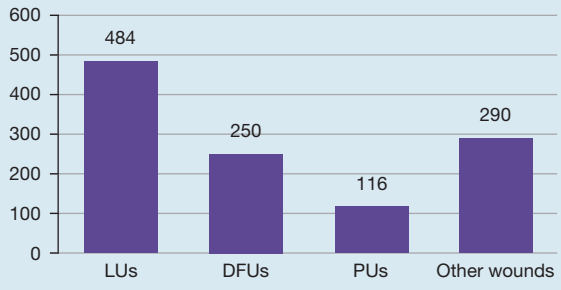
The study was conducted in accordance with the Declaration of Helsinki, the German Medical Devices Act and Federal data protection law (Bundesdatenschutzgesetz, 2009). Due to the non-interventional design of this study performed on two CE-marked devices, used according to the manufacturer's instructions, no ethics committee or authorities approval were required, as this type of observational study presents no particular harm to or benefits for the patients, provided they are treated as they would be in real-life.

Results

Baseline characteristics of the included patients

Between July 2017 and December 2018, a total 1185

Fig 1. Aetiologies of the treated wounds



LUs—leg ulcers; DFUs—diabetic foot ulcers; PUs—pressure ulcers

patients with chronic wounds, treated with the evaluated dressings, were included by 130 active centres. The median number of patients recruited per centre was five (IQR: 4–10). Due to incomplete documentation, 45 files (3.8%) were excluded and the evaluations of 1140 patients were taken into account in the analyses. Patients were followed on average for 55±34 days. There were two interim visits, performed after 17±16 days and 36±26 days of treatment, documented for 1119 (98.2%) and 1054 patients (92.5%), respectively.

As reported in Fig 1, the most frequently treated wounds were LUs (n=484; 42.5%), including 353 VLUs, 45 arterial LUs and 86 LUs of mixed origin; followed by DFUs (n=250; 21.9%) and PUs (n=116; 10.2%). The group of 'others wounds' (n=290; 25.4%) included various other aetiologies such as and lymphatic ulcers and stagnating wounds.

As commonly reported in the literature, DFUs mainly affected men and PUs slightly more women (Table 1). Patients with PUs were, on average, slightly older (77.1±11.3 years old) than the other patients. Globally,

Table 1. Demographics and anamnesis of the treated patients

	Leg ulcers (n=484)	Diabetic foot ulcers (n=250)	Pressure ulcers (n=116)	Other wounds (n=290)
Demographics				
Male/female, n (%)	242 (50.0)/242 (50.0)	164 (65.6)/86 (34.4)	53 (45.7)/63 (54.3)	159 (54.8)/131 (45.2)
Age, years, mean±SD	71.7±13.6	71.0±11.6	77.1±11.3	66.5±18.5
BMI, kg/m², mean±SD	29.3±6.7	30.2±5.7	27.7±7.6	27.7±5.9
Anamnesis, multiple answers possible, n (%)				
Diabetes type 2	164 (33.9)	231 (92.4)	50 (43.1)	82 (28.3)
Diabetes type 1	32 (6.6)	18 (7.2)	3 (2.6)	9 (3.1)
Cardiac insufficiency	173 (35.7)	70 (28.0)	66 (56.9)	87 (30.0)
Limited mobility	158 (32.6)	46 (18.4)	70 (60.3)	77 (26.6)
Confirmed peripheral neuropathy	68 (14.0)	89 (35.6)	15 (12.9)	32 (11.0)
Renal insufficiency	80 (16.5)	64 (25.6)	40 (34.5)	42 (14.5)
Obesity (BMI ≥30kg/m²)*	109 (22.5)	55 (22.0)	15 (12.9)	43 (14.8)
Malnutrition	21 (4.3)	3 (1.2)	16 (13.8)	19 (6.6)
Respiratory insufficiency	47 (9.7)	15 (6.0)	9 (7.8)	19 (6.6)
Missing data	52 (10.7)	0 (0.0)	1 (0.9)	51 (17.6)
Multiple wounds, n (%)	**88 (18.2)**	**41 (16.4)**	**19 (16.4)**	**49 (16.9)**
2 wounds	54 (61.4)	29 (70.7)	15 (78.9)	33 (67.3)
3 wounds	17 (19.3)	11 (26.8)	4 (21.1)	9 (18.4)
4 or more wounds	17 (19.3)	1 (2.4)	0 (0.0)	7 (14.3)
Wound recurrence, n (%)	**118 (24.4)**	**56 (22.4)**	**18 (15.5)**	**43 (14.8)**
1 recurrence	18 (15.3)	14 (25.0)	3 (16.7)	20 (46.5)
2 recurrences	46 (39.0)	25 (44.6)	8 (44.4)	13 (30.2)
3 or more recurrences	54 (45.8)	17 (30.4)	7 (38.9)	10 (23.3)

