Topical Oxygen Therapy in the Management of Hard-to-Heal Wounds in Colombia: A Retrospective Review

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Introduction

- Hard-to-heal wounds pose a significant challenge in healthcare, affecting the quality of life of an estimated 40 million patients worldwide.
- The management of these wounds strains limited medical resources. In 2019, the global expenditure on wound care was estimated at approximately 299.4819 billion USD, with South America alone contributing 11.1619 billion USD.
- Developing regions like the nations in South America have a higher number of nonhealing wounds due to limited healthcare access and financial barriers.
- When conventional treatments fail, alternative therapies such as Continuous Topical Oxygen Therapy (cTOT) are needed. cTOT enhances the wound healing process.
- This retrospective study evaluated the real-world efficacy of treating hard-to-heal wounds using a cTOT device in 69 patients over a three-to-six-month period.

Methods

This was a multi-center, retrospective analysis of real-world use of cTOT to treat a variety of hard-to-heal wound etiologies in Colombia, South America, comparing continuous versus discontinuous treatment regimens.

The following variables were recorded from patient records:

- *Demographic Information:* Age, sex, comorbidities (e.g., type 2 diabetes, hypertension, chronic renal failure).
- *Wound Characteristics:* Type and duration of the wound.
- *Treatment Details:* Duration of cTOT, use of antimicrobial agents before and after cTOT, frequency of treatments, and additional wound care interventions.
- *Primary Outcomes:* Duration of treatment, reduction in wound size, percentage wound area reduction (PWAR), and time to complete healing.
- *Secondary Outcomes:* Changes in pain medication usage and incidence of wound infection.

cTOT Device

Battery-powered NATROX® O_2 Oxygen Generator (OG)

- Simple-to-use, battery-operated device – delivers continuous oxygen to the wound bed at a flow rate of 11ml / hr.
- Rechargeable batteries – One is in use while the other is charging
- Wearable – Patients can remain mobile while receiving therapy
- Lightweight and discreet – Device can be carried in a pocket
- Silent – no alarms that would disturb sleep

NATROX® O_2 Oxygen Delivery System (ODS)

- Sterile, single-use wound interface oxygen delivery system
- Soft and pliable – Easily conforms to the wound's anatomical location
- Used as an adjunct to current standard of care wound management options on formulary, including compression and TCC.
- "Wheel" like design allows free passage of wound exudate into the secondary dressing while optimizing the flow and diffusion of oxygen across the wound bed
- Connects to the OG via a twist-and-lock attachment

Statistical Analysis

- Descriptive statistics were used to summarize the characteristics of the patient population, types of wounds, and treatment outcomes.
- Comparative analyses were performed using t-tests (two-sample unequal variance) to assess differences in treatment outcomes between the continuous and discontinuous therapy groups. A p-value of <0.05 was considered statistically significant.
- *Primary Outcomes Analysis:* The duration of treatment and wound size reduction were compared between the two groups, with the PWAR per week calculated to assess the rate of wound healing.
- *Secondary Outcomes Analysis*: Changes in pain medication usage and the incidence of infections were analyzed to evaluate the broader impact of cTOT.

NATROX® Wound Care

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Results

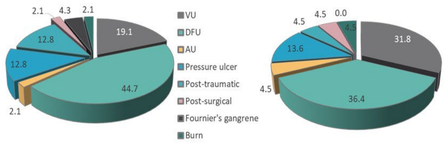


Figure 1. Wound etiologies from the 2 cohorts a) continuous cTOT, n=47 and b) discontinuous cTOT, n= 22.

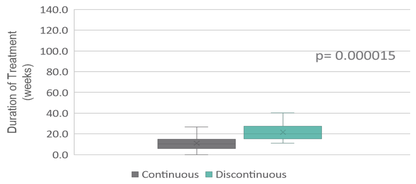


Figure 2. Treatment durations in weeks (mean and median treatment durations) for continuous and discontinuous cTOT. Continuous cTOT treatment achieved a mean PWAR of 97±8% (median=100%). Discontinuous cTOT treatment had a mean PWAR of 94±11% (median=99%).

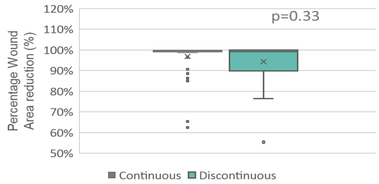


Figure 3: Comparison of Percentage Wound Area Reduction (PWAR). A non-significant difference in PWAR between the two treatment groups is observed (p-value=0.33).

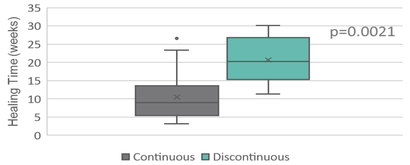
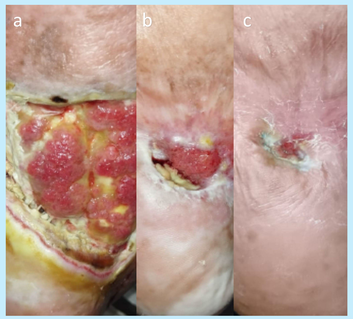
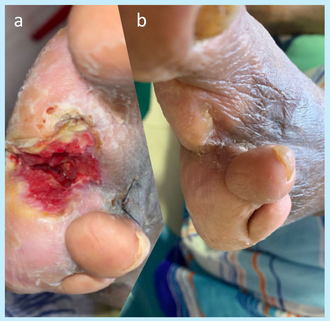


Figure 4. Time to complete healing in weeks between continuous (grey) and discontinuous cTOT (green) treatments. A significant difference in healing time between the two treatment groups was observed (p=0.0021), with continuous cTOT treatment having a faster healing time.

Case Examples



Patient 1: Non-healing DFU dorsal surface, a) beginning of continuous cTOT treatment, b) seven weeks in treatment, and c) at the end of the treatment at 29 weeks.



Patient 23: Non-healing DFU between 1st and 4th toes a) beginning of continuous cTOT treatment, and b) end of treatment at 4.7 weeks.

Patient 48: Non-healing DFU, plantar surface, a) at baseline, b) after 19.5 weeks in treatment, and c) at the end of the treatment at 28.4 weeks.

Discussion

- While cTOT has been proven effective in supporting more rapid wound closure in a variety of wound types worldwide, this trial is the first cohort study to examine the effects of cTOT on a population of patients in Colombia.
- This study assessed the efficacy of continuous and discontinuous cTOT with both groups exhibiting more favorable wound outcomes than with previous standard of care therapies.
- However, the patients receiving continuous cTOT illustrated notably faster healing with a greater proportion of patients achieving complete wound closure compared to the discontinuous cTOT group (64% vs. 36%).
- This concurs with previous studies on both DFU and VU where complete healing was achieved in 44.4% and 40% respectively.
- Additionally, in this study, treatment duration was significantly longer for patients in the discontinuous cTOT group, with a p-value of 0.000015. This trend was especially pronounced among patients with diabetic foot ulcers (DFUs), although the sample size for other wound types was insufficient for a definitive comparison.
- Both treatment groups experienced significant wound size reductions, indicating the overall effectiveness of the cTOT therapy.
- However, patients who received continuous cTOT showed a significantly higher percentage of wound area reduction (PWAR) per week than those receiving discontinuous cTOT.
- This impact on healing concurs with previous data, including level 1 evidence from RCTs and meta-analyses, and has been recognized by inclusion in various international guidance for treatment of non-healing wounds.

References

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