Nano-oligosaccharide factor (sucrose octasulfate dressing based on technology lipido-colloid, TLC-NOSF) in the management of diabetes related diabetic foot ulcers

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The ever-increasing numbers of people suffering from diabetes mellitus is alarming. This intensification has also seen an upsurge in diabetes related lower extremity complications. This poses a rise in the burden on health care professionals who treat these wounds, an increase in financial burdens to health care systems, as well as a decrease in the health-related quality of life of the sufferers. An evidence-based standard of care in the management of these patients, such as recommendations by the International Working Group on the Diabetic Foot (IWGDF), is of utmost importance. Local wound therapy in the form of dressings, has been found to be beneficial in improving wound healing rates. Nano-oligosaccharide factor (sucrose octasulfate dressing based on technology lipido-colloid, TLC-NOSF) is one such treatment that is backed by evidence including double-blind randomised control trials and recommendations by international bodies such as the IWGDF. This paper portrays three cases from Harbin City, China, where the TLC-NOSF dressing was evaluated in patients suffering from diabetic foot ulcers.

Keywords: diabetic foot ulcers, TLC-NOSF, wound healing

Diabetes mellitus (DM) is considered as one of the main global public health issues which proves to be a substantial burden on public health and socioeconomic development [1]. According to the International Diabetes Federation (IDF) estimate in 2021, approximately 537 million adults (20-79 years) are living with diabetes and the total number of people living with diabetes is projected to rise to 643 million by 2030 and 783 million by 2045 [2]. In a 2016 report, The World Health Organization (WHO) suggested that ‘Rate of diabetes in China is “explosive”’, where ‘almost 10% of all adults in China – about 110 million people – currently live with diabetes’ [3].

Additionally, the increase in the pervasiveness of diabetes leads to an increase in the associated complications of the disease, amongst which foot ulcers and lower extremity amputations are notable [4]. Diabetic foot ulcers (DFU) have been described as the main complications of diabetes mellitus major and a foremost source of morbidity and mortality among diabetes mellitus patients with devastating complications [4,5]. The International Working Group on the Diabetic Foot (IWGDF) state that, globally, every 20 seconds a leg is amputated due to DM and, the lifetime incidence of DFU in patients with diabetes is between 15-20% with the possibility of recurrence being between 30-40% within the first year [6,7]. Twelve-point-nine million to 49.0 million persons worldwide have a history of foot ulceration [8]. Moreover, the risk of death at five years for a patient with a diabetic foot ulcer is stated to be 2.5 times as high as the risk for a patient with diabetes who does not have a foot ulcer [9], and mortality after diabetes-related amputation surpasses 70% at 5 years [10].

However, the application of appropriate therapy, including surgical debridement, off-loading of pressure, prevention and management infection, and, where necessary, vascular reconstruction, DFU may heal in many patients, preventing amputation [11,12].

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The IWGDF Practical Guidelines [13] describe the basic principles of prevention and management of diabetic foot disease and consist of evidence-based principles of prevention of foot ulcers in persons with diabetes, offloading foot ulcers in persons with diabetes, diagnosis, prognosis and management of peripheral artery disease in patients with a foot ulcer and diabetes, diagnosis and treatment of foot infection in persons with diabetes, interventions to enhance healing of foot ulcers in persons with diabetes, and classification of diabetic foot ulcers. It is interesting to note, that in the interventions, the IWGDF recommends the consideration of the use of sucrose-octasulfate impregnated dressings as an adjunctive treatment, in addition to best standard of care, in non-infected, neuro-ischaemic diabetic foot ulcers. The recommendation was based on the results obtained in a large double blind multicentre randomised control trial (Explorer Study) [14], which was suggested by the IWGDF as having a low risk of bias.

**Nano-oligosaccharide factor (sucrose octasulfate dressing based on technology lipido-colloid, TLC-NOSF)**

The sucrose octasulfate dressing (UrgoStart® - Laboratoires Urgo, France) based, on technology lipido-colloid (TLC) and nano-oligosaccharide factor (NOSF) contact layer or healing matrix (TLC-NOSF) forms a gel that soaks up wound exudate and decreases levels of matrix metalloproteinases (MMPs) on the wound surface, thus promoting wound repair and shortening time to wound healing [15]. It has also been shown that use of the TLC-NOSF dressing when treating neur-ischaemic DFUs improves the transcutaneous oxygen at site [16]. A recent literature review regarding TLC-NOSF [17], identified a total of 21 publications of different levels, ranging from double-blind randomised control trials to case reports, involving over 12,000 patients. The conclusion of this review states that:

“All the evidence provided suggests that these dressings provide clinicians with an evidence-based option for the management of chronic wounds; that the TLC-NOSF dressings are beneficial in promoting the healing process, reducing healing times, enhancing patients’ HRQoL, and in allowing a more cost-effective procedure”.

**Method**

The authors face challenges on a daily basis when managing patients with DM related lower limb ulcers. Although an evidence-based approach regarding standard of care is implemented in all the centres, these clinicians have shown an interest to evaluate interventions that can assist in reducing healing times for their patients. In review of the recommendations by the IWGDF as well as the robust clinical evidence available, the authors aimed at evaluating the TLC-NOSF contact layer in the management of their patients. The evaluation was conducted by adding the TLC-NOSF wound contact layer to the established standard of care employed by them in their practice.

**Results**

The three cases presented were conducted between March and August 2021 and all went on to healing after application of the evaluated wound contact layer. The clinician feedback regarding the dressing was that it is easy to apply and conforms well to the wound bed. Patient feedback was also positive in all three cases.