BMI—body mass index; SD—standard deviation. *Mean BMI is given for patients ≥17 years old

the included patients were overweight, body mass index (BMI) 28.9±6.5kg/m², especially in the subgroups of patients with a LU or DFU, where the proportion of patients with obesity (BMI ≥30kg/m²) was 22%. In contrast, in the PU subgroup, patients with obesity and those with malnutrition were similarly represented (12.9% and 13.8%, respectively). The proportion of patients with diabetes was particularly high in all patient subgroups, including in patients with a LU (33.9%) and in patients with a PU (43.1%). Cardiac insufficiency and limited mobility were particularly prevalent in patients with a PU or LU. In addition to the comorbidities reported in Table 1, the other conditions affecting patients, with global frequencies <5%, included: immunodeficiency (4.1%), severe hepatic insufficiency (2.5%), current infectious problem independent of the wounds (3.2%), systemic steroid treatment (3.7%), chemotherapy (2.7%), and several previous transfusions (1.4%). Multiple wounds and recurrent wounds were documented for 17.3% (n=197) and 20.6% (n=235) of the patients, respectively. These elevated numbers, consistent with those reported in the literature for patients with chronic wounds, illustrate well the magnitude of the problem usually posed by this type of wound.

Baseline characteristics of the wounds, previous and current treatments and local care

Treatment with the evaluated TLC-NOSF dressings was initiated after a median wound duration of one month for LUs and DFUs, and two weeks for PUs and other wounds. A large proportion of recent wounds were included in the study (n=690; 60.5% of wounds occurred in the previous month) and 11.1% of wounds (n=126) had not yet been covered by any dressing before the inclusion visit (Fig 2). For wounds that had been previously dressed, globally, either an absorbent dressing (hydrocolloid, alginate, hydrofiber, foam or superabsorbent; n=440; 38.6%) or gauze/dry dressings (n=348; 30.5%) were used. In 10.9% of patients (n=124), the wounds were previously treated with an antimicrobial dressing. When a previous evaluation of the wound healing progression was available (n=601), the majority of the wounds were either considered as stagnating (n=295; 49.1%) or deteriorating (n=122; 20.3%).

Most frequently, local care consisted of cleaning the wound with an antiseptic solution (n=597; 52.4%) or a saline solution (n=381; 33.4%; Fig 3). Mechanical wound cleaning and surgical debridement were also performed in 381 (33.4%) and 243 (21.3%) of patients, respectively. At baseline, 184 patients (16.1%) were on systemic antibiotic therapy and 72 (6.3%) were receiving local antibiotic therapy, but mostly, patients were not on antibiotic therapy (n=861; 75.5%) (23 missing data; 2.0%).

The median wound area of the chronic wounds was 6.9cm² (IQR: 3.1–15.7), ranging between 3.1cm² (IQR: 1.4–7.9) for DFUs and 8.1cm² (IQR: 4.0–19.6) for PUs (Table 2). Globally, wound beds were covered by 45±30% sloughy tissue, 46±32% granulation tissue and 9±18% necrotic tissue. However, at baseline, more than a third of the wounds (n=449; 39.4%) were in the granulation stage of the wound healing process, i.e. with a wound bed covered by ≥50% granulation tissue. As expected, wounds with high or moderate exudate levels (n=710; 62.3%) were more frequent than those with few or no

Fig 2. Dressings used on the wounds before the TLC-NOSF dressings (**a**). Clinical assessment at baseline of past wound healing progression, when available (**b**; n=601)

