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A debriding gel in the treatment of post-trauma, non-healing lesions

Michel HE Hermans

Abstract

Background: Topical desiccation agent (TDA) is an acidic species in a gel with a potent hygroscopic action. When in contact with (water in) biofilm and necrosis, rapid desiccation occurs, with the dehydrated tissues typically sloughing off in 1-3 days. This allows for quick

granulation tissue formation which is an essential step for healing by secondary intention or as wound bed preparation for grafting. Methods: A series of nine non-healing, post-trauma lesions on the lower leg were treated with TDA, followed by treatment of the lesion with vaseline gauze. Results: The average age of the patients was 77.0 years and the lesions had been in existence for 5.6 months on average. The average size of the lesion was 15.9 cm^2. Complete granulation of all lesions was reached in an average of 34.1 days while the time to complete reepithelialization averaged, 69.8 days (data from one outlier removed). There were no adverse events. Conclusion: These data suggest TDA treatment is an effective and efficient way to debride lesions, and to prepare them for healing by secondary intention or for grafting.

Keywords: Debridement, desiccation, granulation, non-healing, post-trauma lesion

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Introduction

It is well recognized that lesions such as venous, diabetic and arterial ulcers are a major burden to patients and society. Patients typically suffer for (sometimes very) long periods [1,2], since the lesions are difficult to heal, due to their chronicity [3-6]. They also have a major socioeconomic impact with high costs to the insurance system and overall society [7], with the highest costs associated with inpatient care, particularly hospital admissions and surgical procedures [8]. For example, the cost of treatment of diabetic foot ulcers for US Medicare is between 9 and 13 US$ billion/year (2019 data) [7], while venous leg ulcers are responsible for an increase of $6,391 per patient for the US Medicare system (2014 data) [8].

Certain (skin) trauma may also result in non-healing, which, among other factors, is related to the type and location of the lesion, aged and fragile skin, the presence of exposed structure such as bone or tendon, and/or infection [9-11]. These lesions are less well defined, and it is difficult to find data on their prevalence, but it is safe to assume that

certain wounds (such as pretibial lacerations and skin loss over the Achilles tendon (Figure 1)), often have healing problems. This is especially true in the elderly: among other factors in this part of the population senescence occurs more frequently, particularly in the dermal extracellular matrix, which is progressively damaged. This affects the normal organization of the skin as well as its capability for healing [12]. There is typically also a decrease in (local and systemic) perfusion and in the ability to ward off infection [13].

