

The role of topical oxygen therapy in the treatment of diabetic foot ulceration

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On behalf of the TODFU-2 study group

Introduction: Oxygen is a prerequisite in wound healing. It supports several pathophysiological processes such as cell proliferation, bacterial defence, angiogenesis and collagen synthesis. Even though the role of topical oxygen therapy in wound healing is not completely understood, many experimental and clinical observations have shown that defective wound healing is associated with localised tissue hypoxia. The diabetic foot is particularly susceptible to the adverse effects of tissue hypoxia due to complications arising from autonomic neuropathy which can preclude the systemic delivery of oxygen to the wound bed (**Image 1**). Natrox[®] is a class II medical device which delivers pure humidified oxygen directly to the wound to optimise healing potential (**Image 2**).

Image 1: Neuro-ischaemic DFU at baseline

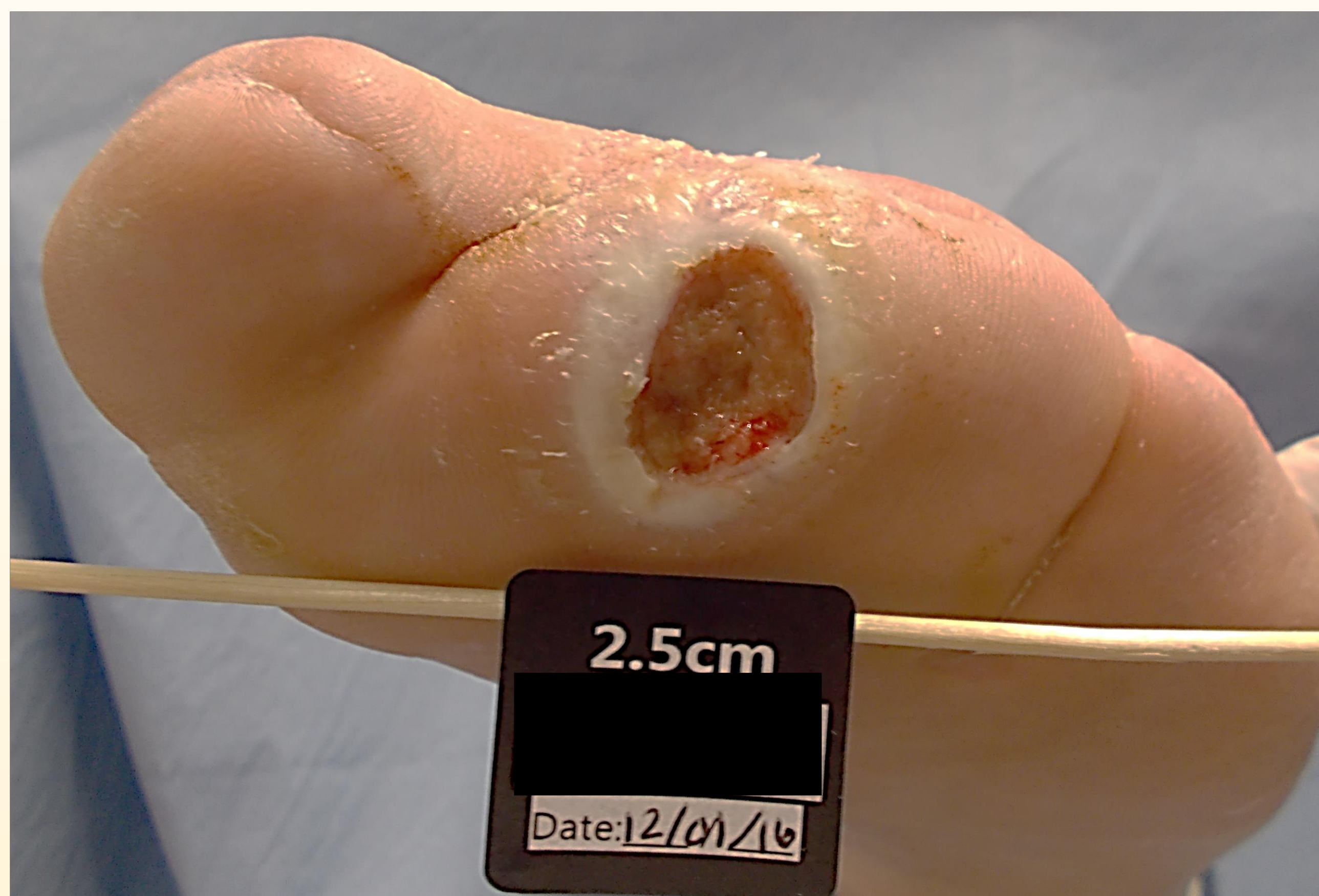


Image 2: Neuro-ischaemic DFU healed at week 16



Method: Patients presenting with non-healing (≥ 6 months) diabetic foot ulcers (DFU) were recruited from 14 specialist foot clinics in the United Kingdom. A comprehensive diabetic foot assessment was performed on the cohort and in contrast to many other diabetic foot related studies, no lower limit on foot perfusion was specified within the exclusion criteria. Reviews were undertaken once a week and data on quality of life and pain was recorded once a month over the 24-week study period. Standardised digital images were taken once a week to assess the change in wound surface area (cm^2).