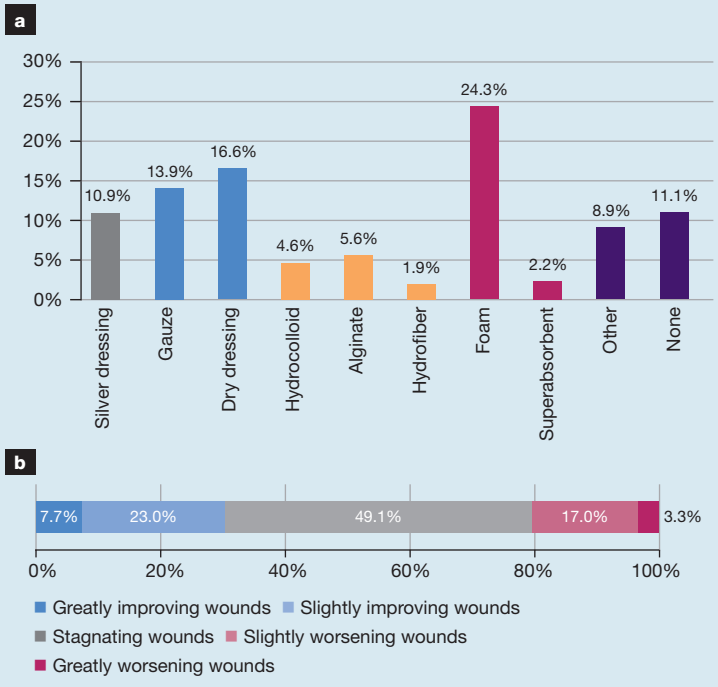


Fig 3. Local wound care

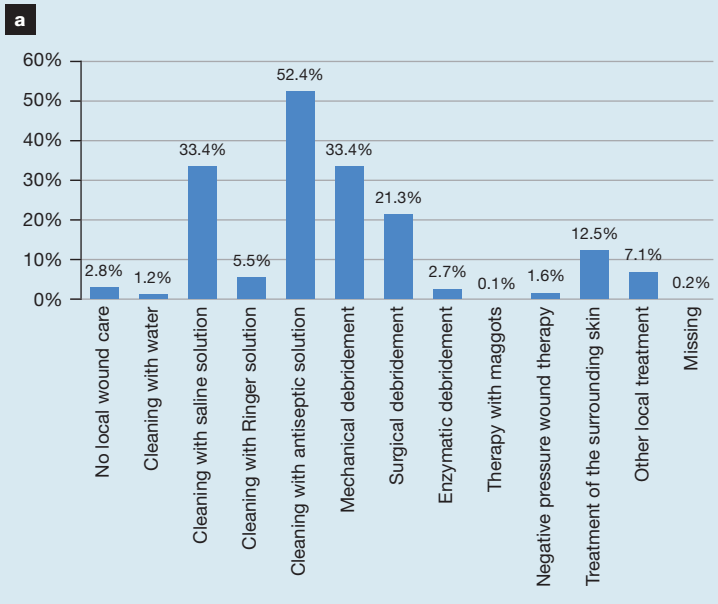
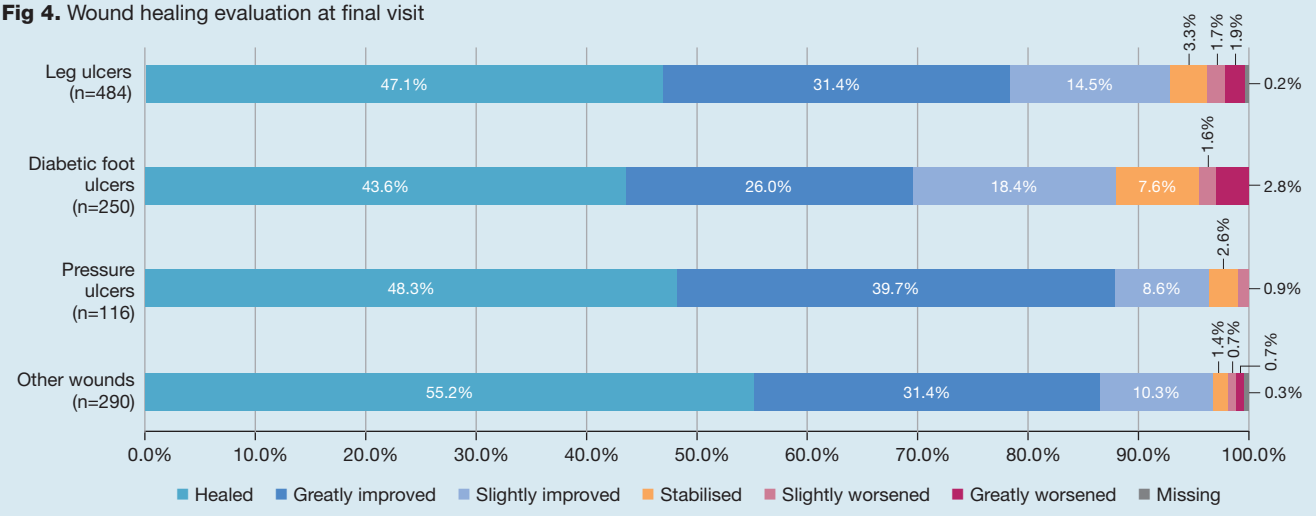


Table 2. Wound characteristics at baseline

	LUs (n=484)		DFUs (n=250)		PUs (n=116)		Other wounds (n=290)	
Median wound duration, days (IQR)	31	(14–92)	31	(11–92)	14	(7 – 40)	14	(6–35)
Duration ≤1 month, n (%)	264	(54.9)	128	(51.2)	84	(73.0)	123	(74.3)
Duration >1 month, n (%)	217	(45.1)	122	(48.8)	31	(27.0)	167	(25.7)
Median wound area, cm² (IQR)	7.9	(3.5; 19.6)	3.1	(1.4–7.9)	8.1	(4.0 –19.6)	6.4	(3.1–15.7)
Wound bed tissue, %								
Granulation tissue, mean ±SD	42±32		51±34		51±31		49±32	
Sloughy tissue, mean ±SD	49±30		41±31		40±27		44±30	
Necrotic tissue, mean ±SD	9±18		8±18		10±18		8±17	
Wound healing stage								
Granulation stage, n (%)	171	(35.3)	104	(41.6)	51	(44.0)	123	(42.4)
Debridement stage, n (%)	313	(64.7)	146	(58.4)	65	(56.0)	167	(57.6)
Level of exudate								
High/moderate exudate, n (%)	323	(66.7)	136	(54.4)	63	(54.3)	188	(64.8)
Few/no exudate, n (%)	159	(32.8)	113	(45.2)	52	(44.8)	102	(35.2)
Missing data	2	(0.4)	1	(0.4)	1	(0.9)	-	-
Periwound skin condition								
Healthy skin	19	(3.9)	15	(6.0)	5	(4.3)	26	(9.0)
Missing data	3	(0.6)	1	(0.4)	1	(0.9)	1	(0.3)

