Service evaluation: the benefits of TLC-NOSF dressings on patients with diabetic foot ulcers

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Key words

- Diabetes foot ulcer
- NOSF Sucrose Octasulfate dressing
- Quality of life
- TLC
- UrgoStart,
- Wound closure

Article points

1. UrgoStart dressings have been demonstrated to significantly improve healing rate, shorten healing time and save costs in the management of patients with DFUs, and are currently recommended by international guidelines in this indication.
2. A service evaluation of the use of UrgoStart contact and UrgoStart Plus pad dressings when used as part of standard of care of the management of non-infected DFUs was performed.
3. The authors showed high wound closure rate, short healing times and substantial improvement in the patients' quality of life when using UrgoStart dressings as first-line local treatment, consistently with the existing clinical evidence and current recommendations.

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Background: Diabetic foot ulcers (DFUs) are frequent but complex chronic wounds, characterised by delayed wound healing, high risk of infection and amputation, impaired patient quality of life and substantial financial burden. Alongside with appropriate metabolic control, offloading, debridement and infection control measures, UrgoStart dressings are recommended by the National Institute for Health and Care Excellence (NICE) guidance to treat patients with DFUs in NHS settings. Aim: A service evaluation was conducted to assess the implementation of UrgoStart dressings as a first-line local treatment and integral part of usual standard of care for the local treatment of DFUs. Methods: All patients presenting to our podiatric clinic over an 8-week period with a non-infected DFU were treated according to standard of care with the UrgoStart dressings range (Laboratoires Urgo). Main outcomes included wound closure rate by week 20 and change in patients' quality of life. Results: Twenty-three patients with a DFU have been included between May 2021 and July 2021. Most wounds were seen for the first time and had just occurred (78% lasting for 1 week or less). By the final visit, wound closure was achieved in 16 patients (70%), with 81% of these closures occurring by the sixth week of treatment. A subgroup analysis regarding the impact of the severity of the wound at baseline showed that 85% of the patients with a neuropathic DFU healed after a median treatment period of 24 days (range 7 to 134 days) and 50% of the patients with peripheral arterial disease (PAD) healed after a median treatment period of 43 days (range 14 to 114 days). A substantial improvement of the patients' quality of life was also reported (with a 10-point difference of the EQ-VAS score on average) at the final visit. During the study period, wound infections were reported in five patients (22%). Conclusion: The results of this real-world evaluation are consistent with previous clinical evidence, underlining the benefits of using TLC-NOSF dressings as a first-line local treatment and integral part of usual standard of care to treat DFUs since their onset. Early referral of patients with new DFUs to specialised centres, as well as close collaboration between community nurses and these centres, must be encouraged to provide optimal management of patients and their wounds and to ensure continuity of care.

Diabetic foot ulcers (DFUs) are a frequent and serious complication of diabetes mellitus, characterised by delayed healing and high recurrence rate (Edmonds et al, 2021). It is estimated that at least 2% of people with diabetes in England develop new DFUs annually (Kerr, 2019). Only 40% to 60% of these wounds heals by 12 months (Guest et al, 2020) and recurrence is reported in approximately 40% of patients within 1 year of ulcer healing (Winkley et al, 2009; Armstrong et al, 2017). Because of long healing duration and weak host immune system response, DFUs are also highly prone to infection. A

recent analysis of The Health Improvement Network (THIN) database found that over a 1-year follow-up period, more than 70% of DFUs had an infection recorded (Guest et al, 2020). In addition to causing wound deterioration, local infection of DFUs can lead to infection spread, hospital admission, prolonged hospital stays, sepsis and are associated with higher risks of minor and major amputations and death, especially when peripheral artery disease (PAD) is also present (Armstrong et al, 2011).

From both clinical and economic points of view, DFUs represent a major public health problem, placing a heavy financial burden on the National Health System (NHS). The cost of a first year of care has been estimated at £2,138 for a healing DFU, £8,786 for an ulcer that remains active, £12,995 for a DFU that becomes infected, and up to £16,941 for a patient who is amputated (Guest, 2018). Adding the costs of inpatient care for ulcers and associated amputations, as well as the cost of post-amputation care, the total represented nearly 1% of the NHS budget (Kerr et al, 2019).

For the patients, these chronic wounds can also present significant challenges and have a profound impact on their quality of life, including frustration due to prolonged time to healing, fear of wound deterioration, sleep disturbance, depression and anxiety, pain and discomfort associated with exudate leakage or malodour, restricted mobility, difficulty with daily activities, and limited leisure activities (Ismail et al, 2007; Reinboldt-Jockenhöfer et al, 2021).