This is an initial evaluation of the dressing that has been previously assessed by means of other cases already published by other clinicians from China, for example, a case series published in 2021 [18], but also from other parts of the globe, that includes clinician testimonials from the United Kingdom [19]. Further evaluation of outcomes of DFU with the management of TLC-NOSF are necessary for the authors to include this dressing as part of their stand of wound care in the management of their DFU patients.

**Case 1**

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A 65-year-old-female, recently diagnosed with Type 2 diabetic, presented with a painful two-week-old blister and ensuing 2.0cm x 2.0cm ulcer that appeared on the lateral aspect of the left great toe after minor trauma which was not being treated (Figure 1A). On examination, she had bilateral lower limb swelling and signs of decreased left lower limb perfusion (sparse fine hair on the left toe and thickened toenails, while the dorsalis pedis and posterior tibial artery pulses were difficult to palpate).
A color-Doppler sonography of both lower limbs was performed which showed uneven intimal thickenings and granular calcified plaques formation in both lower limb arteries; reflux in valve of the left femoral saphenous valve (moderate), and bilateral soft tissue thickening in the lower legs.

She was admitted on March 18th for the management of surrounding erythema and swelling and administration of systemic antibiotics.

Initially, debridement was conducted, wound flushed with saline 0.9% and a non-adherent technology lipidocolloid silver dressing was applied to manage the local infection. After two days the wound bed had improved and the TLC-NOSF contact layer dressing was applied (Figure 1B). Dressing was changed on alternate days. Within two dressing changes of the TLC-NOSF (March 23rd), granulation tissue was visible on the entire wound bed and size of the wound started to decrease (1.5cm x 0.8cm). The same management was continued, and the wound was closed by the 29th March, after only 5 alternate day dressing changes with TLC-NOSF.

Further management of the lower limb ischemia will be followed by the vascular team.
Case 2

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A 73-year-old male patient, known Type 2 diabetic for the past 5 years, presented with an ulcer on the upper heel of the posterior tibia of the right lower limb right lower that was mostly covered with eschar (Figure 2A) that had been present for six months.

He was previously admitted for systematic antibiotics and thereafter the wound was self-managed with traditional dressings. The wound continued to deteriorate and become painful (Figure 2A), and, therefore, he was referred on May 6th for further management. The wound measured 5.0cm×4.0cm. On examination, the dorsalis pedis and posterior tibial arteries of both lower feet were barely palpable. He was admitted on March 18th for the management of surrounding erythema and swelling and administration of systemic antibiotics. Initially, debridement was conducted (Figure 2B), wound flushed with saline 0.9% and TLC-NOSF contact layer applied. Dressing was changed on alternate days. By June 25th, the wound bed was looking healthier, and the wound size had decreased (Figure 2C).
The same management was continued by the family at home, and by July 11th the wound was almost completely healed (Figure 2D) and completely healed in the following weeks.

Further management of the lower limb ischemia will be followed by the vascular team.

**Case 3**

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A 65-year-old male, known Type 2 diabetes for 26 years, sustained trauma on his right foot which went unnoticed initially due to peripheral neuropathy, with ensuing swelling and ulceration around the 2nd toe. The patient self-managed at home with traditional methods. Within two months the wound worsened drastically, and the 2nd toe became gangrenous. He was refereed and an amputation of the second toe of the right foot was conducted. He was discharged after his condition improved with systematic treatment.

However, no improvement was noted, and he was again refereed with a deep right foot ulcer at the junction of the first and second metatarsophalangeal joints, with a large amount of purulent exudate and significant pain (Figure 3A). The wound was debrided and cleaned with 0.9% saline and TLC-NOSF contact layer was applied topically and changed on alternate days thereafter. Systemic antibiotics were initiated. By July 25th, the wound was looking healthier, and the wound size had decreased considerably (Figure 3B). The wound continued to progress. By August 10th the wound was progressing to healing (Figure 3C) and the wound was closed by August 29th (Figure 3D).
Conclusion

That diabetes related lower extremity complications pose a substantial clinical and economic burden to health systems around the world as well as having devastating effects on patients and their families, is very well known [20]. The overall rates of diabetes related lower extremity complications have increased by 15.9% between 1990 and 2016, with the largest increases being recorded in Southern Sub-Saharan Africa, South Asia, and Southeast Asia [21]. Regardless of the cause of the diabetes related lower extremity complication, including DFU, it is essential that correct diagnosis and prompt evidence-based treatment are implemented promptly. Wound healing is a complex process, and even more so in people with diabetes. It is of utmost importance that holistic management is applied for these patients and, moreover, the importance of local wound care by evidence-based dressings has been given more importance in recent years. This has been highlighted in many publications, including recent studies, such as the Explorer RCT [14] and endorsements by the recommendations of IWGDF[13] and the National Institute for Health and Care Excellence (United Kingdom) [22].

The cases discussed represent a small cohort of patients suffering from DFUs which were managed under real-life conditions in Harbin (China). The results obtained with the local management of TLC-NOSF, characterise a fast improvement in the wound-healing process through wound surface area reduction and time to wound healing. The results of these three clinical cases are consistent with other findings achieved in other publications which were portrayed in the systematic review published by Nair et al in 2021 [17], substantiating that TLC-NOSF provides a tangible clinical benefit for the management of chronic wounds, including DFU, and can be positively considered as an evidence-based, viable decision in the management of such chronic wounds in conjunction with an evidence-based standard of wound care.

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The views and opinions expressed in this article are those of the authors and do not necessarily reflect any official policy and are not an official position of the institutions.
Disclosure of relationships

EG is employed by Urgo Medical as the International Medical Director for Australasia, Middle East, and South Africa. The TLC-NOSF discussed in this review is a patented dressing (Laboratoires Urgo, France). All other authors do not have any conflicts of interest.

References


