The Use of Continuous Topical Oxygen Therapy in Tandem with Cellular, Acellular, and Matrix-like Products to Treat Complex, Chronic Wounds: A Retrospective Case Series

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Introduction

- This retrospective case series details an algorithmic approach using a continuous topical oxygen therapy (cTOT) device (NATROX ® O_2, NATROX Wound Care, Cambridge UK) for wound bed preparation prior to application of cellular, acellular, and matrix-like products (CAMPs) in an outpatient wound clinic.
- The objective of this study was to determine feasibility of a larger investigation into the serial use of cTOT and Cellular, Acellular and/or Matrix-like products (CAMPs) in the management of wounds of the lower extremity.

Methods

- This investigational wound therapy algorithm consisted of two weeks of wound bed optimization with cTOT followed by CAMP application.
- All wounds were considered non-healing prior to the use of cTOT as they had failed to achieve at least 50% wound area reduction after at least four-weeks treatment with standard of care.
- Wound measurements captured via an automated 3D wound-imaging device were recorded for each patient visit.
- The cTOT device was applied to the wound per manufacturer's instructions for use.
- Patients were seen at least once weekly in the clinic for two consecutive weeks.
- All wounds had regular debridement to remove devitalized tissue per the clinician's discretion.
- In all cases, plantar foot wounds were offloaded via total contact cast or removable walking boot, and all venous ulcers were treated with compression bandaging as part of standard of care.
- A variety of CAMPs were used based on the lead author's current selection method which considers clinical wound type, wound assessment, goals of healing, and product mechanism of action.
- All CAMPs were applied per the manufacturer's guidelines.
- No products were used off-label.

Results

Four patients with a total of five wounds are included in this case review. Patient demographics are shown in Table 1. The mean patient age was 71.8 years and wound types included three diabetic foot ulcers (DFUs) and two venous leg ulcers (VLUs). All patients had an ankle-brachial index ≥ 0.9 mmHg, but not greater than 1.3 mmHg. Additionally, all wounds were negative for clinical signs and symptoms of infection prior to beginning cTOT.

Patient						Wound		
Number	Sex	Age	Smoker	PAD/ PVD	DM	Type	Location	Duration (weeks)
1	M	81	N	N	Y	DFU Wagner Grade 2	Left Heel Calcaneus	12
2	M	87	N	N	Y	VLU	Left Shin Medial	16
3	M	76	N	N	Y	VLU post Mohs procedure	Left Shin Medial	12
4	M	43	N	N	Y	DFU Wagner Grade 3	Left Foot Dorsal	6
						DFU Wagner Grade 0	Left Foot Lateral	1

Table 1. Patient demographics and baseline wound information
PAD = Peripheral Artery Disease, PVD = Peripheral Vascular Disease, DM = Diabetes Mellitus (type 2), DFU = Diabetic Foot Ulcer, VLU = Venous Leg Ulcer

The mean wound area reduction seen in this patient cohort undergoing therapy with cTOT and subsequent CAMPs was 74.7% and 76.1% at four and six weeks respectively as shown in Figure 1.

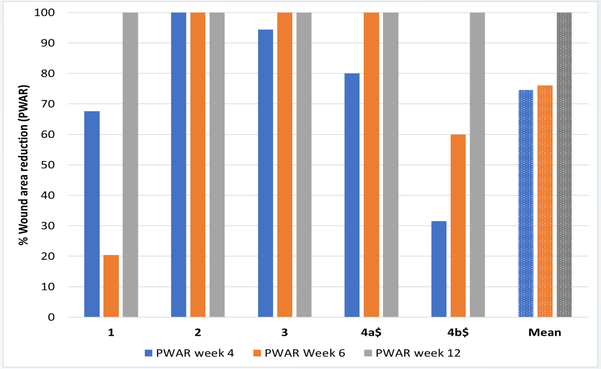

Figure 1. Percentage Wound Area Reduction (PWAR) of the five individual wounds and the mean PWAR, at weeks 4, 6 and 12.

Overall, a mean healing time of eight weeks was noted across all wounds with a mean number of six CAMP applications (Table 2). One wound healed by week four, and another two out of the five wounds healed by week six. The remaining two wounds went on to complete wound resolution by week 12 (Table 2 and Figure 1). No adverse events were reported throughout.

Patient	Time to healing (weeks)	Number of CAMP applications to closure
1	12	10
2	4	2
3	6	4
4a	6	4
4b	12	10
Mean	8	6

Table 2. Time to healing and number of CAMP applications

cTOT Device: NATROX® O_2

Discussion

Case Example

- CAMPs play an important role in wound management.
- These products, when used appropriately, can re-establish a favorable wound environment to expedite wound healing.
- While the mechanism of action varies from product to product, many CAMPs work by bolstering cellular functions or activating intrinsic molecules required for wound closure.
- In a recently published CAMPs Consensus document, the authors stressed the importance of wound bed preparation as a critical step for successful CAMPs use.
- Furthermore, the consensus concluded that inflammation and infection ideally should be resolved prior to CAMP application.
- The publication cautions that lack of adequate optimization of the wound bed will ultimately lead to CAMP failure.
- The benefits of adequate oxygenation of a wound when using tissue substitutes have also been demonstrated previously *in vitro*, with early keratinocyte migration, enhanced collagen deposition, and accelerated epidermal maturation noted in tissue supplemented with oxygen compared to controls.
- Therefore, initiating topical oxygen early for wound bed optimization is very important and should be considered in the wound healing algorithm as recently highlighted in the MOIST wound care guidance document.
- The mean time to complete closure for the five wounds reported in this study was eight weeks, with a mean of six applications of CAMPs.
- While different CAMPs were used in this study which may influence the number of applications, this data highlights an interesting observation to be explored further in comparative studies to ascertain resolutely if the synergy of sequential cTOT and CAMPs use may reduce the number of applications required with a corresponding decrease in time to healing.

References

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