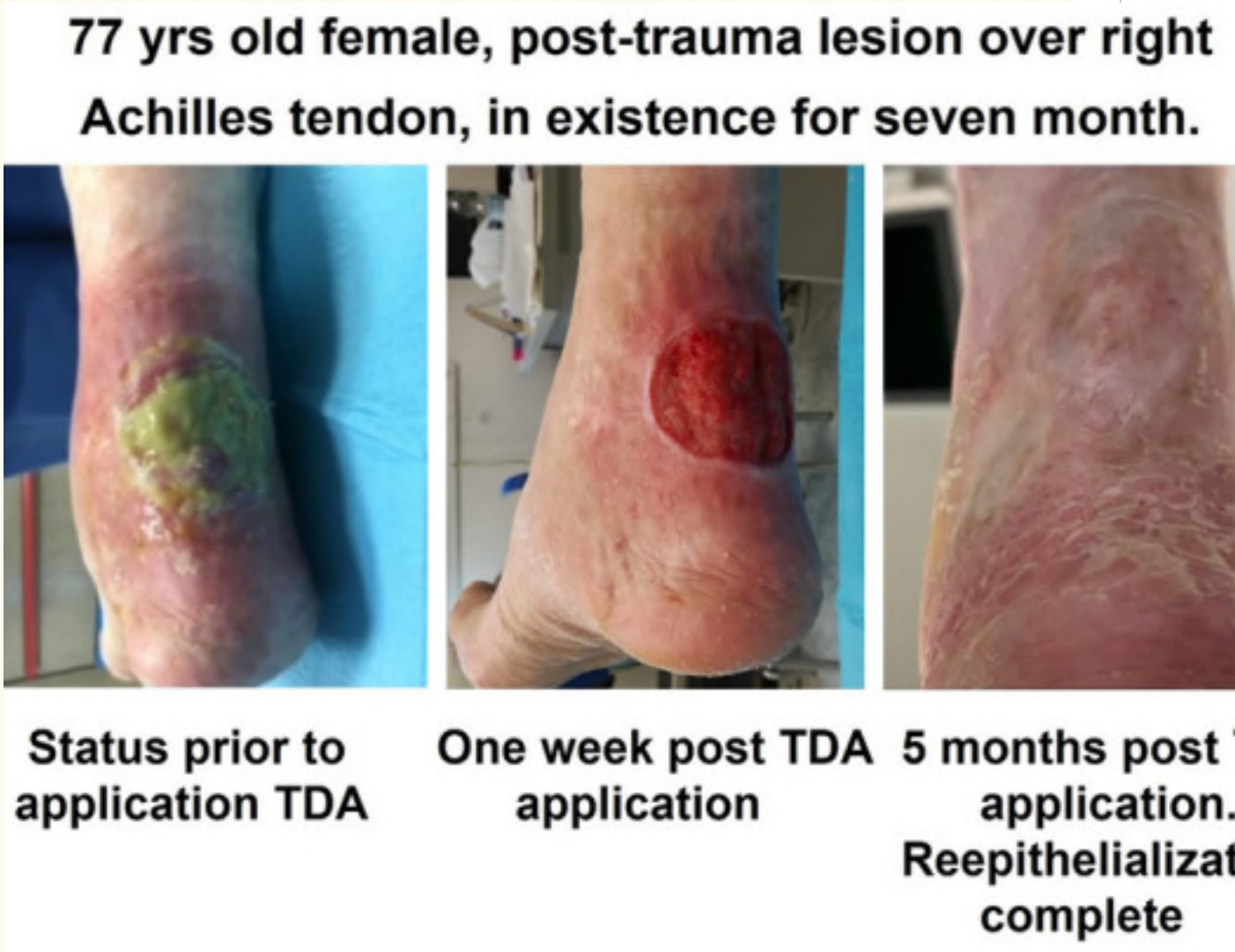

Figure 1

Example of a typical non-healing, post-trauma lesion.

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Ulcers and other non-healing lesions typically are covered with necrosis and biofilm and these have a negative impact on the healing process [14-22]. Thus, removal of these detrimental factors is an essential step in getting wounds or ulcers to heal [23], and it is reflected in different treatment modalities and protocols [16,24].

Regular and rigorous debridement is the preferred way of removing biofilm and necrosis [25].

Among the different ways of debridement, surgery is generally seen as the fastest and most effective therapy [26,27], but it requires specific expertise and settings [28,29] and is relatively expensive [27].

A new compound, topical desiccation agent (TDA (Debrichem. DEBx Medical, BV. Rotterdan, the Netherlands)) contains methane sulfonic acid in a gel.

When TDA comes in contact with water its dissociation produces an amount of energy of the order of 1500 KJ/mol, which is powerful enough to destroy virtually all biochemical bonds in the biofilm and the necrosis. This reaction occurs very rapidly, and typically a one-time application suffices. Thus, TDA may serve as an alternative to surgical debridement.

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Material and methods

TDA has a strong hygroscopic action [30]. When in contact with (water in) necrosis, biofilm and other organic compounds swift desiccation occurs which, in turn, leads to dehydration and denaturation of the proteins in these compounds. The primary goal of using TDA is the elimination of biofilm and necrosis from a lesion, thus decreasing the chance of infection and “restoring” the healing process.

TDA is applied over the lesion, including 1 cm of the peri-wound skin and after 60 seconds the agent is removed by rinsing with water or saline. The short exposure period assures that the periwound skin,

with its low water content in the stratum corneum, is protected from damaging effects of the agent.

The desiccated and denatured tissues and organic compounds tend to quickly separate from the underlying tissues. This leaves the lesion prepared for the development of granulation tissue. The presence of granulation is necessary for healing by secondary intention or for closure by skin grafting.

Selection of the lesions, objectives

The cases described in this article are a subset of patients with "general" non-healing lesions, both ulcers as well as those caused by other etiologies [31]: the study is a retrospective, non-comparative analysis.

The presence of necrosis and a biofilm was an inclusion criterion for the trial: the presence of necrotic tissue was visually confirmed, and the existence of a biofilm was assumed, based on the fact that virtually all longer-existing lesions have one [32]. Additional inclusion criteria were limited and of a minimum age of 18 years and the presence of post-trauma, non-healing lesions of the lower leg or foot that had to have been in existence for four weeks or longer. No other specific inclusion and exclusion criteria were used.

TDA treatment was followed by the use of vaseline gauze: although this is certainly not the most appropriate material for wound treatment [33-35], it was chosen so that judging the results of the TDA treatment *per se* would not be influenced by the subsequent dressings used. Adjunct therapies (i.e., compression, off-loading) were used when indicated. No additional debridement procedures or techniques were used.