The main goals of DFU management are to close the wounds, speed access to appropriate and cost-effective treatment that reduces time to heal, minimise the risk of ulcer complications and unnecessary amputations and improve the patients' health-related quality of life (HRQoL) (NICE, 2019a). Standard of care includes metabolic control, pressure relief (offloading), vascular assessment and control of ischaemia, wound debridement, wound dressings and infection control measures (NICE, 2019a; Schaper et al, 2020).

Regarding wounds dressings, based on the robust clinical evidence available, NICE guidance recommends adopting UrgoStart dressings to treat DFU in the NHS because they are associated with increased closure rate, shorter time-to-closure and cost savings (NICE, 2019b). Cost modelling shows that if 25% of people having treatment for DFUs use UrgoStart dressings, the NHS may save up to £5.4 million each year (NICE, 2019b). The Nice guidance also states that the clinical benefits of using UrgoStart dressings can help improve the day-to-day quality of life of people with a DFU.

UrgoStart dressings

UrgoStart dressings include a range of dressings (contact layers, foams, poly absorbent fibres, with adhesive border or not) benefiting from the TLC-NOSF Technology (Technology Lipido-Colloid - Nano Oligo Saccharide Factor): a lipido-colloid healing matrix impregnated with sucrose octasulfate. The TLC-NOSF healing matrix interacts with the wound microenvironment by limiting the deleterious action of matrix metalloproteinases (MMPs), which in excess lead to continuous degradation of the extracellular matrix components. The delayed healing of chronic wounds such as DFUs, leg ulcers or pressures ulcers have been correlated to this excess of MMPs, present since the onset of the wounds (Lázaro et al, 2016).

The superior efficacy UrgoStart dressings on wound closure rate and time-to-heal, compared to advanced dressing, has been demonstrated in an international double blind randomised controlled trial (RCT) conducted in the management of non-infected DFUs in patients with diabetes, neuropathy and PAD (The EXPLORER study; Edmonds, 2018). Post-hoc analyses of this study established that significant improved healing outcomes were obtained with UrgoStart dressings regardless of the patient and wound characteristics at baseline, but that the greatest benefits compared to the control were achieved when the dressings were used on recent wounds (Lázaro-Martínez et al, 2019). The results from 10 large observational studies, including more than 12,000 patients with chronic wounds and notably 1,773 patients with a DFU treated in real-life practice, confirmed the good performances of the dressings on the wound-healing process and the best outcomes when the dressings were used as first-line treatment (Münter et al, 2017; Dissemond et al, 2020a; Augustin et al, 2021). Augustin and colleagues also showed a significant improvement in the HRQoL of the patients whose wounds healed or improved with UrgoStart (Augustin et al, 2021) and reported, as did the previous cited clinical studies, that these dressings were well tolerated and well accepted by both patients

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and healthcare professionals. Based on this consistent and robust clinical evidence and on recent systematic reviews (Dissemond et al, 2020b; Vas et al, 2020; Nair et al, 2021), the dressings are recommended in national and international guidelines, best practice and consensus documents (NICE, 2019b; Araszkiewicz et al, 2020; Rayman et al, 2020; Binder et al, 2021; Lázaro et al, 2021, Ousey et al, 2021; Wounds UK, 2021), and referenced in several fast-track and structured pathways (Meloni et al, 2019; Atkin et al, 2020; Bouillet et al, 2021, Meloni et al, 2021; Wu et al, 2022) in the management of DFUs.

Aim of this evaluation

Based on the high level of evidence available on the benefits of these dressings in the treatment of patients with DFU, the NICE guidance, and encouraged by the real-world evidence shared by other clinics, we decided to form our own opinion and test these dressings in our podiatry clinic, in association with good standard of care (Atkin et al, 2020).

The Podiatry service at Provide CIC, Mid Essex, UK, is a small team of Specialist Podiatrists who provide treatment for high risk and ulcerated patients within this community. This service runs five days a week and we also work in the diabetic multidisciplinary team at our acute hospital and provide inpatient care for DFUs. Within our team, we are keen to continually innovate and strive to deliver the best evidence-based care. Prior to this evaluation, we were familiar with the UrgoStart dressings and that they are available in different sizes and formats, but for DFUs, we mainly used the contact layers and the polyabsorbent fibres (UrgoStart Plus pad). We had a positive experience with our staff finding these dressings easy to work with, as the range can be cut to fit all shapes and sizes and locations of wounds, and the low adherence helps to keep it in place. It had also helped simplify our dressings choices as the guidance is clear on which wounds each of the range is most suitable for, supporting our team make the best choice for the patients.

