

The Use of a Topical Oxygen Therapy System to Promote Healing in Chronic Wounds

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INTRODUCTION

- The incidence of chronic wounds continues to rise worldwide
- Chronic wounds are a burden on patients' quality of life and increase healthcare costs
- Chronic wounds are defined as those not proceeding through the orderly phases of tissue repair in 30 days
- Ischemia, microcirculatory dysfunction and PVD can cause limitations in blood flow that often result in a delay in the healing process

STUDY

- This is a prospective, single site, single-arm pilot case series
- The aim is to determine the effects of continuous **Topical Oxygen Therapy (TOT)** on wound perfusion (percentage of oxygenated hemoglobin) as measured with a **near-infrared spectroscopy device (NIRS)***
- A secondary end point was total wound area reduction

METHOD

- Five participants >18 years presenting with a history of lower extremity wounds with a duration of more than 30 days qualified for inclusion
- Subjects diagnosed with active infection or osteomyelitis were excluded
- Following informed consent, a standard wound assessment was performed including baseline wound measurements and **NIRS** image
- Active continuous **TOT** was then initiated
- Weekly **NIRS** images were taken to track oxygenated hemoglobin levels in the wound tissues
- Standard wound measurements were also obtained and recorded weekly
- Patients were seen for 6 weekly visits or until wound healing was achieved, whichever occurred first

CONTINUOUS TOPICAL OXYGEN THERAPY SYSTEM

consists of 3 main components:

Oxygen Generator (OG) (fig 1)

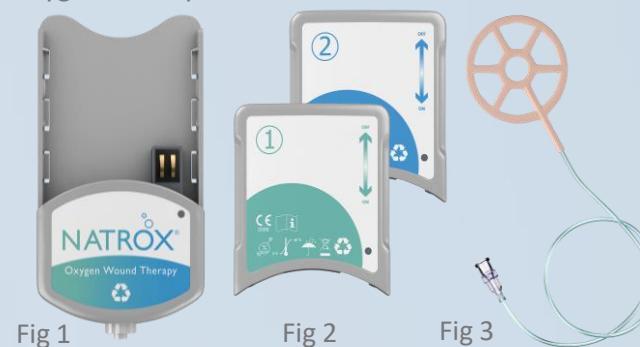
No ON/OFF switch; activation occurs when a fully charged battery is fitted

Batteries (fig 2)

2 batteries supplied, one is fitted to the device whilst the other is left on continuous charge

Oxygen Delivery System (ODS) (fig 3)

Sterile, single use ODS. Connects to the OG providing oxygen directly to the wound bed



PATIENT DEMOGRAPHICS

Patient Age				
Pt 1	Pt 2	Pt 3	Pt 4	Pt 5
91	85	76	42	85
Patient Gender				
M	F	M	F	M
Ulcer Duration (in weeks)				
22	8	54	14	62

- A total of 5 patients were enrolled into this pilot study with a variety of chronic wounds, including VLU, DFU and trauma
- All wounds were considered non-healing prior to inclusion despite appropriate wound management
- Average age of the patients was 75 years and average duration on the wounds was 32 weeks

RESULTS

- All 5 patients receiving **TOT** displayed an increase in oxygenated hemoglobin in the wound base as demonstrated on the **NIRS** images
- Weekly wound measurements were also improved in this patient cohort
- During the 6-week study period 3 of the 5 patients healed completely the other 2 healed shortly thereafter with continuation of **TOT**

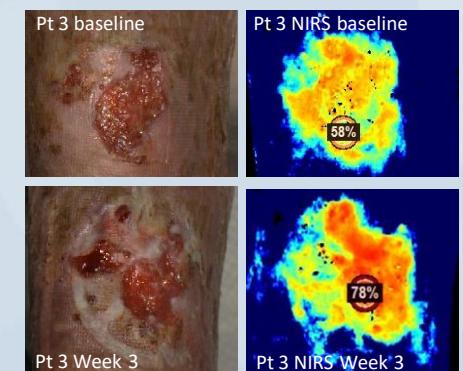
KEY RESULTS

Oxygen Hemoglobin levels					
	Pt 1	Pt 2	Pt 3	Pt 4	Pt 5
Baseline	54	44	58	72	65
Week 3	N/A*	65	78	87	79
Healing Outcome (in weeks)					
Healed	3	5	9	4	11

* Not measured as wound healed

CLINICAL OBSERVATIONS

- As oxygenation at the wound bed increased the wound size reduced
- Average increase in oxygenated hemoglobin over first 3 weeks was 31%



CONCLUSION

In the author's opinion **TOT** offers an effective non-invasive chronic wound treatment that may speed wound healing by improving microcirculation and oxygenated hemoglobin. The **NIRS** proved to be a very user-friendly point of care imaging device to track weekly wound progress.