

A Single Device (From AOTI) With Triple Therapy (Local Oxygen, Compression And Humidification) Enhances Healing Of Non-Healing Lower Extremity Wounds

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November 22, 2021*

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Disclosures

None

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Scientific Background

PubMed National Library of Medicine

Topical oxygen therapy-hocus pocus or science?

2 Andersen C.

Cite J Wound Care. 2021 May 1;30(Sup5):S6. doi: 10.12968/jowc.2021.30.Sup5.S6.
PMID: 33979228 **Free article.** No abstract available.

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Abstract
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Background

While the use of hyperbaric oxygen therapy has been supported by randomized prospective trials for the use of selective lower extremity wounds, it is associated with significant cost, inconvenience and has an incidence of complications related to increased systemic pressure

It is not recommended to routinely apply hyperbaric oxygen therapy to all patients with diabetic foot ulcers, especially those with non-ischemic diabetic foot ulcers.

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Multi-Modality Cyclical Pressurized Topical Oxygen -


O₂

OXYGEN
Higher pressure delivery results in greater tissue diffusion, upregulating wound metabolism, resulting in **faster and more durable healing.**

COMPRESSION
Non-contact, cyclical-compression helps to reduce edema and enhance **peripheral vascular circulation.**

HUMIDIFICATION
Assures an ideal wound healing environment for **effective healing.**

Extremity Chamber for wounds on Extremities



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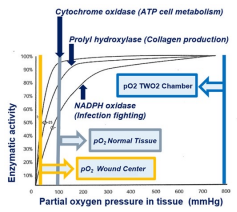
CPTO Therapy has Three Component Mechanisms

O₂ #1 - BENEFITS OF SUPPLEMENTAL OXYGEN

ATP synthesis runs almost at maximum activity at a pO₂ of 100 mmHg, whereas Collagen synthesis is at 80% activity & anti-microbial enzymes are only at 60% activity

Cyclical-pressurized topical oxygen raises pO₂ above normal tissue levels to enhance all enzymatic activity

TWO2 provides the highest penetration of oxygen into the wounded tissue. The immediate availability of oxygen at a partial pressure of approximately 800 mmHg provides the greatest diffusion gradient into the tissue



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CPTO Therapy has Three Component Mechanisms

#2 – BENEFITS OF CYCLICAL COMPRESSION

two

TWO2 therapy utilizes an inflatable chamber, applying non-contact cyclical compression to the limb. The gentle cycling of compression between 10 mb and 50 mb pressure (up to 40 mmHg) 2 times per minute

Reduces of edema which reduces resistance to blood flow mobilizing flow and lymphatic return. This enhances oxygen diffusion and neovascularization within the wound.

The higher positive pressure more effectively delivers oxygen into the wound bed, encouraging granulation from the base.

Extremity Chamber for non-contact cyclical compression

Non-Contact Cyclical Compression...
 Promotes arterial flow
 Encourages venous return
 Reduces Edema/Decreases Hydrostatic pressure
 Activates Lymphatic System

CPTO Therapy has Three Component Mechanisms

#3 – BENEFITS OF HUMIDIFICATION

Assures an ideal wound healing environment, promoting healthy granulation tissues for faster, more effective and durable healing.

Dry vs. Moist Wound Healing

DRY Wound Healing
 Scab
 Dry Exudate
 Dry Tissue
 Dry tissue inhibits the migration of epithelial cells

MOIST Wound Healing
 Wound Covering
 Epidermis
 Dermis
 Epithelial cells
 A moist wound bed creates an environment for fast epithelial cell migration promoting healing

How to Utilize

Applied by the Patient at home
 90 minutes a day
 5 days a week
 Overlying Gas Permeable Dressing

A Multinational Multicenter, Randomized, Double-Blinded Placebo-Controlled Trial to Evaluate the Efficacy of Cyclical Topical Wound Oxygen Therapy (TWO-) in the Treatment of Chronic Diabetic Foot Ulcers: The TWO: Study

Robert G. Fryback, Peter J. Franks, Michael Edmonds, Jonathan N. Bramley, Luc Teat, Thomas Wile, Matthew G. Corofelli, Aliza M. Lee, Janette A. Thompson, Gerard Roach, Cypriani R. Dava, Karim Lochgar, Dirk Grottemeyer, and Sophie C. Kenton, on behalf of the TWO: Study Group

Cox proportional hazards modeling, after adjustment for UTC grade, demonstrated **>4.5 times the likelihood to heal DFUs over 12 weeks** compared with the sham arm with a **hazard ratio of 4.66** (97.8% CI 1.36, 15.98), **P=0.004**

Durability of Healing 12 Months Post Enrollment

TWO2 In-service Review Dec 2019

SIX-FOLD REDUCTION IN RECURRENCE
 Active arm = 6.7%
 Sham arm = 40%

P = 0.070

Diabetic Foot Ulcers and Their Recurrence
 David G. Armstrong, D.F.M., M.D., Ph.D., Andrew M. Boulton, M.D., and Simon A. Bus, Ph.D.
 N Engl J Med 2017;376:2367-75.

Systematic Reviews & Meta-Analyses

All 5 confirm that DFUs treated with SOC + TOT are 2X more likely to heal than SOC alone


Patient Identification:
 Meta-analyses support efficacy in the defined populations: chronic DFUs of at least 4 weeks duration and not adequately responding to SOC alone

All Show Consistent Positive Complete Healing Outcomes


Technical and Clinical Outcome of Topical Wound Oxygen in Comparison to Conventional Compression Dressings in the Management of Refractory Nonhealing Venous Ulcers

Study Design:
 132 refractory (>2 years Duration) VLU patients were enrolled (average was 9 years)
 67 managed using CPTO
 65 managed with conventional compression dressings

End points:
 Proportion of ulcers healed at 12 weeks
 Reduction in ulcer size
 Time to full healing
 Recurrence rates up to 36 months



Wael A. Tawfik, MRCSI, and Sherif Sultan, MD, FRCS
 Vascular and Endovascular Surgery 2013 Jan-9(1):38-7. doi: 10.1177/1538574412467684. epub 2012 Dec 5.

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Results

At 12 weeks 76% of the CPTO managed ulcers had completely healed, compared to 46% of the CCD-managed ulcers (P < .0001)

Mean reduction in ulcer surface area at 12 weeks was 96% in patients managed with CPTO and 61% in patients managed with CCD (P < .0001)

After 36 months follow-up, 47% of the CCD healed ulcers showed recurrence compared to only 6% of the CPTO healed ulcers (P < .0001)

MRSA elimination occurred 46% patients managed with CPTO and 0% patients managed with CCD (<.001)


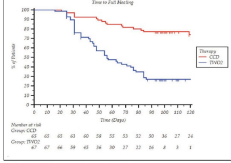




Figure 3. Time to full healing (right) after ulcer closure using oxygen in full ulcer healing. The CPTO-managed ulcers had a significantly shorter median time to full healing (94 days) compared to CCD (127 days).

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How do I use TWO₂ Therapy


No Option Revascularization
 Pre and Post Deep
 Resistant Wounds and



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Conclusions

- Topical Oxygen Therapy combined with Cyclical Compression and Humidification provide a new option for poorly healing arterial and venous wounds
- This had lead to an improvement in:
 - Arterial and venous ulcer healing rates and complete ulcer healing
 - Decreased ulcer recurrence rates
 - Decreased level of hospitalization for infected diabetic foot wound venous ulcers**
 - Decrease rates of amputation

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Thank You



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