

Continuous Topical Oxygen Therapy – Improving Healing in the Diabetic Foot

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AIM:

To assess the impact of continuous topical oxygen wound therapy on healing rates in the diabetic foot. Oxygen is critical to wound healing^{1,2}. Yet, wound perfusion is frequently insufficient in diabetic patients with chronic wounds, thereby reducing the wound's capacity to heal³. This pilot study was initiated to assess whether continuous topical oxygen therapy (cTOT) could improve healing in these diabetic foot patients, particularly in the home care setting.

METHOD:

A pilot involving 5 consecutive patients with complex or non-healing (less than 40% reduction in wound size in 4 weeks) diabetic foot ulcers. Following all relevant consent, patients deemed suitable were initiated on a maximum of 12 weeks of cTOT in conjunction with standard of care (SoC). The small, portable, battery-powered cTOT device generates and delivers a continuous, pure oxygen flow rate (POFR) of 15ml/h directly to the wound bed.

Frequency of dressing changes were dictated by the wound condition. Patients were monitored weekly, and patient feedback was recorded. Wound measurements were captured using a 2D electronic wound measurement tool to ensure consistency.

RESULTS:

Due to the consecutive nature of recruitment, the ulcers included varied in severity, and therefore so did the assigned treatment pathways. Ultimately, this led to the study being more reflective of real-life practice. On recruitment, three wounds were deemed non-healing/slow healing and were prescribed cTOT and Standard of Care (SoC). The remaining wounds were more complex in nature and required advanced interventions and therapies.

Summary of Clinical Outcomes:

Non/Slow Healing Wounds

Patient 1: 88.2% reduction in wound size in 12 weeks

Patient 2: 98.6% reduction in wound size in 12 weeks

Patient 3: Healed in 10 weeks of therapy

(Patient 1 & 2 healed shortly after 12-week study period)

The NATROX® Oxygen Wound Therapy system consists of 3 main components:

NATROX® Oxygen Generator (OG) (Fig 1)

No ON/OFF switch; activation occurs when a fully charged battery is fitted. Flashing green light indicates the device is working.



Fig 1

NATROX® Battery (Fig 2)

2 batteries supplied, one is fitted to the device whilst the other is left on continuous charge. One battery will power the device for a minimum of 24 hours.

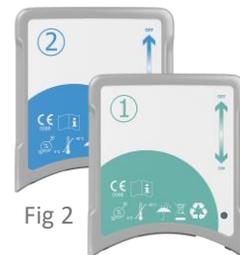


Fig 2

NATROX® Oxygen Delivery System (ODS) (Fig 3)

Sterile and highly conformable the ODS works with all standard secondary dressings. The web-like design allows exudate to pass freely into the secondary dressing.

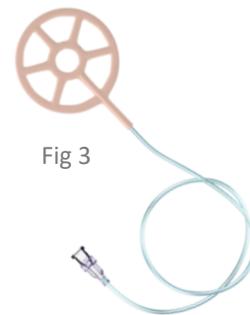


Fig 3

Complex Wounds

Patient 4: Presented with a plantar hallux ulcer. Despite 2 months of SoC, the wound failed to progress. Advanced amniotic product was utilized in conjunction with cTOT. 96% reduction in wound size following 10 weeks of therapy

Patient 5: Underwent partial 1st Ray amputation and multiple revascularizations. Surgical site flap became necrotic and following debridement cTOT was applied. Granulation tissue evident following 4 weeks of therapy.

References

1. Castilla DM, Liu Z-J, Velazquez OC (2012) Oxygen: implications for healing. *Adv Wound Care* 1(6): 225-30
2. Eisenbud DE (2012) Oxygen in wound healing: Nutrient, antibiotic, signaling molecule and therapeutic agent. *Clin Plastic Surg* 39: 293-310
3. Armstrong DG, Cohen K, Courric S et al (2011) Diabetic foot ulcers and vascular insufficiency: our population has changed but our methods have not. *J Diabetes Sci Technol* 5(6): 1591-5

NON-HEALING DIABETIC FOOT ULCERS

Patient 1 - 56 year old male with a history of transmetatarsal amputation (L-side). Presented with an ulcer on his 4th MTP region. Non-healing following 16 weeks of SoC. Initiated cTOT, 88% reduction in wound size in 12 weeks.



Patient 2 - 66 year old male with a history of amputations. Presented with an ulcer on his 1st metatarsal head (L-side). Non-healing following 10 weeks of SoC. Initiated cTOT, 98% reduction in wound size in 12 weeks.



Patient 3 - 52 year old male presented with a deep ulcer on his 1st metatarsal head (R-side). Duration of the ulcer 10 months with little progression. Initiated cTOT, complete wound closure in 10 weeks.



COMPLEX DIABETIC FOOT ULCERS

Patient 4 - An 80 year old diabetic male presented to the clinic with a ulcer plantar hallux and had a prior history of contralateral LE bypass with 1st ray amputation. Standard of care dressings were utilized for 2 months prior to initiation of cTOT.



Advanced amniotic product (AAP) was utilized in conjunction with cTOT. Wound healing achieved with the prescribed therapy despite a tcPO₂ test indicating inadequate tissue oxygenation for healthy wound healing (value of 18 at the 1st MTPJ). This case demonstrates that advanced wound care products can be utilized alone or in conjunction to promote accelerated wound healing.

Patient 5 - 78 year old diabetic male presented with bilateral large fluid filled bulla to his feet due to exacerbation of CHF. Blisters turned into eschars and deteriorated significantly while waiting for vascular intervention. This rapid deterioration led to emergent I&D with partial 1st ray amputation. Although not a candidate for bypass surgery, he did undergo 2 invasive catheterization procedures as an in-patient. As the margins were clean, the foot was closed, PICC line placed and culture guided antibiotic therapy initiated along with weekly reviews. Despite this, the surgical site flap was not viable.



Once stable, the devitalized tissue was removed in-clinic and cTOT was applied to the site. The wound continues to increase granulation despite a tcPO₂ test indicating inadequate tissue oxygenation for healthy wound healing (value of 20). This case demonstrates that topical oxygen products can be utilized to promote wound healing in the absence of adequate circulation.

DISCUSSION / CONCLUSION

For these patient, cTOT was an extremely effective therapy. Not only did it demonstrate wound healing in both non-healing and complex wounds, all the patients reported that it was simple to manage at home. Having the ability to use cTOT in conjunction with other advanced therapies is an advantage and could offer additional clinical benefits.

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