Diabetic Foot Ulceration – Positive Outcomes Utilising Topical Haemoglobin Spray

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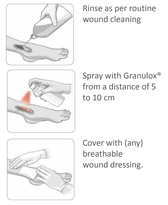
Abstract
Diabetic foot ulceration (DFU) is common and notoriously difficult to manage, in a large part to poor oxygenation. An evaluation an acute clinical setting of Granulox® haemoglobin spray to improve wound oxygenation was conducted in a cohort of 20 patients with chronic (>12 weeks) DFU. Standard wound care was undertaken by 18 health professionals with no changes to products, devices or practice before evaluation. All wounds received the addition of the product on eight set occasions over a four-week period. At four weeks all wounds had demonstrated positive wound reduction, reduced pain, slough elimination, had no adverse events, and all patients and clinicians found the product acceptable and easy to use. At a further 4-week review no patients wounds had regressed.
Conclusion: The incorporation of a haemoglobin spray solution within this cohort of DFU resulted in a positive improvement in wound healing and slough elimination and is supportive of recent consensus guidelines suggesting Granulox® haemoglobin spray to be offered to DFU patients not substantially healed within 2-4 weeks of standard care alone.

Introduction
The development and subsequent deterioration of diabetic foot ulceration (DFU) is a common occurrence across all healthcare divides, concerning all patient groups, age, gender and social environments increasing demand upon clinical resources and unnecessary hardship to our patients. Chronic DFU, for various reasons are challenging to prevent and notoriously difficult to manage due to the complex nature of the patient, often unstable biological status of the tissues and the difficult differentiation of DFU from other foot lesions which can delay appropriate referral and subsequent optimization of care (Walker et al 2015). This poster evaluates the benefits of using Granulox® haemoglobin spray therapy within this group of patients with positive outcomes in regards to wound surface area reduction, patient acceptability and ease of use in a real-world clinic. The full results over 4 weeks is available in Bateman (2015).



Method
A single acute center evaluation with primary outcomes; % reduction in wound surface area after four weeks treatment with Granulox® and secondary outcomes of; patient acceptability, adverse events and ease of use. Inclusion of patients aged over 18 years, a DFU below the ankle persistent for >12 weeks, a Site, Ischemia, Neuropathy, Bacterial Infection, Area and Depth (SINBAD) score maximum of 2, and diabetic foot ulcer located below the ankle. Exclusion criteria related to those patients that presented with infected ulcers, receiving systemic antibiotic therapy and or corticosteroids, that were pregnant or actively lactating, that had a ABPI <0.5mmHg or toe pressure <70mmHg or HBA1c >10% or 86mmol/l. Patient received the same standard of care that they entered the evaluation with, only adding the spray product. Patients had their dressings changed twice per week with the Granulox® administered each time.

KEY POINTS

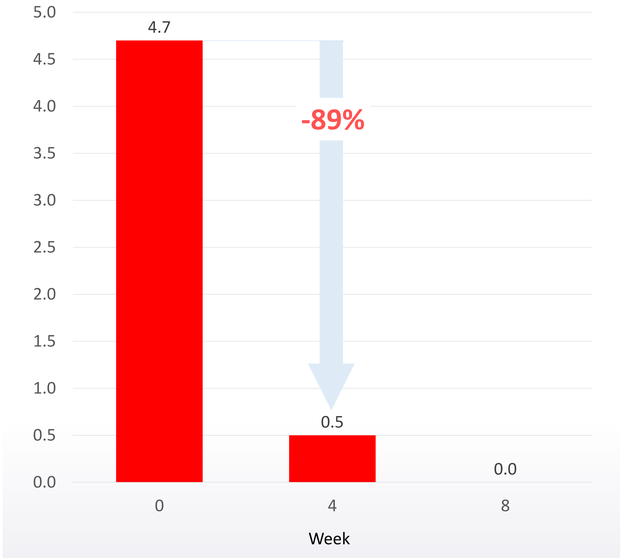
- Chronic diabetic ulceration to the heel and ankle is challenging to prevent and difficult to manage
- Oxygen is essential in wound-healing, but high plasma glucose caused by diabetes often lead to angiopathy and ischaemia, reducing oxygen levels
- Granulox® haemoglobin spray effectively enables increased oxygen diffusion into the wound base, increasing oxygen
- In 20 chronic DFU patients 100% were slough free, pain free, had wound size reduction and 25% had complete wound closure within 4 weeks
- At 8 weeks no wounds had regressed, 40% (8) had achieved full wound closure, and the average wound size reduction was -78% (-62% at week 4).