After this first positive experience, we decided to implement the dressing range within our team and further explore what impact the systematic use of these dressings in our daily practice would have in terms of clinical outcomes.

The objective of this study was, therefore, to evaluate the performance of UrgoStart dressings when used as a first-line local treatment and integral part of usual standard of care in the management of all patients with a DFU.

Patients and methods

Study design and participants

This clinical evaluation was conducted as a prospective, observational, single-arm, study at the Springfield Green Podiatric Clinic, Mid Essex, UK. Adult outpatients (≥18 years old) with uninfected DFUs suitable for application of the evaluated range dressings were eligible if they could follow verbal and written instructions in English, had full mental capacity, and were able to give written informed consent to participate in the study. Patients were excluded if they had a known allergy/hypersensitivity to the dressing, a suspected malignant wound, critical limb ischaemia, or issues following the protocol, including daily wearing of an offloading system. Patients were enrolled over a period of 8 weeks between May 17, 2021 and July 7, 2021. They were treated with the evaluated dressings as part of standard of care, in accordance with NICE recommendations (NICE, 2019a), and monitored for a maximum of 20 weeks.

Premature study withdrawal could be registered in case of patient's consent withdrawal, loss of follow-up, prolonged discontinuation of treatment (four or more consecutive weeks without a dressing change that could be performed by a nurse), non-compliance with the care plan, or referral to the Accident & Emergency department (A&E).

The evaluated dressings

The two evaluated wound dressings (UrgoStart contact and UrgoStart Plus Pad; any sizes available, Laboratoires URGO, France), selected as primary dressing for all the patients, benefit from the TLC-NOSF Technology. UrgoStart Contact is a flexible wound contact layer dressing made of a polyester textile mesh coated with the TLC-NOSF healing matrix, intended for use on wounds mainly covered with granulation tissue, while UrgoStart Plus Pad, a non-woven pad made of cohesive polyabsorbent fibres coated with a soft adherent TLC-NOSF healing matrix is intended for use on exudative wounds, regardless of their level of sloughy tissue. The two CE-marked dressings were expected to be used according to the manufacturer's instructions. The

Table 1: SINBAD ulcer classification score.		
Category	**Definition**	**Score**
Site	Forefoot	0
	Midfoot and hindfoot	1
Ischaemia	Pedal pulse palpable	0
	Clinical evidence of reduced pedal blood flow	1
Bacterial infection	None	0
	Present	1
Area	Ulcer < 1 cm^2	0
	Ulcer ≥ 1 cm^2	1
Depth	Ulcer confined to skin and subcutaneous tissue	0
	Ulcer reaching muscle, tendon or bone	1
Total possible score		0–6

frequency of the dressing change was prescribed by the investigating clinician, considering the manufacturer's recommendations, clinical status of the wounds and specific patient needs.

Clinical assessments

Patients were seen at the clinic on a weekly basis for dressing changes. In the case of shared care, dressing changes were performed between clinic visits by the community nurses, the patients or their relatives. Patients' and wound-related characteristics were documented in a standardised case report form at baseline and every 2 weeks until wound closure, patient withdrawal from the study, or the completion of the 20-week follow-up, whichever occurred first.

The following data were recorded:

■ At the initial visit:

- Patient demographics (age, sex)
- Diabetes mellitus type, peripheral neuropathy confirmed by monofilament test (Schaper, 2020), peripheral arterial disease (PAD) status confirmed by recent vascular assessment (<3 months), such as pedal pulse palpation, pedal doppler waveforms, toe systolic pressures, ankle-brachial index or arterial duplex (Hinchliffe, 2020). If the patient was new to us, the vascular assessment was completed at the initial assessment. If the patient presented with a new ulcer but was previously treated at the clinic and had a recent vascular assessment (<3 months), this recent assessment was used for the evaluation. If any vascular assessment was >3 months old, a new assessment was performed on their first presentation with the DFU. All vascular assessments were performed in our clinic by the podiatrists with the exception of arterial duplex, for which the patient was referred to the hospital vascular team
- Other medical history such as amputation history, ulceration history, renal deficiency, cardiovascular disease, patient mobility ('mobile', 'walks with aids', 'wheelchair/chair bound', 'bedridden'), and metabolic control with glycated haemoglobin test (HbA_{1c} in mmol/mol)
- Patient's health-related quality of life (HRQoL), measured with the EuroQol-visual analogue scale (EQ-VAS) ranging from 0 (the worst imaginable health state that day) to 100 points (the best imaginable health state that day) (Devlin et al, 2020)
- Wound characteristics, such as wound duration reported in weeks, and wound location ('sole of the foot', 'tip of the toe', 'side of the foot', 'dorsum of the foot', 'other'), and severity score using the SINBAD scale ranging from 0 (the less severe) to 6 points (the most severe), as reported in *Table 1* (NICE, 2019a).