LUs—leg ulcers; DFUs—diabetic foot ulcers; PUs—pressure ulcers

Fig 4. Wound healing evaluation at final visit



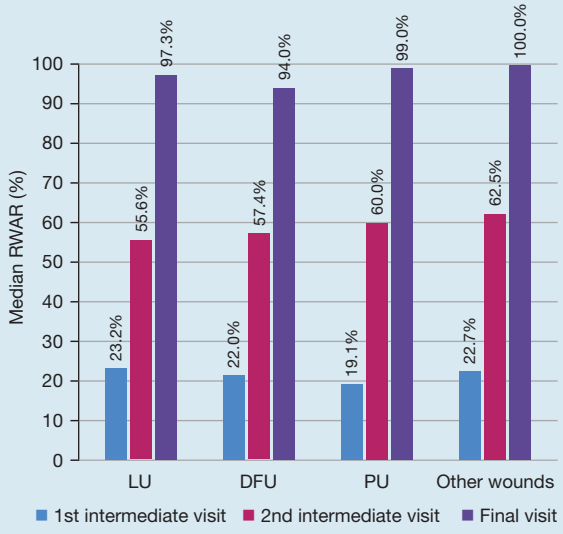
exudate (n=426; 37.4%). Finally, the majority of the patients presented at baseline with an impaired condition of their periwound skin (n=1069; 93.8%).

Wound healing rate and wound healing progression with the TLC-NOSF dressings

By the final visit, a wound closure or an improvement in wound healing was reported in 93.3% of the treated wounds (n=1064; Fig 4). The wound closure rates reached 43.6% in DFUs, 47.1% in LUs, 48.3% in PUs and 55.2% in 'other wounds' (Table 3). The median times to achieve wound closure were 49 days for LUs, DFUs and PUs, and 42 days for other wounds.

The wound area of all wound types continuously

Fig 5. Relative wound area reduction (RWAR) in each aetiology, at the different visits (median values). LU–leg ulcer; DFU–diabetic foot ulcer; PU–pressure ulcer



decreased throughout the treatment period and by the final visit reached a median RWAR of 97.3% (IQR: 61.5–100.0) in LUs, 94.0% (IQR: 37.7–100.0) in DFUs, 99.0% (IQR: 66.1–100.0) in PUs, and 100.0% (71.4–100.0) in other wounds (Fig 5).

Table 3. Time to achieve wound closure with the TLC-NOSF dressings

	Wound healed		Time-to-closure	
	n	%	Median	IQR
LU	228	47.1%	49	38–78
DFU	109	43.6%	49	33–76
PU	56	48.3%	49	25–69
Other wounds	160	55.2%	42	28–64

IQR—interquartile range; LU—leg ulcer; DFU—diabetic foot ulcer; PU—pressure ulcer

Dressing performance depending on wound healing stage at the start of treatment

As the wound healing progressed, all wound types showed a reduction in sloughy tissue and an increase in granulation tissue, and, globally, the proportion of sloughy tissue decreased from 45±30% at baseline to 15±24% at the final visit. In the subgroup of patients for whom the treatment had been initiated in the granulation stage of wound healing (granulation

Fig 6. Final wound healing assessment, depending on the wound healing stage at baseline (debridement versus granulation; **a**). Relative wound area reduction (RWAR) at final visit, depending on the wound healing stage at baseline (debridement versus granulation; median values; **b**). IQR—interquartile range