Results: 42 patients across 12 specialist foot clinics were recruited into the registry arm of the TODFU study. Sixteen (38%) of these non-healing patients had a history of amputation and the mean duration of DFU prior to study inclusion was 17 months ($n=42$). Over the 24-week study period the wound surface area decreased (68%) between baseline and endpoint (**Figure 1**). Complete healing was achieved in 33% of the total cohort and a further 50% reduction in wound surface area was observed in the non-healing group. Only two (5%) patients had no reduction in wound surface area. Patients reported high levels of satisfaction on the visual analogue scale (≥ 8.7) and overall there was no reduction in subjective pain scores documented between baseline and endpoint (**Figure 2**). Six (14%) patients failed to complete the study despite a marked reduction in wound surface area ($\geq 21\%$) observed in 4 of the 6 patients. Only one patient was withdrawn from the study at week 4 due to an increase in wound surface area (23%).

Figure 1: Reduction in wound surface area (cm^2)

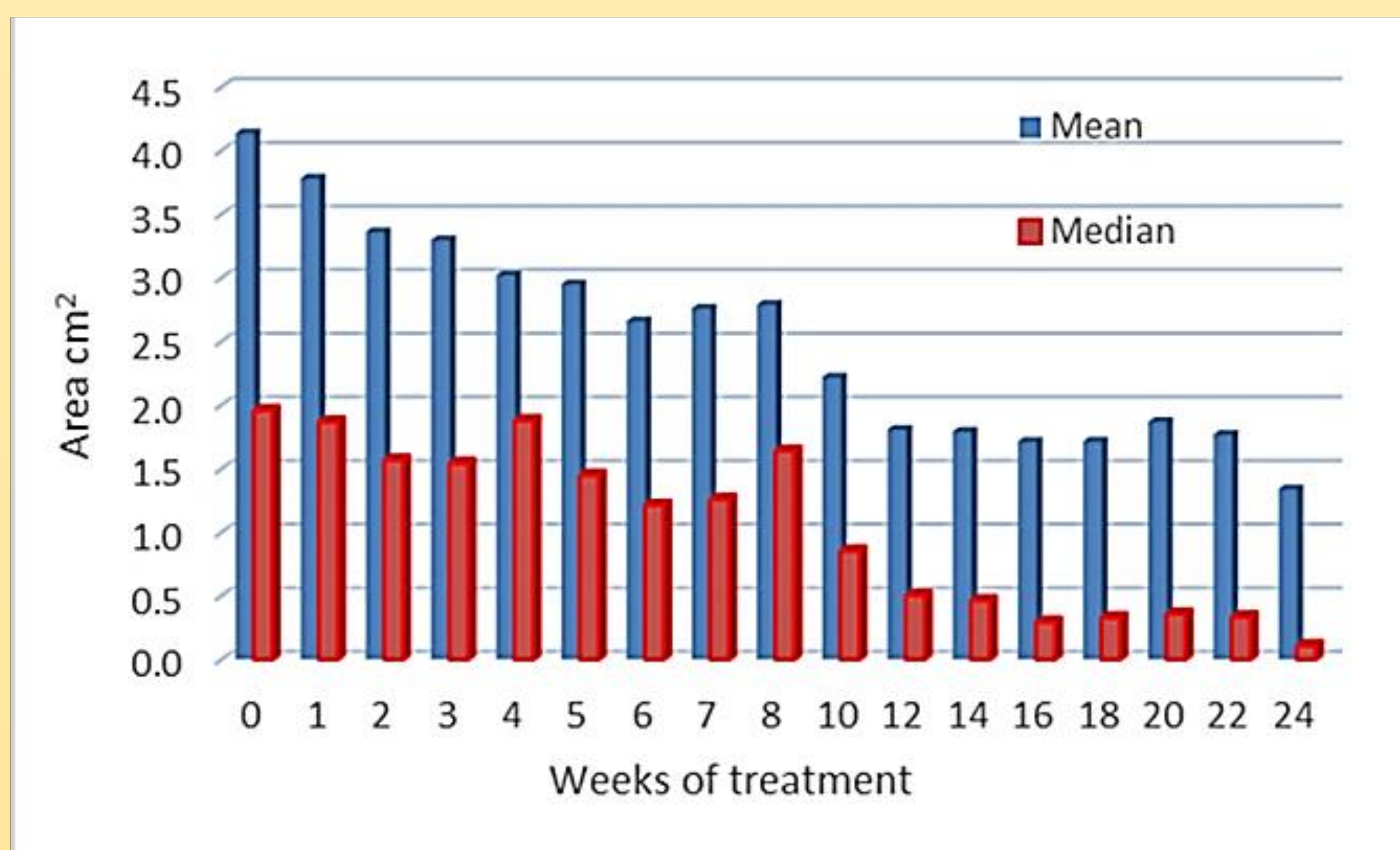
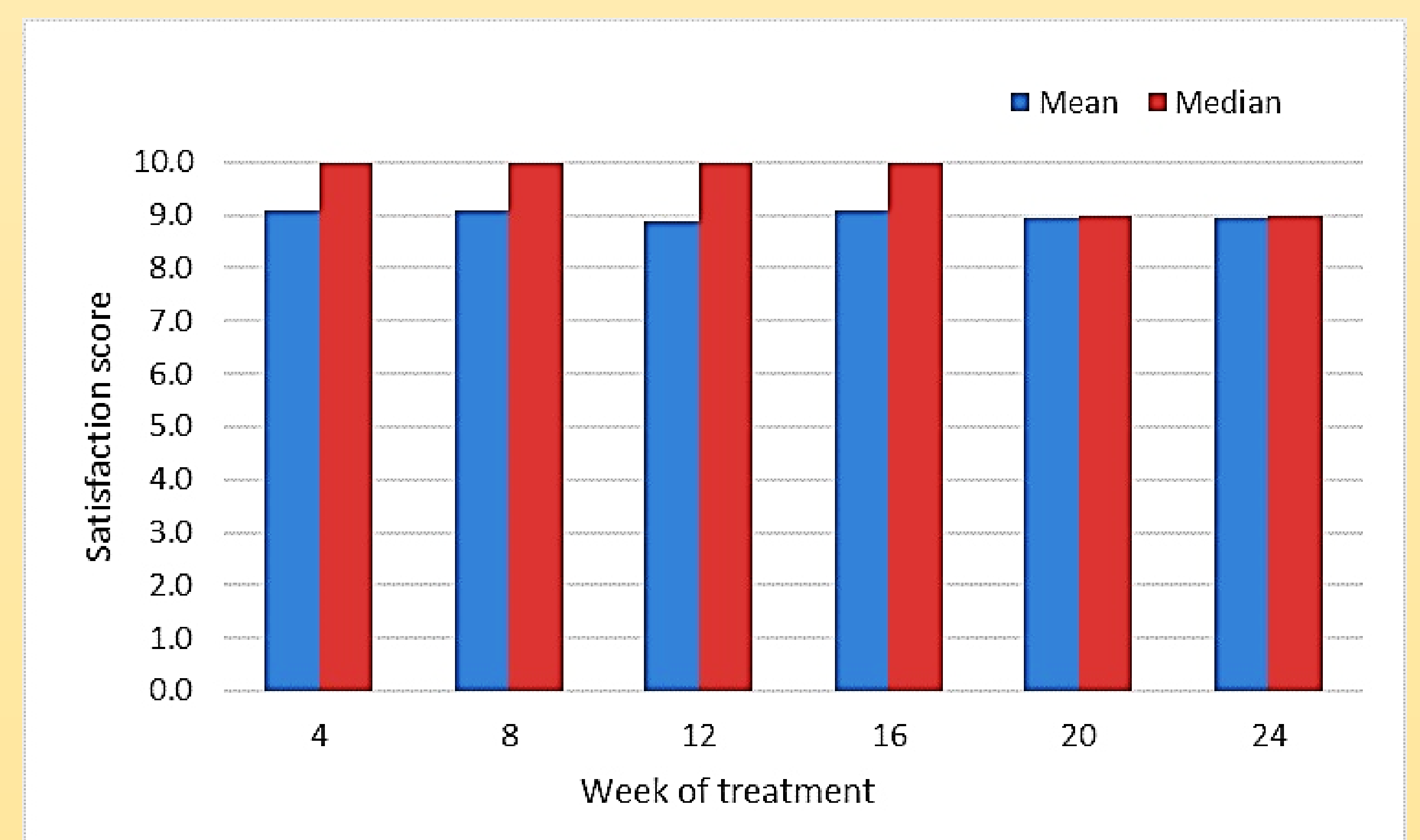


Figure 2: Patient satisfaction scores (VAS)



Conclusion: The data suggests that the application of continuous ambulatory topical oxygen therapy had a beneficial effect on wound healing outcomes in this non-healing cohort. Analysis on the economic significance of these findings provide a compelling argument in favour of Natrox[®] therapy when compared against the estimated cost of delivering long-term standard DFU care.