■ At each visit scheduled in the protocol:

- Wound characteristics including wound area in cm^2 (calculated with the elliptic formula: length /2 * width /2 * 3.14), wound depth in mm, wound bed tissue (percentage of necrotic, sloughy and granulation tissues), exudate levels ('none', 'low', 'moderate', 'high'), and surrounding skin condition ('healthy', 'dry', 'erythematous', 'macerated', 'eczematous'), overall wound healing assessment since the last visit ('healed', 'improved', 'stabilised', 'deteriorated')
- Pain assessed with a VAS from 0 (no pain) to 10 (the worst pain)
- Method of debridement, if any performed
- Primary and secondary dressings applied and number of dressing changes per week
- Offloading device used ('none', 'total contact cast which can be opened', 'removable device that can be rendered non-removable', 'removable device that immobilise the ankle joint', 'removable device that doesn't immobilise the ankle joint', 'customised shoes with adaptive sole or insole', 'customised felt', 'wheelchair without offloading device', 'wheelchair with offloading

device', 'bedridden')
- Occurrence of any adverse event, including the incidence of infection and the associated treatment initiated
- Any other relevant comments, including shared care and whether care plans were followed

■ At the final visit: The patient's HRQoL, using the EQ-VAS.

Clinical outcomes and data analysis

The primary evaluation criteria was wound closure rate by week 20. Wound closure was defined as wound covered by 100% epithelialisation and no exudate. Secondary evaluation criteria included: time to reach wound closure, relative wound area reduction at week 20, change in pain and patients' quality of life at the final visit, and occurrence of wound infection or of any adverse event throughout the study period.

Demographic data, clinical characteristics and outcome parameters were analysed using descriptive statistics: mean, standard deviation (SD), median value, range (min – max). Sub-group analyses were conducted depending on the presence of PAD and SINBAD score at baseline.

Ethical considerations

This service evaluation was approved by Provide CIC Quality and Safety Committee on April 26, 2021. Ethics Committee approval was not required in line with the NHS Trust's policy on clinical evaluation of CE-marked products used within their licensed indications without randomisation. The study protocol did not involve changing treatment or care from accepted standards used in daily practice. All patients were provided with a patient information leaflet on the study objectives and protocol and have given written informed consent for both their participation and the use of their anonymised data before their inclusion. We also made shared care information leaflets that we used for any patient in this evaluation that had shared care with nurses, to ensure they understood what the patient was participating in and the importance of following the care plan.

Results

Characteristics of the patients and their wounds at baseline

In total, 23 patients with a non-infected DFU treated with UrgoStart contact or UrgoStart Plus dressings were included in this clinical study. The age of the patients was on average 65.3 (SD 15.0), but ranged from 35 to 85 years old. The majority of the patients were male (70%) and had type 2 diabetes (74%). Comorbidities were reported in all patients but one: 96% had peripheral neuropathy, 43% PAD, 30% reduced mobility and 26% history of amputation (*Table 2*). A mean EQ-VAS score of 60.2 (SD 21.9), on a scale of 0–100 (100 being the best health condition the patient can imagine), indicated an overall impairment in the patients' HRQoL at baseline. Patients with reduced mobility, women and older patients (≥75 years old) had on average a lower EQ-VAS score and, therefore, poorer HRQoL than the others.

Most wounds were seen for the first time, with 78% lasting 1 week or less (*Table 3*). Four wounds (17%) were previously treated with antimicrobial dressings, six (26%) by a simple plaster or gauze, and 13 (57%) were not covered by any dressing at presentation. The majority of wounds were located on the sole of the

Table 2: Baseline characteristics of the patients.