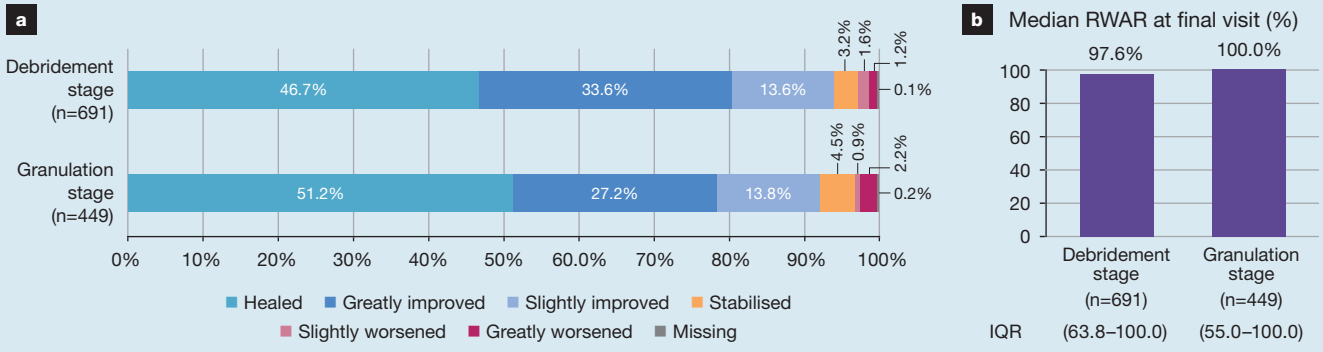


Fig 7. Final wound healing assessment, depending on wound duration at baseline (**a**). Relative wound area reduction (RWAR) at final visit, depending on wound duration at baseline (median values; **b**). IQR—interquartile range

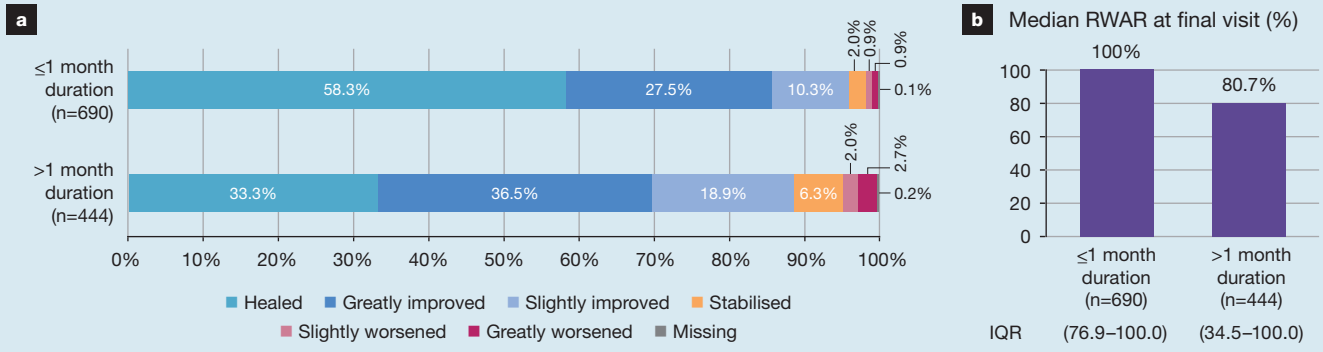
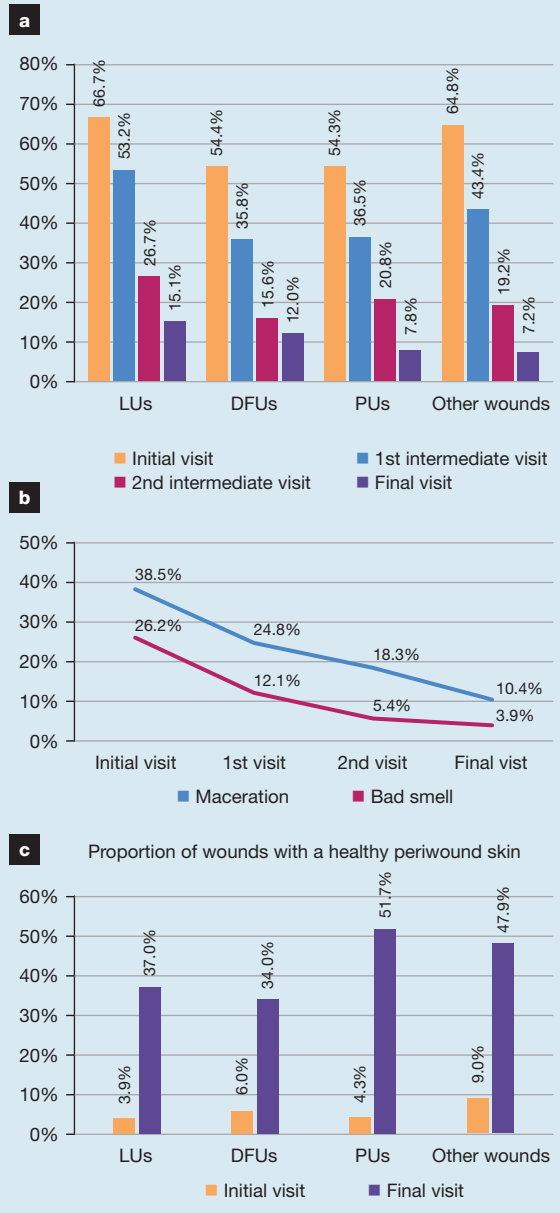


