

# Topical Wound Oxygen Therapy in the Treatment of Severe Diabetic Foot Ulcers: A Prospective Cohort Study

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## Introduction

Diabetic foot ulcers (DFU) are frequent, difficult to treat and show high rates of complications.

We examined the clinical efficacy of a unique pressurized topical oxygen therapy (TWO<sub>2</sub>) device in an outpatient setting in 28 patients with severe diabetic foot ulcers (DFU). Patients visiting a community wound care clinic for treatment of severe DFU's were offered TWO<sub>2</sub> or advanced moist wound treatment (AMWT).

## Method

TWO<sub>2</sub> patients were treated daily for 60-minutes 5 times a week. The device delivered humidified medical grade oxygen with pressure cycles between 5 and 50 mb.

## Results

The primary endpoint was complete ulcer closure after 90 days. 28 patients were included into the study. The TWO<sub>2</sub> treatment group recruited more severe wounds. The TWO<sub>2</sub> treatment group had significantly more complete ulcer closures after 90 days than the AMWT group (14/17, 82.4%, median 56 days vs. 5/11, 45.5%, median 93 days; (p=0.04)). There was no reoccurrence at the ulcer site after 24 months follow up in either group.

## Conclusion

Patients with severe DFU's treated with TWO<sub>2</sub> demonstrated significantly higher and faster healing rates with no ulcer reoccurrence after two years compared to AMWT. TWO<sub>2</sub> has the potential to provide substantial quality of life and cost savings benefits to both patients and the health care system as a whole.

Figure 1: Study Population

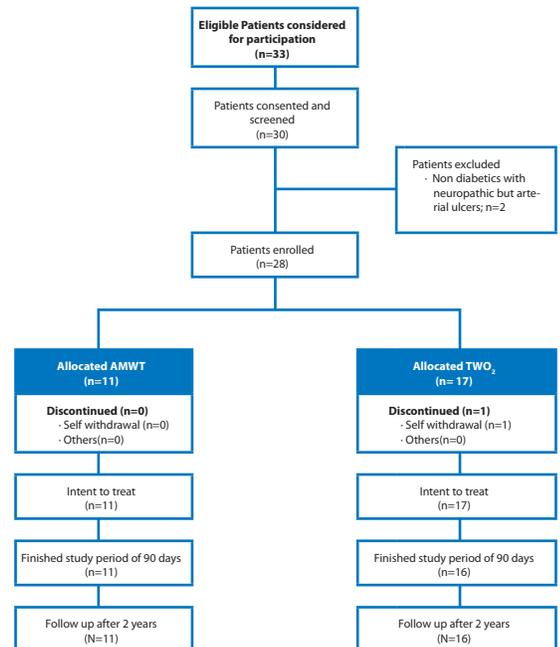


Figure 2: Kaplan-Meier estimated for time to complete wound closure