Patient's characteristics	***n*=23**
Age: Mean (SD) [range]	A 65.3 (15.0) [35-85]
Sex: Male/female, *n* (%)	16 (70%) / 7 (30%)
Diabetes: Type 2 / Type 1, *n* (%)	17 (74%) / 6 (26%)
Metabolic control (HbA_{1c} in mmol/mol)	75.1 (17.5) [49-111]
HbA_{1c} > 85 mmol/mol (10%)	10 (43%)
Relevant medical history, n(%) – multiple answers possible	
Peripheral neuropathy	22 (96%)
Peripheral arterial disease	10 (43%)
Cardio-vascular disease	8 (35%)
Previous amputation	6 (26%)
Previous ulceration	2 (9%)
Renal disease	2 (9%)
Other comorbidities	5 (22%)
Patient mobility, *n* (%)	
Mobile	16 (70%)
Walks with aids	4 (17%)
Wheelchair/chair bound	3 (13%)
Pre-treatment patients' HRQoL	60.2 (21.9) [10-100]
EQ-VAS score [0-100 scale], mean (SD) [min-max]	
EQ-VAS score [76-100]	4 (17%)
EQ-VAS score [51-75]	8 (35%)
EQ-VAS score [26-50]	9 (39%)
EQ-VAS score [1-25]	2 (9%)

Table 3: Baseline characteristics of the DFUs.	
DFUs' characteristics	***n*=23**
Wound duration, *n* (%)	
1 week or less > 1 week to 4 weeks > 4 weeks to 9 weeks	18 (78%) 3 (13%) 2 (9%)
DFU location, *n* (%)	
Sole of foot Tip of toe Dorsum Other: Side of foot, hallux, amputation site	9 (39%) 6 (26%) 4 (17%) 4 (17%)
Wound surface area, *n* (%)	
≤ 1.0 cm²]1.0 – 5.0 cm²] > 5.0 cm²	15 (65%) 6 (26%) 2 (9%)
Wound depth, *n* (%)	
1 to 5 mm 6 to 10 mm missing	20 (87%) 2 (9%) 1 (4%)
Wound bed tissue, *n* (%)	
Granulation tissue > 50% Sloughy tissue ≥ 50%	14 (61) 9 (39)
Level of exudate	
Low Moderate High	16 (70%) 3 (13%) 4 (17%)
Surrounding skin	
Healthy Dry Erythematous Macerated	13 (57%) 8 (35%) 1 (4%) 1 (4%)
Associated pain [VAS score 0-10]	
No pain (VAS score = 0) Pain (VAS score > 0) Missing	17 (74%) 4 (17%) 2 (9%)
SINBAD score (on a 0-6 scale), *n* (%)	
1 2 3	8 (35%) 9 (39%) 6 (26%)

foot or tip of the toes (65%), superficial (87%) with a surface area (65% ≤1cm²) covered by more than 50% granulation tissue (61%), had a low level of exudate (70%) and healthy surrounding skin (57%), and were associated with no pain (74%). Based on the presence of neuropathy, PAD, wound location, area or depth, a SINBAD score of 1, 2 or 3 was determined for 35%, 39% and 26% of the wounds, respectively.

Debridement, primary and secondary dressings

Sharp debridement was performed in all patients at each visit in order to remove callus and/or wound debris. At the initial visit, 14 patients (69%) were treated with UrgoStart Contact (5cm x 7cm) and nine patients (39%) with UrgoStart Plus Pad (6cm x 6cm). The contact layer was used to treat wounds covered by 30% or less of sloughy tissue, most often with low level of exudate, while the polyabsorbent dressing was selected to treat wounds covered by 50% or more of sloughy tissue, with low to high level of exudate. All wounds were then covered by an absorbent secondary dressing.

During the course of the study, the dressings were changed once or twice a week.

Offloading

At the initial visit, 11 (48%) patients had a customised felt, 4 (17%) patients had customised shoes with adaptive sole or insole, one patient (4%) had a removable device than can be rendered non-removable, one patient (4%) had a removable device that does not immobilise the ankle and one patient (4%) had a total contact cast which can be opened. Five patients (22%) had no offloading device yet (four of these patients had their wounds for less than one week and one was in wheelchair).

During the course of the study, 14 patients (61%) had an offloading device reported at all documented visits, seven patients (30%) were wearing their offloading device at all visits, except one or two (at presentation or at the final visit before healing or withdrawal) and poor adherence to offloading was reporting in two patients (9%), one being in a wheelchair.