Fig 8. Evolution of the proportion of wounds with high or moderate levels of exudate during the treatment period (**a**). Evolution of the proportion of macerated and malodourous wounds during the treatment period (**b**). Change in periwound skin condition with the TLC-NOSF dressings (**c**)



LUs—leg ulcers; DFUs—diabetic foot ulcers; PUs—pressure ulcers

tissue: ≥50%), the median RWAR reached 100.0% (IQR: 50.0–100.0%) at the final visit (Fig 6). By then, 51.2% of the wounds had healed and 41.0% had 'greatly' or 'slightly' improved. Very good healing outcomes were similarly reported in the subgroup of patients whose treatment had been initiated in the debridement stage, with a wound closure rate of 46.7%, 47.2% of improving wounds and a median RWAR of 97.6% (IQR: 63.8–100.0%). In both subgroups, the proportion of worsening wounds was similar and low (n=19; 2.7% and n=14; 3.1%, respectively), confirming the good performance of the polyabsorbent dressing, regardless of wound healing stage at treatment initiation.

Dressing performance depending on wound duration at the start of treatment

Unlike the wound healing stage, the duration of the wounds at initiation of treatment had a negative impact on wound healing outcomes. As represented in Fig 7, while a healing rate of 58.3% was obtained with wounds occurring in the previous month, only 33.3% of wounds of >1 month's duration healed at the last visit. Similar results were reported regardless of the wound aetiology (wound closure rate of LU ≤1 month: 58.3% versus LU >1 month: 32.7%; DFU ≤1 month: 57.0% versus DFU >1 month: 29.5%; PU ≤1 month: 54.8% versus PU >1 month: 32.3%; other wounds ≤1 month: 60.3% versus >1 month: 41.9%). Although favourable, the median RWAR of wounds of the longest duration was lower than that of recent wounds: 80.7% (IQR: 34.5–100.0) versus 100.0% (IQR: 76.9–100.0). In addition, while the number of stagnating wounds has substantially decreased since the inclusion visit; the proportion of wounds still stagnant at the last visit was higher in the subgroup of older wounds than in the other subgroup (6.3% versus 2.0% in recent wounds).

Dressing performance: exudate management

By the final visit, levels of exudate had decreased in 67.7% of wounds (n=772), remained unchanged in 17.8% of the cases (n=203) and increased in 4.2% of them (n=48) (data missing for 113 wounds, 9.9%). As reported in Fig 8, the proportion of wounds with high or moderate levels of exudate continuously decreased during the treatment period in all types of wounds.

The proportion of malodorous wounds decreased from 38.5% to 10.4%, as did the proportion of macerated periwound skin (from 26.2% to 3.9%). At the final visit, the periwound skin condition globally improved in 804 patients (70.5%), remained unchanged in 285 patients (25.0%) and worsened in 39 patients (3.4%). The proportion of patients with a healthy skin condition rose from 5.7% (n=65) at baseline to 40.6% (n=463) at the end of the study period.

