Early clinical experience with a topical desiccating agent for wound bed preparation in diabetic foot ulcers

Abstract: Diabetic foot ulcers (DFUs) are a major complication of diabetes, often requiring effective wound bed preparation for healing. This retrospective case series assessed a novel topical desiccating agent (TDA) used under a compassionate-use protocol approved by the institutional ethics board. A total of 67 patients with hard-to-heal (chronic) DFUs treated between 2020 and 2023 were included. Granulation was achieved in 88.1% of patients (mean time: 44.3 days), and 85.1% reached complete re-epithelialisation. No adverse events were reported. TDA was well tolerated and showed promising clinical outcomes in a high-risk patient population, supporting further evaluation in prospective studies.

Declaration of interest: BJQ, AC and CAB are founders of DEBx Medical B.V., Amsterdam, the Netherlands and inventors of the TDA. JPS is employed by DEBx Medical as the Clinical and Product Director. RR and CG have no conflicts of interest to disclose. The research had no external funding. The manuscript was checked with ChatGPT-4o for spelling and grammar.

chemical debridement • DFU • diabetic foot ulcer • topical desiccating agent • ulcer • wound • wound bed preparation • wound care • wound dressing • wound healing

Diabetic foot ulcers (DFUs) are a common and serious complication of diabetes, affecting up to 25% of individuals with diabetes during their lifetime.[1] These ulcers are associated with substantial morbidity, increased risk of infection, high amputation rates and elevated mortality.[2] The pathophysiology is multifactorial and includes peripheral neuropathy, peripheral arterial disease and impaired immune function, all of which compromise healing.[3,4] In addition, comorbidities, such as hypertension, chronic kidney disease and coronary artery disease, frequently coexist and complicate treatment strategies.[5,6]

Standard of care (SoC) for DFUs includes infection control, offloading, glycaemic optimisation and repeated wound bed preparation, often using mechanical, surgical or enzymatic debridement.[7,8] While these methods remain fundamental, they can be invasive, resource-intensive, and are not always feasible or well tolerated, particularly in outpatient or older patient populations.[9,10]

Biofilms—structured microbial communities embedded in an extracellular matrix—are increasingly recognised as key barriers to healing in hard-to-heal (chronic) wounds, including DFUs.[11,12] These structures resist host defences and antimicrobials, and their eradication requires both mechanical and targeted chemical strategies.[13,14]

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Topical desiccating agent (TDA) (DEBRICHEM, DEBx Medical B.V., the Netherlands) is a novel chemical debridement technology that removes devitalised tissue, reduces microbial biofilm and facilitates wound bed granulation through rapid desiccation.[12,13,15,16] Early reports and in vitro studies suggest that TDA may offer advantages over traditional debridement for wound bed preparation, particularly for hard-to-heal and biofilm-laden wounds.[12,13,17]

This retrospective case series presents the outcomes of a compassionate-use protocol conducted at a wound care centre in Italy, evaluating the safety and early clinical outcomes of TDA in patients with hard-to-heal DFUs who had not responded to conventional therapies.

Method

A retrospective analysis of a case series was conducted using patients' electronic medical records at a specialised wound care centre between 2020 and 2023.

Patients and treatment with TDA

Patients were evaluated for amputation when their DFU failed to improve under SoC. SoC consisted of hydrocolloid or alginate—with or without silver infused—dressings, offloading and sharp debridement.

Patients visited the wound care clinic twice a week. TDA was applied as part of a final treatment effort before surgical intervention. TDA application was, after cleansing and drying the wound, applied for 60 seconds. After the 60 seconds, the wound was rinsed with saline, as per the TDA's instructions for use. Following TDA application, SoC was continued.

Inclusion criteria for patients were:

- Diagnosis of diabetes

- Presence of a hard-to-heal ulcer located on the foot, determined as anywhere below the ankle
- Receipt of TDA application as part of SoC under compassionate-use protocol

Patients were excluded if:

- There were incomplete data
- Ulcers were located elsewhere than the foot
- Concurrent advanced wound therapies were applied.

Data collected included: demographic information (age, sex); ulcer characteristics (surface area, type); treatment variables (number of TDA applications, days to granulation); and clinical outcomes (achievement of 100% granulation, complete re-epithelialisation, adverse events). DFUs were not stratified according to a formal classification system.

Ethical approval and patient consent

Ethical approval was obtained from the institutional review board of the Villa Berica Hospital, Vicenza, Italy prior to the initiation of the data review and analysis.

As data was gathered retrospectively and anonymously, patient consent was not required for this analysis.