Wound healing outcomes

By the end of the 20-week study period, wound closure was achieved in 16 patients (70%), with 81% of these closures occurring by the sixth week of treatment. The three latest wound closures appear to have been affected by episodes of wound infection, suspected wound infection, and a large wound area at initial visit. While half of the patients with

PAD (50%, 5/10 patients) healed by week 20 with a median time to heal of 43 days (range 14 to 114 days), the highest wound closure rate was unsurprisingly reached in patients without PAD (85%, 11/13 patients) (*Figure 1*) with a median time to heal of 24 days (range 7 to 134 days). Similarly, higher wound closure rate and shorter time to heal were achieved in patients with a Sinbad score of 1 than in patients with a Sinbad score ≥2 (*Table 4*). Of the unhealed patients, two (9%) were followed up to week 20 with a relative wound area reduction of 99% and 19%, respectively, and five (22%) withdrew before the end of the follow-up period. The reasons for these study withdrawals included the referral of two patients to the A&E department due to wound infection, prolonged treatment discontinuation in two patients (due to shared care and the patient's holiday), and loss of follow-up for one patient when he left the area.

Table 4. Wound healing outcomes depending on SINBAD scores at presentation.

Sinbad score at presentation [on a 0-6 scale]	Wound closure rate by week 20, in %	Time to heal in days, median value (range)
1 (*n*=8)	88%	16 (7–45)
2 or 3 (*n*=15)	60%	43 (30–134)

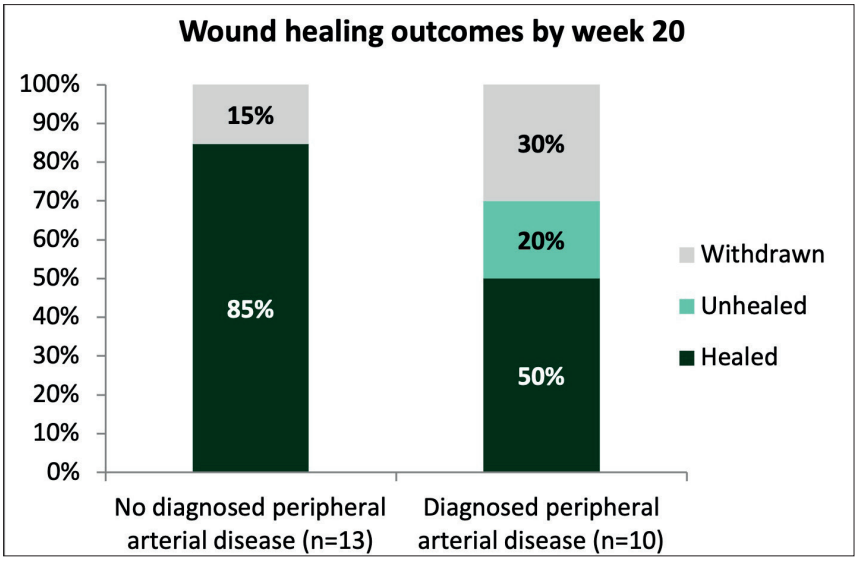

Figure 1. Wound healing outcomes by week 20 depending on the diagnosis of peripheral arterial disease at presentation.

Wound infection

In total, wound infections were reported in five patients (22%) at 13 visits. These events were often associated with high levels of exudate (8/13), increased levels of exudate (5/13), sudden wound deterioration or enlargement (7/13), and/or periwound erythema (5/13), but none was associated with any pain. The evaluated dressing was temporary replaced by an antimicrobial dressing at 15 visits, two patients (9%) received systemic antibiotics, and two patients (9%) were referred to the A&E department and, therefore, withdrew the study.

A temporary switch to antimicrobial dressings was also reported in two additional patients (at two consecutive visits for each) when presenting an enlargement or deepening of their wound and an increase level of exudate (but no definitive diagnosis of wound infection established yet).

Patients with PAD were more frequently diagnosed with wound infection than others (30% vs 17%) and were also more frequently subjected to a change to antimicrobial dressings than others (50% vs 17%).

