Clinical Efficacy of Transdermal Continuous Oxygen Therapy (TCOT) in patients with Diabetic Foot Ulcers

N. Park DPM[1], H. Hasturk DDS[2], A. Kantarci DDS[2],M. J. Ogbonna DPM, Yao MD MPH[1] G. Gu MD[1], [1]V. Driver MS, DPM, FACFAS[1]

[1] Clinical Research Limb Preservation and Wound Healing, Department of Surgery, Boston University Medical Center Boston University [2] Forsyth Institute

Background/Aim:
Hypoxia is an important factor in delayed wound healing[1,2]. Oxygen delivery to tissues has shown accelerated wound healing[1]. It has been shown to prevent infection, to play a role in epithelialization, collagen synthesis and angiogenesis Moreover, it has been hypothesized that oxygen and reactive oxygen species (ROS) may play an important role as messengers in the inflammatory cascade. Our aim is to explore clinical efficacy in response to TCOT in Diabetic Foot Ulcers (DFUs).

Methods: A prospective randomized clinical trial was conducted to evaluate 12 subjects with chronic DFUs who received standard of care (SOC) with TCOT for 4-weeks as compared to those who received SOC alone.

Patients were randomized to receive either treatment with topical oxygen or standard of care treatment during screen visit. . Patients with critical limb ischemia as defined by and ABI < 0.6 or a TcPO2 < 30 mmHg, were excluded from the study. Patients were followed up weekly for the assessment of wound characteristics , and photo was taken during each visit.

Table 1: Demographic

	Non_Oxygen (n=8)	Oxygen (n=9)	P-value
gender			
male	6	6	
female	2	3	>0.05
race			
black	2	2	
white	5	3	
hispanic	1	4	>0.05
wagner grade			
0	0	1	
1	6	2	
2	2	6	>0.05
history of infection			
yes	6	8	
no	2	1	>0.05
ulcer location			
dosal	0	3	
heel	0	1	
lateral	0	2	
medial	0	1	
planter	8	2	>0.05
history of amputation			
yes	1	3	
no	7	6	>0.05
Age (year)	58.6 ±7.1	59.9 ±12.6	>0.05
Weight (lb)	230.6 ± 44.9	199.4 ± 91.7	>0.05
Ulcer age (month)	14.3 ± 26.8	20.7 ± 21.1	>0.05
ABI	0.50 ± 0.75	0.25 ± 0.71	>0.05
Pain Score	2.8 ± 2.6	1.4 ± 2.7	>0.05

Graph 1: Change of Wound Area

Graph2: Change of Wound Volume

Table 2: Comparison of O_2 vs. SOC

	wound area reduction (%)	wound volume reduction(%)
Control(Non-O_2)	62	52
O_2	82	88
O_2 Benefit	**20**	**36**
P-value	0.34	0.09

Result: At week 4, Percent volume reduction (PVR) was calculated as 88% in the TCOT group and 52% in the control (P=0.09). We found a strong trend in healing between the two groups. The difference is 36% between the two groups, which suggests further evaluation of TCOT.

Conclusion: TCOT promotes healing of DFUs. A larger study is recommended (based on the observed results), to evaluate the significance of TCOT in treating DFUs.

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