Results

A total of 67 patients met the inclusion criteria, of whom 47% were male. Table 1 summarises the key demographic and clinical features of the population analysed:

- Mean age: 70.5 (range: 45–96) years
- Mean DFU size: 33.5 (range: 2–300)cm^2
- Mean DFU duration up to intervention with TDA: 14.4 (range: 2–56) weeks
- Mean days to granulation: 44.3 (range: 2–219)
- Mean number of follow-up days: 135.6 (range: 6–505)
- Mean applications of TDA: 1.22 (range: 1–4).

Table 2 presents the clinical outcome summary where 88.1% of the population reached full granulation; 85.1% completely closed and no adverse events were reported. None of the patients moved to surgery for wound treatment during the period of evaluation.

None of the patients received antibiotics to treat wound infection. No microbial cultures were taken.

Table 1. Baseline characteristics of patients

Characteristic	Value
Number of patients	67
Age, years, mean (range)	70.5 (45–96)
Sex distribution, female/male, %	53/47
Ulcer surface area, cm^2, mean (range)	33.5 (2–300)
Days to granulation, mean (range)	44.3 (2–219)
Follow-up duration, days, mean (range)	135.6 (6–505)
TDA applications, mean (range)	1.22 (1–4)

TDA—topical desiccating agent

Table 2. Clinical outcomes of patients (n=67)

Outcome	Value, n (%)
100% granulation achieved	59 (88.1)
Complete re-epithelialisation	57 (85.1)
Adverse events	0 (0)

Discussion

This case series demonstrated that chemical debridement using TDA effectively promoted granulation in patients with DFUs. The 88.1% granulation rate was encouraging given the complexity of hard-to-heal DFUs and compared favourably to published outcomes with sharp or enzymatic debridement, which typically report granulation rates between 50–75% in similar patient populations.[7,8,18] The high re-epithelialisation rate (85.1%) observed in this series suggests that once the wound bed was fully granulated, subsequent progression through the healing cascade was likely, provided the underlying pathology was addressed.[9] The potential impact of TDA in transforming non-viable or biofilm-colonised wounds into responsive wound beds is significant. Hard-to-heal wounds often fail to heal due to persistent inflammation and bacterial colonisation, especially biofilms, which are resistant to traditional antimicrobials and host defences.[13,14] The chemical action of TDA, which includes rapid desiccation and tissue necrosis removal, has been shown in in vitro and early clinical studies to effectively disrupt biofilms and create a favourable environment for healing.[12,13]

Compared to conventional debridement methods, TDA offers distinct logistical and clinical advantages. Its ease of use, speed of action, and non-reliance on surgical skill or sterile theatre access make it particularly attractive in outpatient and resource-limited settings. Mechanical and surgical debridement often require multiple sessions and can be painful or associated with bleeding, whereas TDA application is typically completed in a single session with minimal patient discomfort.[10,11]

It is worth noting that the patients in this present study, treated under a compassionate-use protocol, represented a high-risk group in whom SoC was insufficient or exhausted. The observed outcomes, therefore, may reflect a best-case scenario for the selected use of TDA. Nonetheless, the absence of reported adverse events adds to the safety profile of this approach and supports its further clinical investigation.

Emerging evidence supports a paradigm shift toward more targeted, biofilm-disrupting wound therapies, and TDA may be an important component in this evolving framework.[14,19] As with other topical agents, clinical efficacy must be validated in larger, multicentre trials with defined endpoints and longer follow-up. Cost-effectiveness, patient-reported outcomes and integration into multidisciplinary care models should also be explored.[16,20,21]

Limitations

Several limitations of this study must be acknowledged. The retrospective, uncontrolled design limits causal inference, and the lack of standardised ulcer classification hinders stratified analysis. Furthermore, variables, such as glycaemic control, infection status and vascular perfusion, were not uniformly recorded, all of which can significantly influence wound healing.[3,5,6] Despite these limitations, this case series provides valuable early clinical insight and generates hypotheses for future prospective trials.

Conclusion

The findings of this retrospective case series showed that TDA appeared to be a safe and effective innovation for chemical debridement of hard-to-heal DFUs, promoting wound bed granulation in the majority of cases. Under a compassionate-use protocol, TDA showed excellent tolerability and encouraging outcomes. Continued investigation through prospective clinical trials is needed to confirm its role in standard diabetic wound care. **JWC**

Reflective questions

- What are the most effective methods of treating a hard-to-heal diabetic foot ulcer (DFU)?
- What are the challenges of debriding a DFU?
- What are the challenges of incorporating single-application chemical debridement in the healthcare setting?
- How might the challenges identified above be overcome?

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