The analysis was approved by the ethical committee of the Villa Berica Hospital, Vicenza, Italy, in line with the declaration of Helsinki.

Assessment of the safety (by measuring product-related adverse events) and efficacy of a one-time TDA application was the primary

objective of the project. Efficacy was measured by visual assessment over time of the percentage of the lesion covered with granulation tissue: this, of course is an indirect but reliable way of testing the removal of biofilm and necrosis since the development of granulation is seriously hampered, if not impossible, when these detrimental influences are present.

Time to complete reepithelialization was not an official endpoint in this analysis but, where possible, patients were followed until reepithelialization was complete.

Demographics

From August 2018 through September 2019 nine lesions in nine patients qualified for participation in this analysis. Six patients (66.6%) were male. The average age of the patients was 77.0 years (range: 39-89) (Figure 2). Two patients were obese (BMI: ≥ 30.0) and one was underweight (BMI: ≤ 18.5). All lesions were located on the lower leg (left leg: four lesions, 44.4%). The average size of the lesion was 15.9 cm^2 (range: 2-40). The lesions had been in existence for 5.6 months on average, with a minimum of 2.0 months. Three lesions were 12 months or older (Figure 2).

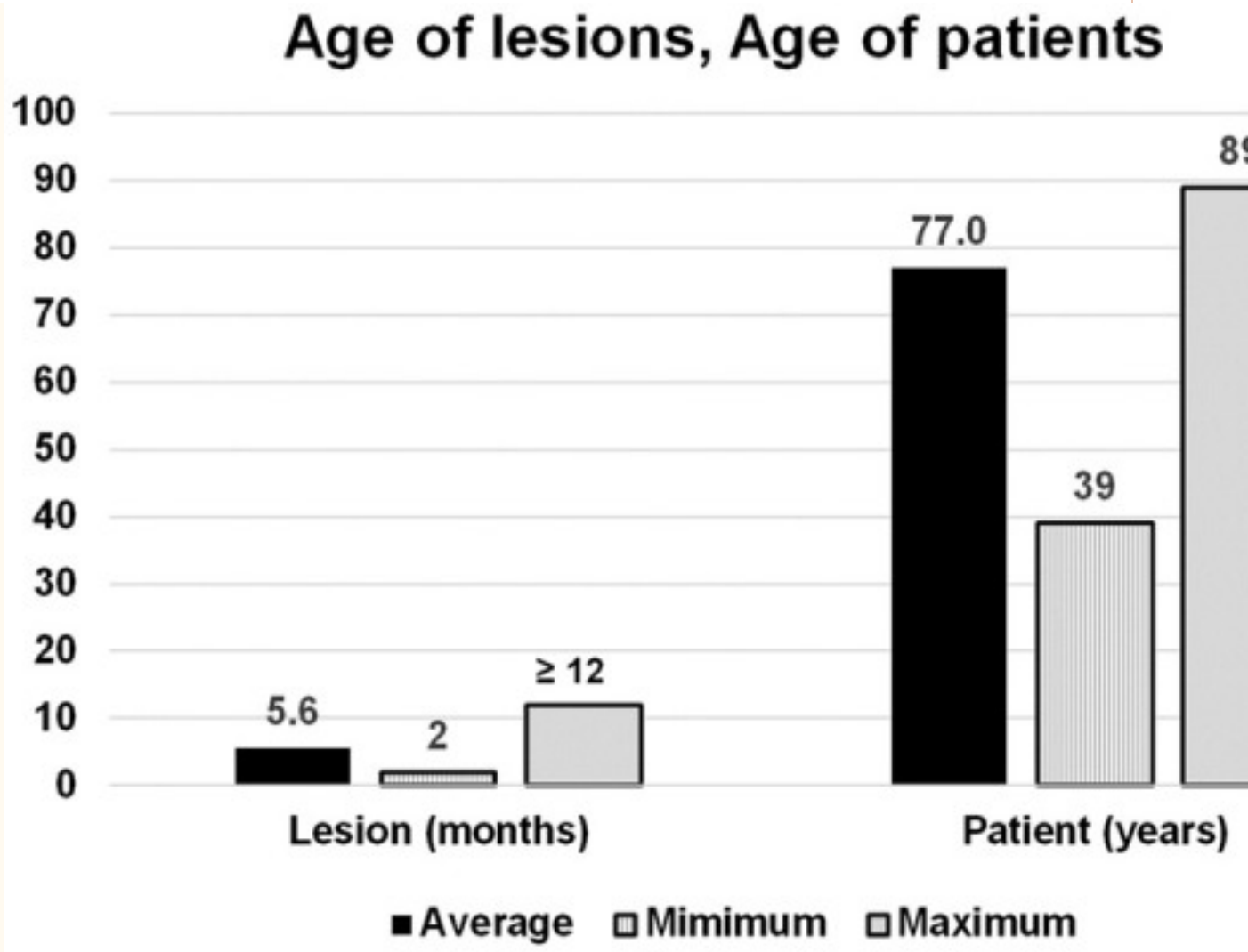

Figure 2

The age of the lesions as well as the age of the patients.