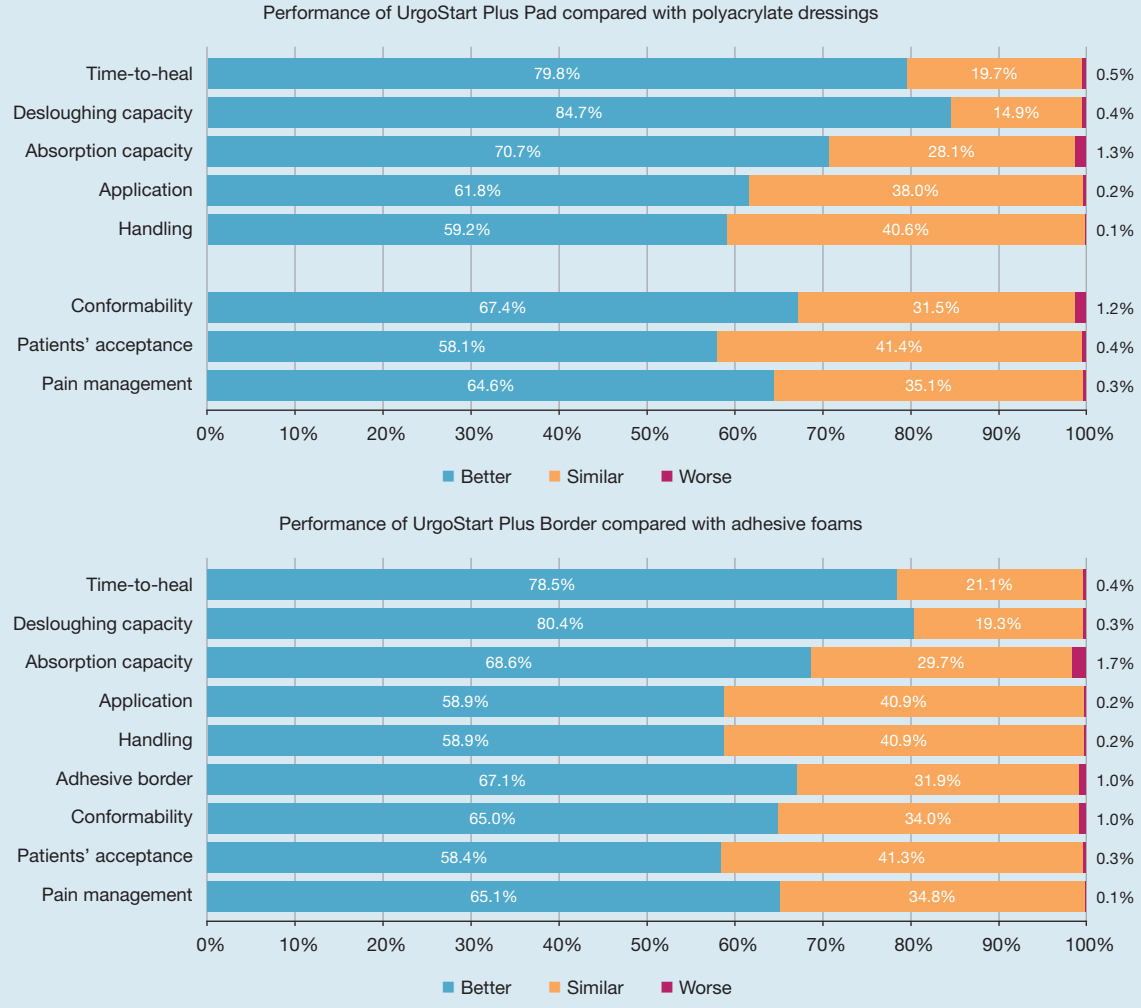
Safety assessment: local tolerance

The local tolerance of the dressings was assessed by the health professionals as 'very good' in 928 patients (81.4%) and 'good' in 197 patients (17.3%). Poor local tolerance was reported in seven cases (0.6%):

- Five patients with a VLU
- One with an arterial LU
- One with another type of wound.

The data were missing for eight patients (0.7%). During the course of this observational study, two adverse events (0.2%) have been documented in two

Fig 9. Performance of UrgoStart Plus Pad and UrgoStart Plus Border, compared with that of polyacrylate dressings and adhesive foams, according to the physicians' point of view



patients with a LU treated with the pad dressing:

- A case of itching associated with skin cracks in a 37-year-old man, for whom a treatment discontinuation had been judged unnecessary
- A suspicion of allergic reaction in an 80-year-old woman presenting with redness, red pimples and itching. In this case, it was decided to discontinue the use of the evaluated dressing.

No adverse event was reported with the adhesive dressing.

Acceptability, handling and overall assessment of dressing performance compared with other dressings

At the initial visit, UrgoStart Plus Pad was applied in 627 patients (55.0%) and UrgoStart Plus Border in 513 patients (45.0%). The pad version was slightly more frequently applied on LUs and DFUs (58.7% and 58.4%, respectively) than on PUs and other wounds (50.9% and 47.6%, respectively), while the border version was slightly more frequenlty applied on PUs and on other wounds (49.1% and 52.4%, respectively) than on LUs and DFUs (41.3% and 41.6%, respectively). These proportions remained unchanged until the final visit. Throughout the course of the study, UrgoStart Plus Pad had been changed on average 2.5±1.1 times a week (minimum 0; maximum 9) and UrgoStart Plus Border changed 2.3±1.1 times a week (minimum 0; maximum 7). According to the physicians of the 130 centres involved in this study, both dressings were judged, in the majority of cases, as 'very easy' or 'easy' to apply since first application (97.4% for the pad and 97.3% for the border), and 'very conformable' or 'conformable' (95.5% for the pad and 95.1% for the border).

At the final visit, the UrgoStart Plus dressings were judged by the investigators as 'extremely useful' or 'useful' in 94.6% of patients, to be associated with 'no pain' or 'slightly short pain' (pain of short duration and merely detectable) in 96.9% of patients, and 'very well accepted' or 'well accepted' by 98.1% of patients.

Based on their global experience during this study,

Reflective questions

- What key elements are included in the standard of care of chronic wounds?
- What benefits can be expected by treating patients with the polyabsorbent TLC-NOSF dressings?
- When should TLC-NOSF dressings be initiated for optimal management of chronic wounds?

the physicians expressed their preference towards the evaluated dressings, compared with their previous experience of using other polyacrylate dressings or adhesive foams (Fig 9). In particular, they judged the performance of the evaluated dressings as better in terms of wound healing efficacy (time-to-heal), desloughing capacity, absorption capacity, handling, conformability, adhesivity of the border edges (for the border/adhesive dressing), pain management and patients' acceptance.

Discussion

The present clinical study is the first to assess the performance of the pad and border versions of the polyabsorbent TLC-NOSF dressings under real-life conditions, in a large, unselected cohort of patients with chronic wounds.