Pain assessment

Pain data were measured using a 10-point scale, with higher scores indicating higher levels of pain. Almost all patients (*n*=19; 83%) reported no pain (score = 0) at all of their wound observations. Four patients reported positive pain scores over the duration of the study:

- A 68-year-old man, with neuropathy, PAD and a DFU located on the sole rated his pain with a score of 8 points at presentation and week 2 and then zero at the following visit, when his wound healed
- A 63 year-old women, with neuropathy and a DFU located on the sole rated her pain with a score of 6 points at presentation, 4 points at week 2 and then zero at the final visit, when her wound healed
- A 60 year-old man with neuropathy, PAD, and a DFU located at the tip of the toe rated his pain with a score of 5 points at presentation and week 2, and then zero until week 20
- An 85 year-old man, with neuropathy, PAD and a DFU located on the tip of the toe rated his pain with a score of 3 at presentation, and then zero at week 2 and week 4, after which he withdrew the study.

Change in patients' HRQoL

During the course of the study, the overall HRQoL of the patients improved with an increase of the mean EQ-VAS score from 60.2 (SD 21.9) at baseline to 70.0 (SD23.9) at the final visit (a 10-point difference). The highest gains of EQ-VAS scores (20 to 60 points) were

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Disclosure

The authors have no conflicts of interest to declare.

reported in patients whose wounds healed by week 20 and who had the lowest score at baseline (10–50).

Discussion

The results of this clinical evaluation showed that the use of UrgoStart dressings as a first-line local treatment and integral part of good standard of care was beneficial to the management of patients with a recent DFU.

Analysis of the National Diabetic Foot Care Audit (NDFA) have established that early referral to specialists (in less than 14 days) is associated with lower wound severity at presentation, a greater proportion of patients alive and ulcer-free at 3 months, fewer major amputations and hospital admissions, and shorter hospital stays within 6 months (Jeffcoate, 2020). NICE guidelines recommends prompt expert assessment of new DFUs. In the past years, early referral to specialist centres has been supported by the development of fast-track pathways by the International Diabetic Foot Care Group and D-Foot International (Meloni, 2019; 2021). Podiatrists and podiatric clinics in the UK have a major role to play on this front line to assess people at risk to develop a DFU and to ensure an appropriate management of these wounds since their onset, in compliance with latest evidence-based recommendations. Clinical evidence from the EXPLORER double-blind RCT showed that the earlier UrgoStart dressings were used in the wound healing process of the DFUs, the greater the benefits over control dressings, in terms of closure rate, healing time or cost saving (Lázaro et al, 2019; Lobmann et al, 2020; Maunoury et al, 2021). The extent of these benefits has also been confirmed in several studies conducted in real-life practice (Münter et al, 2017, Dissemond et al, 2020a; Augustin et al, 2021). Based on the robust evidence available, the NICE and several pathways recommend the use of UrgoStart dressings in standard of care to treat patients with a DFU (Meloni et al, 2019; 2021; NICE, 2019; Tickle et al, 2021).

In this evaluation, 78% of the included patients had their DFU for 1 week or less, illustrating the effectiveness of the referral system for patients with new ulcers to a specialised centre in our area.

The 70% wound closure rate and 34 days median time-to-heal achieved were not only consistent with the previous evidence on these dressings (Münter et al, 2017; Lázaro et al, 2019; Dissemond et al, 2020; Augustin et al, 2021; Tickle et al, 2021; Meloni et al, 2022) but also meaningful in relation to the real-life data reported in patients with similar profile, wound characteristics and referral timeline in the UK (NHS Digital, 2022). Consistently with the literature (Ince et al, 2008; Armstrong et al, 2011), the best outcomes were achieved in the less severe DFUs, while the more severe wounds, i.e. the wounds with higher SINBAD scores, PAD, and large area at baseline were associated with more modest healing outcomes, although the wound closure rate and time-to-heal were still considerable in these patients despite their bad prognosis.

In this clinical study, the presence of PAD was detected in 43% of the patients. A recent vascular assessment (<3 months) was available or performed in accordance with NICE and International Working Group on the Diabetic Foot (IWGDF) guidelines (Hinchliffe et al, 2019; NICE, 2019a). For the vascular assessments it required the use of different methods as for example ankle-brachial index could not be done in a patient with oedema, and toe-brachial index was not possible in some amputated patients. PAD is known to be associated with higher risk of DFU, lower probability of healing, longer healing times, higher probability of recurrence, greater risks of wound infection, minor and major amputations, and higher mortality (Armstrong et al, 2011). During the course of this study, in this subgroup of patients with PAD, wound closure was reported in 50%, wound infection in 30%, a temporary switch to antimicrobial dressings was deemed necessary in 50% and one patient required referral to the A&E, confirming the high risk of complications, particularly of local infection, in these patients and the importance to have a closer monitoring and enhanced infection control measures for these patients.