Arenbergerova et al (2013). Effect of topical haemoglobin on venous leg ulcer healing. EWMA Journal 13(2)
Bateman (2015) Topical haemoglobin spray for diabetic foot ulceration. Br J Nurs. 24(12):S24-9
Walker et al (2015) Differentiating between pressure ulcer or foot ulcer. Wounds UK 11(1):27-31

Easy to use by patients and clinicians – Supporting self-care
[Percent of patients rating easy of use, 15 of 20 self-caring]

Of the 20 patients, 15 patients, after limited demonstration, were able to apply Granulox® independently as part of their own dressing regimen. 5 patients were unable to apply their own dressings due to mental health or physical disability, three of the five had dementia, and two had end-stage rheumatoid arthritis. All the clinicians involved in the evaluation, 18 in total, both healthcare assistants and registered nurses, were satisfied with the easy use of Granulox®, scoring it "Extremely easy to use". Of the 15 patients that administered the Granulox® on their own, ten (67%) stated it to be "Extremely easy" and five "Very Easy" (33%).

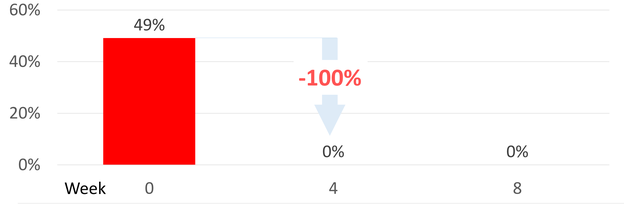
Significant pain reduction – 89% reduction - within 4 weeks
[Average reported pain scores in not neuropathic patients, 10 of 20 patients]



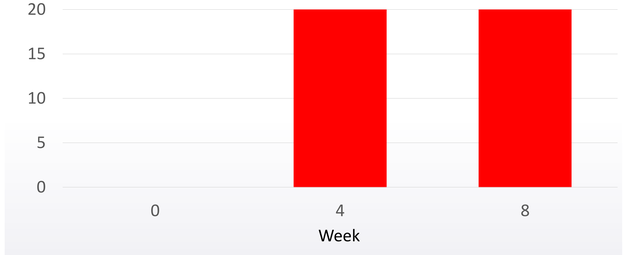
In Diabetic Foot Ulceration, patients often don't have any pain or sensation in the feet due to neuropathy. Among the 20 patients in this study, ten were neuropathic, and ten were not. Among the patients able to feel pain, the average pain score at baseline was 4.7 on a ten point scale. Granulox® has previously been demonstrated to be highly effective at reducing wound pain (Arenbergerova et al 2013), showing a 68% reduction in wound pain within 13 weeks in chronic venous leg ulcers (61% better than standard care alone). In this case series, average pain scores were reduced to 0.5 by week 4 (-89%), and to 0 by week 8 (-100%).

Effective slough elimination – 100% slough free by 4 weeks
[Coverage of slough in wounds. All 20 wounds had ≥10% slough at baseline]

Average slough coverage, by week



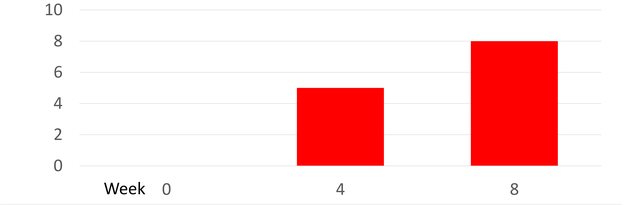
Patients, slough-free by week



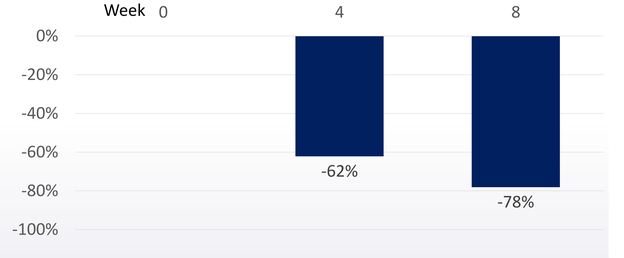
While not originally outlines as an endpoint in the study, one of the main findings of the case series was the effective slough elimination demonstrated in the evaluation. Previous work have noted significant slough reduction, i.e. Arenbergerova et al (2013) but has made little point of it. In this evaluation slough elimination was very effective. At the start of the evaluation all wounds had ≥10% slough coverage, with and average of 49% of the wound area covered in slough. By week 4, all wounds were deemed slough free, and remained slough free also at week 8 (if still open). Wound debridement was not performed on any patient.

Rapid wound healing – 40% healed within 8 weeks
[Wound size reduction and wound healing by week, all 20 patients]

Wounds achieving full wounds closure, by week



Average wound size reduction, by week



No dressing or off-loading regimens were changed, with Granulox® the only adjustment to their treatment. Despite persisting for more than 3 months prior to Granulox®, 5 wounds fully healed within 4 week and 8 within 8 weeks, with average size reductions of -62% and -78% respectively. Wounds closed by Week 4 were on average 2.6cm^2 at baseline and were persistency for 3-4 months. The three additional wounds healed by week 8 were 1.2cm^2 and had persisted for 4-5 months. The 5 largest (avg. 12.7cm^2) and 5 most persistent (avg. 12 mths) reduced by -72% and -51% respectively at 8 weeks.