The results reveal a use for these new dressings in a variety of wound aetiologies, at different wound healing stages and until wound closure. The positive outcomes achieved in terms of wound closure rate, time-to-closure and healing progression are consistent with those of previous interventional studies conducted with TLC-NOSF dressings in the local management of LUs, DFUs or PUs.[14,18–22,24–26]

In this observational study, a high proportion of included patients received the polyabsorbent TLC-NOSF dressings as a first-line treatment, with 60.5% of patients presenting with a wound occurring during the previous month, and 11.1% of the wounds not having been covered yet by another dressing before the dressings under evaluation. Growing clinical evidence had pointed to better wound healing benefits with an earlier initiation of TLC-NOSF treatment in the local management of chronic wounds.[21,22,23,26] In a double-blind RCT conducted in neuroischaemic DFUs. The superior efficacy of the TLC-NOSF dressings in terms of wound closure rate has been demonstrated in a double blind RCT conducted in neuroischaemic DFUs, compared with modern dressings, notably in recent wounds lasting for less than six months.[21]

A posthoc analysis of the data from this RCT, further analysed the wound duration impact on wound healing outcomes in this indication, and reported the most substantial difference of wound closure rate between TLC-NOSF dressing and modern dressing (71% versus 41%) in the subgroup of patients with wounds of ≤2 months' duration.[22] Better wound healing outcomes, in terms of wound healing rate and relative wound area reduction, for the most recent wounds treated with the polyabsorbent TLC-NOSF dressings, were similarly reported in two different prospective clinical trials on the management of VLUs.[26] Furthermore, in a pooled analysis of six observational studies, significantly shorter time-to-closure was found when the TLC-NOSF dressings were used as a first-line intervention compared with as a second line intervention ($p<0.001$).[23] The clinically relevant gains in mean time-to-closure reached 33 days in LUs, 20 days in DFUs and 30 days in PUs.

As in previously published clinical studies, in this observational study, the more recent the wounds treated with the evaluated dressings, the better the wound healing outcomes. In the group of wounds with the longest duration, the results were still substantially positive, however it seems as if the healing process, although put back on the right trajectory, needed more time to be relaunched. As an aside, it is noteworthy to report that the clinical evaluations of the wound healing progression at baseline were similar in both wound duration subgroups, while the wounds at the debridement stage were more frequently reported as stagnating than wounds at the granulation stage. This may suggest that the chronicity and deterioration of the wound over time is not as visible as other clinical signs, which in some cases may delay decision-making of a necessary change in wound management. Altogether, this evidence highlights the importance of initiating adequate treatment as soon as possible.

To be able to use a dressing as a first-line intervention, it is necessary that this dressing suits the characteristics of the wound. In particular, sloughy tissue is usually considered to have a significant negative impact on the wound healing process. The presence of >50% of sloughy tissue on the wound bed has been correlated with poorer healing outcomes in studies evaluating various dressings.[27,28] The TLC-NOSF dressings with polyabsorbent fibres allow the treatment of chronic wounds, regardless of healing stage (or proportion of sloughy tissue on the wound bed) and until wound healing, as supported by the results of previous interventional prospective multicentre trials.[26] In this observational study, we report consistent results with similar RWARs (67.6% versus 100.0%, respectively) and wound healing rate (46.7% and 51.2%, respectively), regardless of the healing stage of the wounds at start of treatment (granulation stage or debridement stage). The polyabsorbent capacities of the evaluated dressings allow the treatment of wounds covered by sloughy tissue and wounds in the granulation stage. Enhancing the wound healing process, without having to wait for the debridement stage to end, could help save weeks of treatment and shorten time to wound healing.

The management of exudates by both evaluated dressings was also particularly appreciated and supported

the improvement of the condition of the periwound skin, regardless of the aetiology of the wound. The painless dressing change and the reduction of malodour have certainly, with the visualisation of the rapid wound healing, played a part in the acceptability of the dressings by the patients. Meanwhile, the good conformability of the dressings and the adapted adhesiveness of the border version facilitated wound dressing.

Limitations

A limitation of observational studies is that no additional assessments, such as vascular measurement, could be requested for the study, therefore the number of parameters recorded may be more limited than in interventional studies. With more than one thousand patients included in this study, and without any exclusion criteria at baseline, we have a representative picture of the variety of the patients treated with the polyabsorbent TLC-NOSF dressings in the German community.

Conclusion

This clinical evidence, based on a large cohort of 1140 patients treated under real-life conditions, completes the efficacy and safety profile of the UrgoStart Plus dressings. The TLC-NOSF dressings with polyabsorbent fibres enhance wound healing in chronic wounds, regardless of their aetiology or their wound healing stage. The dressings were well tolerated and accepted, rated highly by clinicians and patients. These results join the ranks of the growing evidence supporting the use of these dressings, as a first-line intervention and until wound healing, in the local management of chronic wounds. **JWC**

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