All lesions had been treated with several different therapies prior to the application of TDA, but since many of these were difficult to trace, only those immediately prior to TDA treatment were analysed. These were moisture retentive dressings (N=3), collagenase (N=2) and silver dressings (N=3). For one lesion, the last previous treatment was not known.

Regarding comorbidities, three patients suffered from hypertension, one from rheumatoid arthritis, and in one patient the leg with the non-healing lesion was paralyzed. Two patients were using systemic

steroids. After TDA application, one patient received compression of the leg and in one patient off-loading was used.

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Results

All patients reached (visually assessed) complete granulation in, on average, 34.1 days (range: 7-72) (Figure 2). With vaseline gauze as subsequent dressing, 88.8% (eighth patients) also reached complete reepithelialization in, on average, 116.3 days (range: 20-395). One patient, who's lesion had been in existence for more than a year, was an outlier, for unidentifiable reasons. If the outlying number (395 days to complete reepithelialization) is removed, the average time to complete reepithelialization is 69.8 days (range: 20-154) (Figure 3).

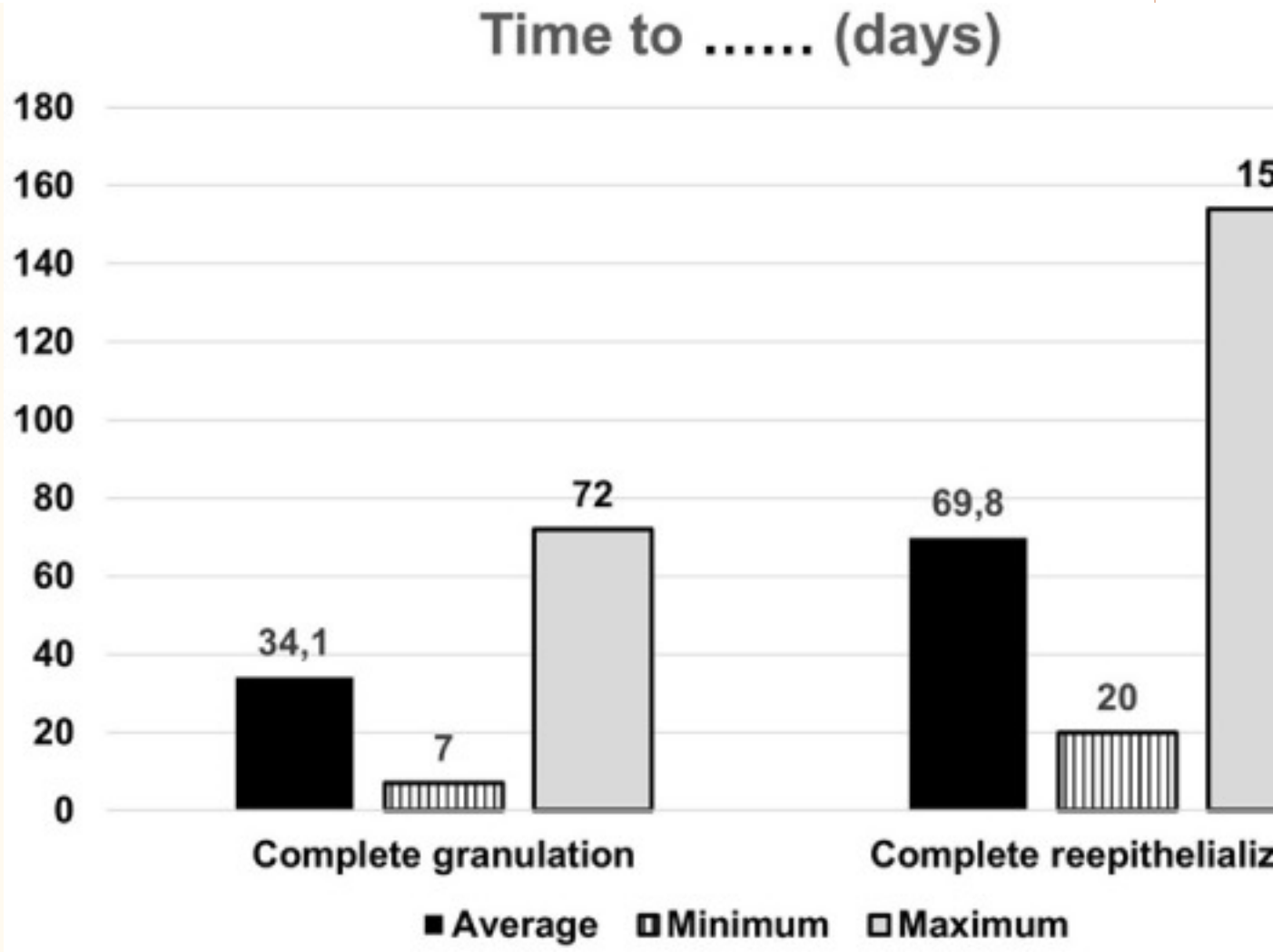

Figure 3

The time to granulation and reepithelialization.

The average number of visits to the clinic to reach complete reepithelialization was 16.9 days (range: 2-57). If the data of the 57-visits-patient are removed (this is the “outlier” patient), the average number of visits is reduced to 11.9 (range: 2-36).

All patients and their physicians considered TDA treatment better or considerably better than the previous treatment.

No adverse events related to the tested materials occurred.

Procedural pain, using a visual analogue scale (with 0 indicating no pain, 5 indicating very serious pain) was rated 2.0 on average, with a range of 0 to 5. One patient rated the pain as 5 and two patients did not suffer from any procedural pain.

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Discussion

The primary objective of the analysis of this case series was to assess the efficacy of TDA, namely to what extent removal of biofilm and necrosis wound lead to complete granulation: as mentioned this is an essential step for successful wound healing to occur [36-40], either by secondary intention or by creating a woundbed that is ready for grafting. The results on time to complete granulation and reepithelialization, 34.1 and 69.8 days, respectively, indicate that the TDA treatment is effective.

The additional primary objective was to evaluate safety, which was assessed by analyzing compound-related adverse event: none occurred.

