

Home Topical Oxygen for Therapy for Healing DFU and VLU

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Disclosure Slide

- AH is on the Scientific Advisory Board for Advanced Oxygen Therapy Inc

Limb Salvage - CLTI

The diagram consists of three overlapping circles representing different aspects of limb salvage for CLTI:

- Medical Management:** Primary Care, Cardiology, Endocrinology, Infectious Disease, Diabetes
- Wound Care:** Podiatry, Vascular Surgery, Wound Care/Healing, Orthopedic Surgery, Plastic Surgery
- Revascularization:** Interventional Radiology, Interventional Cardiology, Vascular Surgery

Introduction:

- Randomized prospective trials have supported the use of Hyperbaric Oxygen chambers for lower extremity wounds
- However, significant cost, inconvenience and are associated with small risks - pneumothorax from lung blebs, barotrauma to the tympanic membrane, & severe hypoglycemia
- Topical hyperbaric oxygen therapy (tHBOT) is less expensive, can be done at home, and avoids these risks

Adjunctive HBOT

- Use of HBOT described in 1937 for treatment of decompression sickness

Behnke and Shaw *American J Physiology* 114 (3): 526-533

RCT Data DFU

73 patients with DFU randomized to tOT with SOC & SOC

University of Texas Classification (UTC) grade 1 or 2 DFU

ABI >0.7

4.5 odds ratio for complete wound healing at 12 weeks

Frykberg, *Diabetes Care* 2020

Time (Weeks)	tOT with SOC (%)	SOC (%)
0	0	0
4	~10	~5
8	~25	~10
12	~45	~15

TWO2 for VLU

- 67 patients - TWO(2)
- 65 patients - conventional compression dressings (CCDs) for 12 weeks or till full healing
- Mean reduction in ulcer surface area at 12 weeks was 96% in patients managed with TWO(2) and 61% (CCD)
- At 12 weeks, 76% of the TWO(2)-managed ulcers had completely healed, compared to 46% of the CCD-managed ulcers (P < .0001)

*Sultan Vase Endovascular Surg
2013 Jan;47(1):30-7*

TWO2 for VLU

- Median time to full healing 57 days in patients with TWO(2)
- 107 days in patients with CCD (P< .0001)
- After 36 months follow-up, 14 of the 30 healed CCD ulcers showed recurrence compared to 3 of the 51 TWO(2)-healed ulcers

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Topical oxygen therapy for diabetes-related foot ulcers: A systematic review and meta-analysis

6 RCTs involving 530 participants with a DFU testing tOT
tOT significantly increased the likelihood of ulcer healing compared to controls (Risk ratio [RR] 1.94; 95% CI 1.19, 3.17; I2 = 57%; NNT = 5.33) & findings were robust in sensitivity analyses
Analysis of the three trials judged to be at low risk of bias suggested that tOT increased the likelihood of ulcer healing compared to controls (RR 2.37; 95% CI 1.52, 3.68; I2 = 0%).

Conclusion: This meta-analysis suggests that tOT improves the likelihood of DFU healing; however, its effect on amputation and cost-effectiveness are unclear

Thanigaimani .Diabet Med. 2021 Aug;38(8):e14585

TWO 2

- Single-use extremity chamber over the patient's limb
- Humidified oxygen is cycled between 10 mb (7.5 mmHg) and 50 mb (37.5 mmHg)
- Cycles about 2X per minute
- 10 liters per minute oxygen concentrator was used to provide the oxygen supply
- 90 min daily 5 times per week



Equipment and personnel



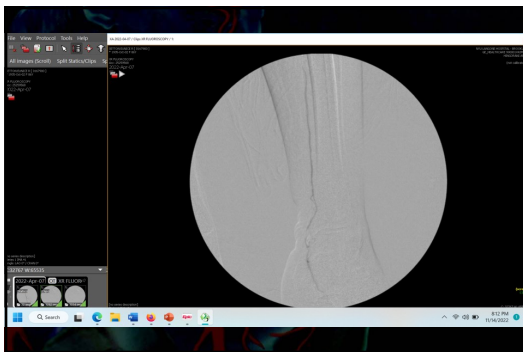
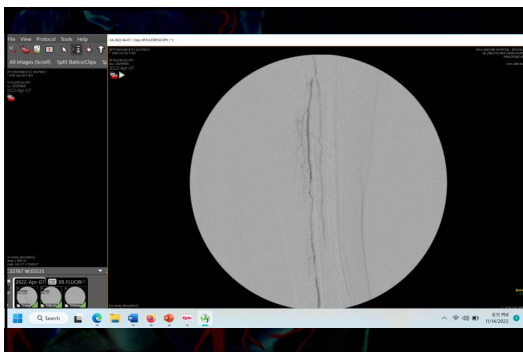
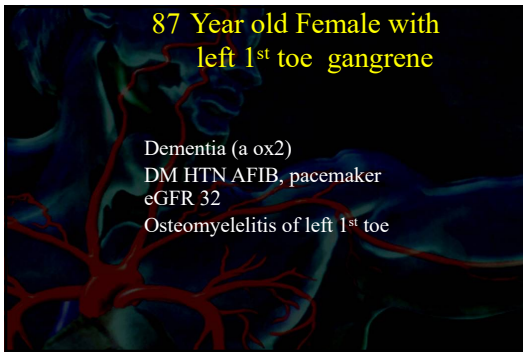
Topical oxygen therapy

Still accumulating data for tOT

Initial experience suggest possible role for wound healing as an adjunct to standard care

**87 Year old Female with
left 1st toe gangrene**

Dementia (a ox2)
DM HTN AFIB, pacemaker
eGFR 32
Osteomyelitis of left 1st toe



**With tOT, debridment and
culture specific abx: Healed**