In the global cohort, wound infection was reported in 22% of the patients and antimicrobial dressings were temporarily prescribed to 31%. These wound infections and suspicions of wound infection were strongly associated with later wound closure, slow healing and early withdrawals. According to national and international guidelines, a local wound infection of DFU is defined by the presence of at least two of the following signs: local swelling or induration, erythema, local tenderness or pain, local warmth, and purulent discharge (NICE, 2019a;

Lipsky et al, 2020). These complications are very frequent and challenging. The absence of certain signs such as pain due to neuropathy and a weakened host immune response may delay their identification, while the localisation of the wounds, their proximity with bone structure and the presence of PAD increase the risk of rapid deterioration and limit the availability of antibiotics to the site of infection (Edmonds, 2021). It is estimated that approximately 20% of diabetic foot infection progress to moderate or severe infection (Senneville, 2020), and diabetic foot infection remain the most frequent diabetic complication requiring hospitalisation and the most common precipitating event leading to lower extremity amputation in people with diabetes (Lipsky et al, 2020). In this context, identification of patients at risk of infection, rapid closure of the wounds, early diagnosis of wound infection and timely initiation of appropriate treatment can be limb-saving.

Debridement is another key element of standard of care in the management of DFU (Schaper et al, 2020). In this study, wound debridement was performed in all patients at each visit in order to remove callus that contributes to pressure, free the wound edge and remove slough and non-viable, necrotic tissue that can delay the healing process and facilitate infection. Dressings with strong desloughing capacity like polyabsorbent fibres, which superior desloughing capacity had been demonstrated in a RCT versus hydrofiber (Meaume et al, 2014), can be a real asset and time-saver for wounds that are covered with sloughy tissue. After removal of the sloughy tissue, which may reappear during the healing process, this dressing is still beneficial on the granulation phase and until healing. However, in our centre, we tended to switch to the contact layer as the level of exudate was also rapidly decreasing. As maceration can also affect the migration of the epithelialised cells from the wound edge, it appears important to appropriately choose a primary dressing adapted to the characteristics of each wound, in close contact with the wound bed, and, when necessary, to use a secondary dressing to support the exudate management.

In our centre, the dressings were changed only once or twice a week, but mostly weekly. Some patients were able to do their dressing changes by themself between their visit to the podiatric clinic or the district community nurse visits, but it was rare. This is our standard practice within Provide CIC as we are only commissioned to see patients once per week. Additionally, all of the dressings that we use including the UrgoStart treatment range are licenced to stay in place for up to 7 days and they work effectively throughout that timeframe. Of course, if patients have very high levels of exudate or deteriorating infection, then we arrange for shared care with practice or community nurses, to ensure a closer follow-up and review frequency of dressing changes.

Dialogue with the patient is also essential in the management of DFU. The severity of the condition should be explained to patients, their discomfort and pain assessed and managed, and their expectations discussed. The closure of the wound requires several weeks to months, and it is important that the patients adhere to their treatment, especially to pressure relief measures. In this study, all the patients were provided offloading devices, although of different types, in order to take into account their needs and daily constraints and facilitate their adherence to the offloading therapy.

The analysis of the EQ-VAS scores at the initial and final visits showed that the rapid wound closure helped to improve the overall quality of life of the patients, which is consistent with previous real-world data on these dressings reporting such improvement (Augustin et al, 2021; Tickle et al, 2021). Finally, addressing the constraints of the patient's daily life can also include the organisation of shared care, when needed, and take the time to strengthen the connections with community and practice nurses for better compliance with the care plan and optimise the clinical outcomes for the patients. Developing better connections with other healthcare colleagues who share patient care with you is vital to ensure continuity of care, the prompt identification of deterioration and opening better communication channels to discuss better suited options for patients.

Conclusion

In conclusion, implementing new strategies, changing structured pathways or standard of care can be challenging but also very rewarding (Bullen, 2020). The results of this service evaluation support the use of UrgoStart dressings as first-line local treatment and part of the standard of care for the management of patients with a DFU. From a clinician's point of view, the benefits include high closure rate and short healing times and, therefore, released time for care,

reduced variability in dressings applied by the different caregivers involved, and increased clinical confidence. Patients experienced increased confidence, reduced pain and discomfort, more ulcer-free days and an improved quality of life. ■

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