Procedural pain was rated 2.0 on average. While pain should be prevented in the future use of TDA by using an appropriate way of anaesthesia, it should be stated that many debridement techniques are painful. This is particularly true for surgical debridement, for which TDA-usage could be an alternative since both techniques provide quick results, generally in a one-time procedure. TDA and surgical debridement also differ, however, in that TDA application does not require specific technical skills or a special setting [31]. This may help reduce the price of treatment. Indeed, in a separate analysis on UK-generated data, the use of TDA was found to be cost-effective in patients with venous leg ulcers [41].

The results obtained in this project cannot be directly compared to those on other compounds used for the same indication and outcome.

Literature on post-trauma, non-healing lesions is virtually non-existent. Typically, these lesions are called post-trauma ulcers, which in the mind of the author is incorrect [42]: physiologically, post-trauma lesions are not ulcers in the sense that ulcers are caused by an underlying etiology [42]. Because of the terminology used (post-trauma ulcer), however, in the literature post-trauma lesions are usually part of a much larger group of non-healing lesions, with diabetic foot ulcers and venous leg ulcers typically included in the same study cohort, without stratification of the different etiologies.

We were also not able to find literature on treatment of skin lesions where debriding and subsequent complete granulation were the primary study objectives.

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Limitations

The data presented here are the results of a retrospective analysis of a group of patients with non-healing post-trauma lesions. Our approach has several inherent drawbacks: there is a very limited set of inclusion and exclusion criteria which allows for lesions with potentially different characteristics to be included in the data analysis. The fact that there was no specific cut-off time or limitation to the period to complete granulation and reepithelialization makes TDA analysis results difficult to compare with the results of RCT's, as presented in the literature. Such comparisons are also very difficult since the literature does not provide specific data on our defined indications and study outcomes.

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Conclusion

A retrospectively analysis of data on a desiccating agent, used for the removal of biofilm and necrotic material in nine post-trauma lesions of

the lower leg was conducted to analyze the efficacy and safety of this agent.

Data analysis showed rapid granulation formation and reepithelialization, the result of successfully creating a proper wound bed without necrosis and biofilm. These clinical findings indicate the efficacy of TDA as a debriding agent and they suggest that the use of TDA may contribute considerably to fast and easy removal of both biofilms and necrosis.

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Disclosure of conflict of interest

The author is consultant to DEBx Medical, Amsterdam, the Netherlands.

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